Article

Access to genetic material: reproductive technologies and bioethical issues

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Abstract

New assisted reproduction technologies provide access to, and require the handling of, genetic material. Such material includes gametes or early-stage embryos. After a selective appraisal of some of the most relevant developments facilitated by the access to germ cells and embryos, this paper identifies some major ethical challenges created by the assisted reproduction technologies, with a special focus on Germany. The rapid progress in medical technology makes it difficult to prohibit or allow assisted reproduction technologies on the basis of such traditional criteria as the protection of human life, medical indications or a preference to adhere to natural processes. Instead, a more open discussion and a flexible application of ethical principles may be more helpful, such as: (i) considering DNA as a biological data file which allows potential access to a person’s biography or identity; (ii) reconciling the protection of the early embryo with patients’ needs; and (iii) placing both the mother and her embryo at the centre of bioethical and legal considerations, instead of exclusively relying on ethical principles and expert opinions with regard to the embryo alone. To continue the success of assisted reproduction, more attention should be given to the ‘lifeworld’ philosophy, as some authors have put it.

Keywords: assisted reproductive techniques, bioethics, embryo research, Germany, germ cells, IVF

Introduction

Scientists are increasingly being required to distinguish between procedures that are practicable and those that are justifiable. In view of the advanced possibilities offered by modern medicine, questions of medical ethics are of growing importance for doctors, the general public and medical philosophy.

A good example of these new challenges is the development of assisted reproduction techniques, which provide access to genetic material of germ cells and embryos in the laboratory. This raises legal and ethical questions as to whether, and to what degree, medical science should interfere with natural reproduction. Acceptance of natural reproduction only would lead to the rejection of all types of infertility treatment. From the perspective of reproductive health (Michelmann and Himmel, 2005), this would preclude an infertile couple’s right to take all reasonable steps necessary to have children of their own. On the other hand, the introduction of assisted reproduction technologies sometimes interferes with ethical standards, especially with regard to questions concerning the protection of preimplantation human embryos.

To discuss and apply appropriate ethical standards, we first describe some of the most advanced techniques in assisted reproduction that provide access to genetic material before focusing on ethical consequences that arise from this access. In reviewing the relevant literature, we have systematized some of the ethical issues associated with current or future treatment options for childless couples.
Access to genetic material and associated ethical issues

Genetic material, made accessible through assisted reproduction technologies, refers to spermatozoa, oocytes and early-stage embryos. The use of these technologies generates ethical problems especially in relation to gamete and embryo selection, donation and cryopreservation, and also in relation to research on the early embryo, and confronts doctors, patients, researchers and the general public with a variety of controversial facts. Of particular importance from an ethical point of view are: (i) the possibility of gender selection; (ii) infertility treatment without a medical indication; (iii) embryo selection; and (iv) research on embryos beyond infertility treatment. In most of the cases, we witness a lack of criteria for the handling of human material during assisted reproduction treatments or difficulties in the application of existing guidelines.

Gender selection

A rather new ethical conflict relates to gender selection. This can easily be performed today on early embryos by preimplantation genetic diagnosis (PGD) or preconceptionally on spermatozoa by flow cytometry (cell sorting). The latter might be considered to be a highly advisable option, because only gametes are involved. In the past, preconceptional gender selection has produced numerous unproven and unsuccessful theories and techniques for sex selection (Michelmann et al., 2000). So far, only the in-vitro technique of flow cytometry (fluorescence activating cell sorting, FACS) seems to function satisfactorily for separating human X-bearing, but not yet Y-bearing, spermatozoa (Fugger et al., 1998). In the future, this approach could become a realistic option for patients with severe, sex-linked hereditary diseases. As well as haemophilia, these diseases include Duchenne’s muscular dystrophy and Tay Sach’s disease. The alternative for such families is to wait until pregnancy is established and to use prenatal diagnosis with the possible consequence of an abortion.

In view of the extraordinary pace of technological and scientific progress, the clinical and commercial application of preconceptional sex selection will become a reality in the near future. It might be applied to patients not only with sex-linked hereditary diseases but will also confront reproductive medicine with those couples that have precise expectations of sex preselection. So, the thin line between gender balancing and gender discrimination can easily be crossed with this technique (Robertson, 2001).

In contrast to Germany, where sex preselection is not allowed, the issue of whether the freedom to procreate outweighs certain societal concerns has not yet been settled in most countries and further legislative action, public discussion and decision-making, may be required.

Oocyte donation and freezing and the menopause

Egg donation is one way in which women, unable to produce their own eggs, can become pregnant. This does not exclusively apply to women with primary ovarian failure or who have undergone ovariectomy, but also to elderly post-menopausal women. Normally, women undergoing egg collection for in-vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) donate the excess eggs. In a few countries, patients receive financial support if they agree to donate some of their eggs. Because of an obviously flourishing market, many women, particularly in the USA, are willing to produce oocytes solely for payment (Steinbock, 2004).

While the donation of spermatozoa is an ethically and legally accepted form of assisted conception, oocyte donation remains controversial and is not permitted in many countries. This restriction contrasts with the fact that bone marrow, blood and sperm donation have been approved for a very long time (Gunning, 1998). Moreover, oocyte donation has opened the possibility of a successful pregnancy, not only for young women unable to produce oocytes, but also for older, premenopausal or menopausal women. These options have caused some heated debates as to whether an upper age limit should be recommended for oocyte receipt (Kortman et al., 2006) and whether fertile individuals should also have access to IVF (Ratcliffe et al., 1990). In many countries, the reproductive period is shifting continuously to a later age. In Germany in 1975, for example, women had their first child on average at the age of 24.8 years. That age continuously increased to 28.2 years in 2005 (Federal Statistical Office Germany, 2006). This increase mirrors IVF/ICSI patients whose average age has increased from 32.6 in 1997 to 34.3 years in 2005 (Felberbaum et al., 2007).

For many women, there is a conflict between having a career and having children at a younger age. However, women who delay childbearing are often unaware of the reduced probability of pregnancy with increased age. The number of oocytes decreases with age, while the number of chromosomal aberrations increases. More than 50% of all oocytes in women aged 35 years and over have a numerical chromosome aberration.

Therefore, oocyte freezing has been discussed as a means to allow young women to first pursue their career and then have a child later using their cryopreserved ‘young’ oocytes (Dawson and Singer, 1990). Apart from the fact that this possibility is always associated with a stressful and invasive IVF and that there are reduced survival rates of frozen–thawed oocytes, this kind of assisted reproduction would exceed strict medical indications. So, the question as to whether medical intervention could also be used to accommodate lifestyle choices or social dynamics has not yet been sufficiently addressed and should be discussed, not only by experts but by the public.

Embryo selection

Normally, during IVF/ICSI, more than one embryo is cultured and transferred back to the woman to achieve acceptable pregnancy rates. This is, or was, associated with a risk of multiple pregnancies. Therefore, to avoid multiple pregnancies and simultaneously increase the pregnancy rate, a selective (or elective) embryo culture of all fertilized oocytes is performed in many countries nowadays. This enables the identification of viable embryos able to reach day 5 (blastocyst stage) and to recognize the most promising embryo for a single embryo transfer (Gardner et al., 2004), thereby essentially eliminating the possibility of triplets or a higher number of gestations. The pregnancy rates after single blastocyst transfer are the same as
would be expected if several embryos would have been transferred at an earlier stage at day 2 or 3. If more than one embryo reaches day 5 (blastocyst stage), they can be cryopreserved and stored for later use. However, the selection procedure has caused fears that this technique may end in positive eugenics.

As early as 1991, the Embryo Protection Act became effective in Germany, which strictly banned manipulation of human embryos for the purposes of research, embryo donation, sexing (except for the diagnosis of sex-related diseases), cloning, PGD or the production of chimeras and allowed the cryopreservation of embryos only in exceptional cases. Oocyte donation and the use of surrogates mothers are also forbidden. At first sight, such high ethical standards appear to represent a compromise, allowing all members of society to recognize that assisted reproduction represents a successful therapy from which justified fears of misuse have been eliminated.

However, these standards and medical guidelines have created problems in performing assisted reproduction treatments in Germany (Michelmann and Himmel, 2005). According to the German Embryo Protection Act, the fertilized oocyte is recognized as an embryo after syngamy of both pronuclei. All created embryos, up to a maximum of three, must be transferred back into the mother’s uterus without selecting for the most promising embryo with the highest potential to implant.

Parallel to the development of selective embryo culture techniques, another selection method has emerged: preimplantation genetic diagnosis (PGD). This cytotropic technique is performed before embryo transfer to identify genetic defects in embryos created by IVF or ICSI (Thornhill et al., 2005). As a result, only unaffected embryos are transferred back into the uterus, thereby avoiding the need for post-conceptional diagnosis, such as amniocentesis, and the decision whether or not to terminate the pregnancy in the event of a positive test result. PGD is praised as it is less destructive than fetal selection during pregnancy, but it also permits the preferential selection of one gender and will open up more extensive selection processes in the near future.

Independent of whether embryo selection and PGD will be further prohibited in Germany, we should be aware that the restrictions of the German Embryo Protection Act cause many German couples to travel to other European countries for assisted reproduction treatments, creating a form of reproductive tourism (Michelmann and Himmel, 2007).

Embryo research

The introduction of IVF/ICSI for sterility treatment has provided access to human preimplantation embryos that could be used for different research purposes, such as: enhancement of fertility treatment options, e.g. by the investigation of better cryopreservation techniques or the development of sequential media for prolonged embryo culture (blastocyst culture); information about in-vitro maturation of gametes, zygotes and embryos; assessment of the therapeutic potential of embryonic stem cells (therapeutic cloning); and refinement of PGD.

To use embryos for those purposes can either be justified, rejected or conditionally allowed on the basis of different moral standpoints. These could be mutually exclusive positions that either regard the fertilized egg as a human being or, alternatively, ascribe little or no moral value to the embryo. There is also the gradualist position which considers the fertilized egg to be a gradually developing human being from the point of viability until birth at the latest. Accordingly, some people assign maximum protection to the fertilized oocyte, while others regard surplus embryos as distinct from the reproductive process and so consider that they should be allowed for use in research, including stem cell research.

Traditional criteria for resolving ethical conflicts with assisted reproduction

Generally speaking, ethical conflicts that arise in science, medicine or economics can be addressed by applying appropriate values or criteria that have been stable over the time. To assess assisted reproduction treatments, several more or less traditional criteria seem to be available. To name just a few: (i) preference for natural human development; (ii) medicine’s mandate to heal; (iii) medical indication; or (iv) informed consent. Do these criteria help to evaluate, i.e. to accept, refuse or modify, such advanced technologies?

Preference for natural human development

The biology of natural development seems to be one criterion to ethically assess, for example: (i) oocyte donation to older women; and (ii) the development of the embryo in vitro.

Oocyte donation to older women

If we consider that fertility is a ‘biological’ norm during a woman’s natural reproductive life, medical intervention via oocyte donation seems to be justified when trying to circumvent a reproductive malfunction, including premature ovarian failure. Furthermore, if we believe that infertility should remain the natural feature of menopause, menopausal pregnancies with the assistance of donated oocytes should be discouraged. However, medicine often does not follow these general guidelines but, instead, focuses on helping individuals. As a result, each single successive treatment leads, as Levitt (2004) puts it, to an ‘unruly’ systematic liberalization of policy, which is supported not only by the media but also by commercial and scientific pressure to do everything possible. So, much more attention was given in the media to the live baby of the world’s oldest mother (Adriana Iliescu at age 67) than to the medical complications of her treatment concerning ovum donation, stillbirth, prematurity and Caesarean section (Nwandison and Bewley, 2006).

If women were given clear information on the success rates of pregnancy at the age of 35 years and over, of the significant adverse outcomes, and the limited success rate of assisted reproduction, it might lead to more informed and realistic choices to delay childbirth. Women receive contradictory information and mixed messages in the media about celebrities achieving successful pregnancies in their forties. Clearly such women are unlikely to publicise their grief about infertility, miscarriages and ill health.
‘Natural development’ might also be an argument to prohibit embryo selection, including selective embryo culture in the laboratory. However, selection not only occurs during in-vitro development, but also in vivo and thus must be considered a purely natural process. In general, more than 50% of all fertilized oocytes fail to reach the blastocyst stage. One major cause of this low developmental capacity is a non-diploid chromosomal constitution in the early embryo, especially in older women. Cytogenetic investigations on preimplantation embryos by PGD have revealed a rate of chromosome aberrations greater than 50%. Rubio et al. (2005) analysed 1347 embryos by FISH in two groups of patients (<37 years of age versus ≥37 years of age) and found 63.5% respectively 72.7% of embryos with chromosomal abnormalities which, in general, arise de novo from random errors produced during gametogenesis and embryonic development.

Medicine’s mandate to heal

A simple and valid criterion to assess reproductive technologies seems to be medicine’s mandate to heal. If we define ‘healing’ as assisting the reintegration of the organism and restoring its autonomy, the ‘artificiality’ of medical intervention should always be subordinated to the preservation or restitution of autonomous natural processes without giving natural course an absolute priority over any artificial intervention (Fuchs, 1998). The natural and autonomous development from the embryonic stage to a born child could then be a criterion to protect the embryo and to prohibit any access to it.

Singer and Dawson (1988) question this because in the laboratory situation the embryo is incapable of autonomous development. The blastocyst outside the womb in the laboratory has no chance of developing into a child: there has to be some deliberate human act (the transfer into the uterus). Nevertheless, for FitzPatrick (2004), the difference that matters is that embryos are totally different from all other body cells. Each embryo is the natural beginning of a human being and therefore it is irrelevant whether it is created in vivo or in vitro.

Medical indication

Medical indication also seems to be a rational and stable criterion. However, whenever respective technologies are available, including sex selection or the donation of oocytes for elderly women, their use will always be motivated by some kind of medical indication. To put it another way: is it really justified to bar young healthy women from freezing their oocytes for future use based on the argument of a restrictive understanding of medical indication?

Informed consent

Similar to the problem of medical indication is the criterion of informed consent. Kalbian (2005) has described how women struggle to practice an authentic form of agency, which goes beyond a simple notion of autonomy, when making an informed consent to assisted reproduction procedures. The potential success of this kind of treatment makes resistance to these technologies difficult or maybe, in some cases, impossible, because there always seems to be another chance or another new and perhaps ethically dubious technology. Once women believe in these technologies, they are in danger of losing their ability to give truly informed consent.

Possible solutions

One reason why it is difficult to use the above-mentioned criteria for a valid assessment of assisted reproduction technologies is the development of science. Medical technologies especially are rapidly changing the way we think and act. Fredriksen (2003) stated that our life is affected by medical technologies and that we are strongly focused to solve problems in a purposive and rational way. With such influence on, or colonization of, our thinking and feelings, it seems rather useless to allow or prohibit medical technologies according to medical or non-medical indications. At the same time, it cannot be denied that all of these possibilities have contributed to significant progress in assisted reproduction, and probably will continue to do so.

In the following, we will argue that it is not so much the ethical principles per se but their open discussion and flexible application to new scientific developments that may be helpful. This discussion may include: (i) new concepts and ideas for regulating access to human material; (ii) a new balance between selection and natural development, in the case of selective embryo culture, to eliminate both the fear of eugenics and the risk of multiple pregnancies; and (iii) a more active consideration of public opinions to overcome the confrontational ethical positions we experience; especially in the context of research on embryos and the discussion about their protection.

Genetic material as a file self

Before IVF was introduced in 1978, oocytes and early embryos were inaccessible. Therefore, there was no need for any legal, moral or ethical debate. This was not the case with spermatozoa. Despite or because of the fact that they had been used in vitro decades before IVF, their use was not regulated at all. This situation changed during the 1980s and 1990s. Nowadays, any identifiable human cell, inside or outside the body, is protected either by strict scientific regulation or legislation. There is general agreement that researchers should not have free access to body material. This applies especially to the use and storage of body material during assisted reproduction treatments. Therefore, the European Parliament and Council adopted Directive 2004/23/EC that lays down standards of quality and safety for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (European Commission, 2004).

Moreover, since genetic material can be accessed and manipulated during assisted reproduction, we not only need protection of body material such as gametes and early embryos, but also a new definition. Hoedemaekers and Dekkers (2002) have suggested that DNA is considered as a kind of biological file or, as they call it, a ‘file self’. This file self is a part of ourselves, a limited biography. This concept may sensitize us to the fact that access to genetic material is more than an issue of ownership, but also a question of human identity, which has also to be considered in the case of oocyte and sperm donation.
Balance between human protection and selection

It seems possible to keep the preference for natural development and, at the same time, to allow selective embryo culture. We accept the principle of Habermas (2003) that nobody should view others’ lives as being subject either to their control or their disposal. He calls this concept ‘indisposability’ (Unverfügbarkeit), which includes the indisposability of pre-personal human life.

However, the total protection of the embryo, as established by German legislators, prevents childless couples from receiving optimal treatment. So, with regard to the advantage of single blastocyst transfer, we would favour a change in the Embryo Protection Act towards selective embryo culture, which has not been permitted in Germany until now. If this was to happen, there would be surplus embryos for the first time in Germany. Such a situation calls for a discussion about the nature and status of the embryo. The issue of excess embryos is directly linked to the pros and cons of embryo research. However, in our opinion, it is possible to maintain high ethical standards in countries such as Germany. The only way to avoid embryo destruction or their use in research or stem cell production is to allow prenatal adoption of the embryo by another infertile couple. This would not only help childless couples, but also result in optimal protection of embryos.

Technologies, experts, ethicists and the lay public: who defines the criteria?

In a very recent report from the Marburg Centre for Conflict Studies on bioethical issues, both experts and the public were questioned about the nature and status of the early embryo (Krones et al., 2006). This report revealed opinions that were surprisingly pluralistic and sometimes at odds with the German Embryo Protection Act. Whereas the existing law defines the moment of syngamy of the two genomes as the beginning of human life, a considerable proportion of the public (>20%) regarded the fourth month as representing the point in time at which human life actually begins, while for others, nearly 50% of the public and most IVF couples (70%), this point is reached with implantation. The implantation window represents the establishment of the physical connection of the embryo with the mother, while the 4-month time point corresponds to the time when the pregnant woman can feel the fetus moving inside her womb (Cameron and Williamson, 2005). Proponents have argued that the best way to protect the embryo is to recognize the mother and embryo as a reproductive entity. This is what Krones et al. (2006) and Wiesemann (2006) call a ‘lifeworld’ perspective or ‘lifeworld’ ethics, considering human development in its bio-psycho-social context in relation to the mother and the future family and so protecting the reproductive unity of the mother and the embryo.

This concept is in line with attitudes that Parry (2006) found in her studies detailing the importance of early embryos for people during infertility treatments. Some IVF patients were willing to donate non-viable embryos (embryos graded by embryologists in the clinic as unlikely to develop into a fetus/child) for research to develop better infertility treatments or for stem cell research. However, all patients agreed that viable embryos should only be used for reproductive purposes. This again seems to mirror a ‘lifeworld’ perspective. Parry (2006) underlines the importance of considering how people regard embryos as potential human lives. If this was not the case, there would be the real risk of coercion or moral obligation to donate embryos while participating in an IVF treatment.

Compared with these clear views from the public, Brock (2006) and George (2004) simplified the problem of embryo protection and embryonic stem cell research by stating that, if couples agree to donate embryos for research, their creation should be permitted solely for this purpose. Obviously, they are not able to empathize with the apparent ambivalence of couples undergoing assisted reproduction treatment. On the one hand, these couples realize that embryo research may lead to the destruction of early human life, but on the other, they sometimes have irrational hopes that such research may solve their individual problems. The differentiation between viable and non-viable embryos, although not convincing in view of medical ethics, is understandable from a ‘lifeworld’ ethics perspective.

Conclusion

As with any new medical technology, several unexpected problems have been created by the access to germ cells and embryos in the course of assisted reproduction, such as how best to deal with gametes and preimplantation embryos or whether to restrict assisted reproduction technologies to certain groups of patients. Hopes, as well as challenges, have been raised as a result of the development of new treatment options and methods of selection. As most laboratory techniques used in treating infertility do not correspond to natural processes, traditional criteria used to justify these procedures, such as the orientation towards human protection, natural processes, medicine’s healing mandate or medical indications, are largely inadequate or difficult to apply. Moreover, there is a problematic interplay between social development and medical progress.

How to deal with this ethically makes assisted reproduction treatment an interesting example, or even a paradigm, of modern medicine. Assisted reproduction has allowed open access to hitherto inaccessible material from the human body and the establishment of medical practices that may interfere with traditional viewpoints such as conception as a natural process. The application of the technology demonstrates the limits of legal regulations and ethical criteria. And, at the same time as providing help for those who suffer greatly from involuntary childlessness, assisted reproduction tends to increase medical colonization.

Intensive embryo research led to the birth of the first IVF baby in 1978 and many scientists believe that such research will continue to be necessary in the future (Edwards, 2005). Despite the fact that assisted reproduction treatments are performed primarily to treat childless couples, embryo research is encouraged not only by parts of the scientific community but also by infertile couples and patients eager for stem cell therapies – even if this research leads to the
destruction of early forms of human life. Addressing questions about the status of preimplantation embryos always necessitates the assignment of values in moral and ethical terms. Biological realities help to clarify natural phenomena but do not assist in the definition of moral standards. It is our opinion that the protection afforded to the individual human being must be applicable uniformly throughout all stages of development and in all situations, in the uterus as well as in the laboratory, from the very beginning. Although we do not accept Devolder’s (2005) plea to use embryos for human embryonic stem cell research, we do agree with her refusal to differentiate between the moral status of excess embryos from IVF and those created in vivo.

To date, more than three million children have been born who, without assisted reproduction technologies, would never have had the chance to exist. However, we should be cautious not to use this success to urge for an immoderate liberalization of these techniques. Instead, it seems possible to continue even to enlarge this success story if we start to discuss new criteria for ethical standards, as proposed in this paper. Such discussions could be centred on the following themes: (i) informed consent: by enhancing patients’ knowledge, they should feel empowered to refuse certain infertility treatments without feeling that such a refusal is tantamount to a decision not to have children at all (George, 2004); (ii) file self: we should be careful to consider germ cells, embryos and the genetic information that they contain not so much as material but a representation of human identity, even in the case of spermatozoa; and (iii) selective embryo culture: treatment could be optimized by performing selective embryo culture while simultaneously protecting the embryo. This could be achieved for excess embryos by permitting prenatal adoption by another infertile couple. This represents one paradigmatic example to cope with the new demands created by modern technologies in reproductive medicine. Therefore, particularly in Germany, it is necessary that rules be slightly modified in the face of biotechnological progress in order to optimize the treatment outcome for patients; and finally (iv) the lifeworld: to satisfactorily address the multiple issues raised by IVF across the broad spectrum of opinions, it would probably be helpful to consider treatment decisions not only by relying on ethical principles and expert opinions with regard to the embryo alone, but more in the context of the lifeworld and the public.

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