

Risk Assessment in Advanced Biomedical Technology

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Introduction

This paper examines the possible influences and effects on our ethical thinking and practice as well as our society through the development of Advanced Biomedical Technologies (ABT as an abbreviation) from the viewpoint of risk assessment. Of various ABT, we consider certain technologies of intervention in human life that have become available mainly through reproductive technologies, genetic modification, embryology and cloning techniques. Embryo selection after preimplantation diagnosis, germline manipulation for designing babies, somatic cell nucleus transfer for making cloned embryos, etc. are examples of such technologies. Through these technologies, people have acquired the means not only to have a baby but also to have a baby with particular qualities.

With the development of new ABT, since safety has not been established because of the number of abnormal cases in animal experimentation, we should refrain from clinical application for human beings. This is the restraining argument from technological and biological risk. However, if the technology is refined, reducing risk and raising safety to a level equal that of similar technologies, this restraining argument will lose its power.

On the one hand, confirming biological safety is necessary for the application of ABT to human beings, and this means that biological risk should be strictly verified and managed. Most researchers claim that it is sufficient when biological safety and respect for human rights, including obtaining informed consent and protecting privacy, are ensured.

On the other hand, however, some insist that; there is a possibility of discrimination in employment or insurance contracts through the use of genetic information; economic disparity will expand due to unequal accessibility to the technologies; violation of humanity and human dignity will accelerate; instrumentalization or commodification of human life will rise. These are "social or moral risks" as distinguished from technological or biological risks. These are not risks in that they can be assessed and managed based on scientific quantification and analysis. These arguments should be

verified in terms of possibility, extent and frequency as known or potential adverse effects.

This paper examines criticism of the desire to design or manipulate human life with various ABT from the viewpoint of social and moral risk. In particular, the validity of the moral risk argument is related to human dignity. With this in mind, I propose an alternative version of moral risk as a crisis of interaction and communication.

1. Techniques of Intervention in Reproduction as the Desire for Quality of Life

There are several types of ABT for reproduction with intervention in the beginning of human life.

- (a) Assisted reproductive technologies: using donated sperm or eggs, in vitro fertilization, etc.
- (b) Preimplantation genetic diagnosis (=PGD) and embryo selection by in vitro fertilization: prevention of the birth of babies with genetic disorders, selecting babies with a desirable genotype for donating cord blood or bone marrow, and for screening for superior traits such as a high IQ.
- (c) Germline genetic modification: treatment (=cure dysfunctions) or enhancement (improve functions, capabilities, traits)
- (d) Regenerative medicine: creating and using embryonic stem cells or embryonic germ cells
- (e) Cloning techniques: regenerative medicine using cloned embryos (=therapeutic cloning) or making cloned babies (=reproductive cloning)

Assisted reproductive technologies (a) are regarded as "normal" rather than "advanced," but they have made the extracorporeal manipulation of life possible as clients may desire further intervention, so it can be included among ABT. Although techniques (d) and (e) are not for reproduction, they need to use embryos for biomedical research, so we should also refer to these technologies. Techniques (c) and (d) are of particular importance as techniques for intervening in, that is, selecting or manipulating, the quality of a person's life at the beginning.

People who access such techniques want not only to have a child, but also to have (or avoid having) a child with particular qualities. A baby is not a gift of nature, but a product capable of being quality controlled for such people. We have to be careful about the effects of this way of thinking, because of the close connection with how we

understand other people and our relationships with them, which is the essential meaning of ethics. In considering the adverse effects of ABT, new models of social and moral risk assessment are required.

2. Various Discourse on Risk concerning Preimplantation Genetic Diagnosis and Germline Genetic Modification

There are three modes of intervening in the quality of the beginning of life: negative-eliminative, corrective-therapeutic and positive-enhancive. Each of them eliminates life with undesirable qualities, correcting or repairing "abnormal parts," and enhancing or improving "normal parts," respectively. While the second type of intervention (corrective) is regarded as valid in general, there is severe opposition and conflict of opinions concerning the negative and positive modes.

Embryo selection with PGD and germline genetic enhancement is a typical example. It can be argued that these techniques should be permitted because of the right to pursue happiness; others claim that if these interventions are allowed, humankind will suffer irreparable harmful effects. We will examine some of these harmful effects.

First, we refer to some criticisms of PGD and preventive embryo selection, which means adopting normal embryos and screening out abnormal embryos before implantation.

"Selecting the quality of human life will infringe the idea of equality of life-value."

"Human dignity in the sense of irreplaceability would be violated."

"To prevent the birth of people with impairments will threaten people who have disabilities."

"The practice will promote discrimination against people with disabilities or be a eugenics practice."

"Selected birth will affect the sense of identity of the child born."

These views are of some religious groups and people disabilities and their advocates. On the other hand, there are a number of arguments that justify these technologies based on the individual's right to choose, the personal pursuit of happiness and reducing public spending for the medicine and welfare of people with disabilities.

Secondly, we consider some objections to germline genetic enhancement. There are two ways of enhancement; one is preventive such as the reinforcement of immunity

and delay of aging, the other is additive, such as strengthening muscle power or raising IQ. ¹

Because of the inequality of access to the technique, the social gap between the rich and the poor will grow.

It will involve the instrumentalization of a child or the imposition of desirable qualities by parents.

The expectations of the parents will put pressure and have harmful psychological effects on the child.

The sense of the gift of life and the value of the dignity of life will be lost.

Let us consider these social and moral risks.

3. Uncertainty in Risks of ABT

There are four levels of risks of ABT:

- (a) Biological risk: physical or mental defects
- (b) Psychological risk: harmful effect on the sense of identity of children,
- (c) Social risk: violation of social justice (discrimination, inequality, eugenics),
- (d) Moral risk: threat to humanity and human dignity.

Confirming biological or technical safety is essential in medical research and clinical trials, which acts as a brake on technology runaway. However, intervention in the beginning of life may have adverse effects on the person concerned after growing up and his or her children. This uncertainty problem has not only a biological dimension but also psychological, social and moral dimensions. Let me explain these risks.²

Uncertainty is often applied to situations where the possibility of adverse effects is anticipated, but the probability is not known. It is called "technical uncertainty," which can be predicted in terms of content and degree or scale, so the scope can be estimated quantitatively or verified empirically. According to this point of view, risk assessment is possible through scientific analysis and evaluation.

¹ cf. Shimoda 2004.

² As far as the psychological risk concerned, it is regarded as an issue to be tackled in the assisted reproductive technologies using donor sperm or egg; the child's right to know one's genetic parents or need for supporting system such as counseling. This problem needs to be argued independently.

However, we are faced with future risk which itself is controversial regarding its harmfulness and the necessity for taking action beforehand. Some emphasize the potential importance of its harmfulness and coping, others deny the negative potential, focusing on the benefits of the technique. We cannot quantitatively estimate the risk because of the many other related factors, but the risk potential should not be ignored. In analogy, consider the long-term adverse effects of chemical substances or electromagnetic waves at a biological level, and the influence of TV or computer game violence on children at a psychological, social and moral level. We will call this last type "structural uncertainty." (cf. Wynne 2001)

Thus, to evaluate the effects and implications of these risks, scientific rationality is not sufficient. We need another concept of rationality, i.e., one based on the social sciences especially from philosophical and ethical viewpoints, political, economical and public policy-making considerations, in other words, "social rationality." (cf. Beck 1986)

How do we assess unknown risks that have structural uncertainty brought about by ABT? And how can we manage these risks and take measures? Or do we need to do something to deal with these risks in the first place?

4. Social Risk: Spread of Discrimination and Eugenics, Violation of Social Justice

As the importance of genetics and genetic information has increased in clinical medicine, the possibility of discrimination in employment, insurance and education has risen. In other words, people are concerned about the violation of fairness by invading ultimate privacy rights through the use of genetic information. However, these issues mostly arise in relation to genetic testing or diagnosis, and there is social consensus on the necessity coping with this risk. In discussing the possible adverse effects of intervention in reproduction by ABT at the social level, we should consider the influence of selecting or remodeling genetic makeup on the values of quality of life, i.e. the possibility of spreading discrimination and eugenics practices against disabled people and expanding social inequality.

On the one hand, if PGD and embryo selection to prevent the birth of a baby with a genetic disorder become common, preventing undesirable qualities will be required for all parents-to-be who have genetic factors of inheritable disease. Thus, people with genetic disease are likely to be regarded as having a less valid existence, which is a threat to people living with disabilities.

On the other hand, positive intervention in the genetic makeup of future generations may increase the chance of expanding social disparity because of the difference in the availability of genetic enhancement techniques. There is currently a huge gap among social groups in terms of access to medical services depending on nation, race, class, region, etc. By genetically modifying future generations, the rich would gain not only further chances to win in society, but also biological, evolutionary advances as "transhumans" or "posthumans."³

Furthermore, some critics claim that a meritocracy will be formed by the genetically privileged classes, those genetically enhanced at the beginning of their life. (Silver 1997; Steenbergen 2002) If this forecast is accurate, the idea of modern democracy, which is social integration through fair dealing, and cooperation and solidarity despite unequal natural gifts, would be fundamentally undermined. This is a social risk.

Meanwhile, a number of people deny these harmful effects, claiming that they are not really risks. They claim that not only in the market economy and employment but also in science and education, the principle of free competition in a merit-based system leads a free and democratic society, and it should be applied to reproduction as well. The right to free choice or self-determination has to be guaranteed, and selecting or producing a certain quality of baby is a reproductive right. Of course, discrimination and eugenics practices at the public level would not be permitted, and strict regulation would be needed. However, these social risks, which are only a subjective evaluation of social affairs, do not mean that authorities can limit individual rights because the decision is not based on scientific, objective qualification.

According to this argument, institutional discrimination and eugenics practices must be regulated, but as long as fair opportunities and free competition are established, social justice can be maintained. Thus, the concept of "social risk" has no sense. In spite of this justification, however, we cannot ignore the potential fundamental adverse effects that underlie intervention in the quality of life driven by the desire for the 'best' baby. We must recognize that these are moral risks.

5. Moral Risk: Threat to Humanity and Human Dignity

Many opponents of reproductive cloning claim that reproductive cloning is an infringement of humanity and human dignity, an argument also found in discussion on

³ cf. <http://www.transhumanism.com/index.php>; <http://www.extropy.org/>

PGD and genetic modification. Phrases such as the "instrumentalization of human beings" or "playing God" are often heard in this context. However, we have no way of appropriately measuring these risks, which is why most life science researchers consider these expressions as being of subjective emotion and fear. Before too readily reaching a conclusion, let us listen to two prominent people who share a common view in this respect in not using the term "moral risk." ⁴

First, Leon R. Kass, chairman of the President's Council on Bioethics in the USA, insists that fundamental questions raised by human biotechnology such as cloning techniques and genetic engineering are not "the threat to confidentiality" or "the risk of 'genetic discrimination' in employment or insurance," even though these problems are of practical importance. Instead, the problem is of "the challenge to human dignity and humanity," which is the deepest problem. There are benefits of developing human biotechnology such as the treatment of intractable diseases and the relief of suffering. Nevertheless, we must not ignore the "moral crisis," the loss of "modesty" and "respect for the other person," "hubris" to manipulate human life, and "manufacture and commodification" of human life. (cf. Kass 2002: chap.4) ⁵

On the other hand, the German philosopher, Hans Jonas, who considers the crisis in an era of environmental destruction and nuclear energy, insists that people should listen to warnings to avoid catastrophes caused by ABT. "Crisis (=Gefahr) alarms us from the future," "predictable crisis becomes the compass," -- are his insights at the beginning of his investigation. They constitute an ethical core and the human obligation to be cautious about the future because of risk "uncertainty (=Ungewissheit)," to protect "the idea of humanity (=die Idee der Menschheit)," and to prohibit "the remodeling of human nature (=Umschaffung der Menschennatur)" by genetic modification. Avoiding the worst situation and to gain "the heuristic method based on fear (=Heuristik der Frucht)," that is the methodology to detect the signs of crisis as annihilation of human race. According to Jonas, the metaphysical imperative that "human kind shall be" is "the unconditional duty of human kind." He says that "this kind of risk (=Risiko) cannot be justified," even though it may bring great benefits. (cf. Jonas 1979: Kap.2)

⁴ There are some critics that mention "ethical and cultural risk" or "moral risk," distinguished from "technical risk." (cf. Renn 1992; Sass 1995; Leiss 2001) In those discussions, however, the concepts are only presented as such, not examined at length.

⁵ Francis Fukuyama, a political thinker of the USA, has a similar opinion when he claims that the basic problem of human biotechnology consists in the threat to "human nature" and "human dignity." cf. Fukuyama 2002: chap.1,8,9.

6. Some Objections to Discourse on Moral Risk: Pluralism and Individualism of Values

Those who emphasize moral risk depend on the belief in universal substantive ethical values such as humanity and human dignity. These inviolable values, as well as the sanctity of life, are traditional ethical standpoints. However, it is difficult for these values to compete with new ethical values of liberal-individualism and value-pluralism. They can be overridden by "reproductive rights," "freedom of choice" and "respect for individual preference and self-determination" that some advocates of ABT use as justification.⁶ According to these advocates, we should consider the benefits such as responding to the needs and desires of the persons concerned, academic freedom, increase in social utility as satisfaction of the majority, and expansion of business opportunities, etc. Compared with these benefits, the moral risks are less clear and convincing.

In individualistic and pluralistic views of values, any kind of intervention in the beginning of life, including human cloning, is permissible in the name of reproductive freedom and rights, on condition that technical and biological safety have been confirmed. Therefore, interfering with personal freedom of selection because of moral risk cannot be justified because it violates individual rights. The idea of preimplantation genetic diagnosis and embryo selection discriminating against people with disabilities, germline genetic enhancement being the instrumentalization of a child, and most human biotechnologies undermining human dignity, are considered to be merely expressions of subjective belief, and should not be brought into the public decision-making process. Those who advocate designing life through genetic intervention, not compulsorily by the government but through individual voluntary choice, would also justify eugenics practices in "excluding the inferior" and "adopting the superior."

We cannot regard these practices as risks in the sense of quantifiable adverse or harmful effects. However, these practices challenge ethics as normative and evaluative thinking of relationship with or relating to the other person in the interaction or communication. We cannot counter the threat posed by these practices to the concepts of humanity and human dignity as substantive values. Thus, we must take an

⁶ See the literature of A.L.Caplan, L.M.Silver, J.Harris, G.Stock, J.Robertson etc. I have tried to discuss these types of justification theories as "new eugenics." cf. Shimoda 2004.

alternative moral risk standpoint.

Conclusion: Toward Public Communication concerning Moral Risk

There are opposite views on moral risk through ABT. One is that we should not only manage but also fight threats caused by these risks because they violate important human values. The other is that these risks have no objective basis and are overridden by the individual right to choose and by potential social benefits. It is unfruitful to continue debate on concepts of humanity and human dignity in the sense of substantial ethical values. I therefore refer to moral risk as treating another person merely as a means, or as the instrumentalization of a human being; this is one meaning of violating human dignity.

People use others to realize their own purposes in ordinary life, e.g., in the relationship between consumer and producer, client and service provider, and employer and employee. When parents have children and raise them as they wish, by making the children take piano lessons or go to tennis school, for example, they are realizing their own desires. Despite this, if the parents love their children and allow them to choose their own lifestyle including not obeying their parents' wish, the children are treated not only as means but also as "ends in themselves" in a Kantian ethical sense, so human dignity is not violated in this case. Therefore, can we accept this argument for germline genetic intervention and reproductive cloning?

The answer is "No," because the ethical implications of the instrumentalization of another person in interaction and communication are overlooked, and therefore the threat to the framework of collective, cooperative human life is not seriously considered. Although intervention in reproduction through ABT cannot be blamed only for the instrumentalization of a baby, we have to recognize that such an activity is driven by the desire for relationships with other people who can be controlled to one's satisfaction.

We need to carefully monitor the moral risk of both increasing this desire and removing its restraints, which would reinforce the tendency to select the qualities of human life. Here, a baby is not so much "a blessed gift" as "a product of design." In other words, the real problem of violating human dignity is not undermining substantial or invariant ethical values as Kass and Jonas insist, but strengthening the hubris that tells us we can determine which qualities are good/bad for a human being.

So, what can we do to regulate the moral risk of the threat to the way we view our

relationship with others? There may not be a method of "scientific" risk management as there is for biological risk. First of all, we have to be cautious about changes in ways of living, ways of thinking and social values; we must then identify degeneration interaction and everyday communication and consider it as a moral risk. Managing this risk should be an interdisciplinary decision-making process, i.e. among diverse professions and non-professions. This is risk communication that itself forms the process of the co-existence of human beings in a biomedical, technological era.

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