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Technologies of child production from genetic material of three "parents": legal and bioethical aspects ***

1 - Problem description

The adopted UK-wide regulatory act legitimating technologies of so-called mitochondrial donations for the production of human embryos – entitled the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations, 2015, No. 572[1] (which shall come into force on October 29, 2015) – will create a lot of new risks and raise specific new bioethical and legal questions and problems.

These questions also become relevant for Russia, given the fact that, first, the administration of the Ministry of Health of the Russian Federation tends on liberal line to underestimate and disregard the rules of bioethics when making many, if not most, decisions in the area of health protection and, second, it is anticipated that in the near future Russian 'innovators' will try to adopt and slavishly borrow whatever might be of a commercial interest, disregarding ethical issues.

2 - Legal and bioethical evaluation

It is claimed that new methods of artificial insemination from three parents by modifying the mitochondrion (a part of the cell structure responsible for the energy supply to cells)[2] developed at the University of

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[1] The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations, 2015, № 572 (*http://www.legislation.gov.uk/uksi/2015/572/contents/made*).

[2] **J. GALLAGHER**, *Three-person babies "in two years", Says science review* (*http://www.bbc.com/news/health-27678464*) – 03.VI.2014.

Newcastle (UK) allow to prevent the birth of children with incurable genetic disorders.

According to S. Burns, legal expert in the area of biotechnology and ethics at the University of Sheffield (UK), the above-mentioned Regulations, which actually reflect the occurring commercialization and instrumentalization of the treatment of human embryos, allows to use third-person mitochondria for the purpose of conception using two technologies[3]. However, each of these technologies has major drawbacks. One of these two technologies significantly increases the risk of certain chromosomal abnormalities. The other technology (one of two legitimated in the UK) requires destroying and, as a result, killing at least one or even more healthy human embryos within one procedure (strictly speaking, in this case they shall be already considered as persons with a certain ethical and legal status), which, in the reasonable opinion of opponents of the use thereof, totally contradicts with the objectives claimed.

It should be noted that these two 'mitochondrial donation' technologies were legitimated, as stated, through the adoption of this act in view of the fact that it was unclear and uncertain which of these technologies is more efficient and safe[4].

The ability to use mitochondria of a third person to produce the human embryo raises serious debates about the ethics of this process, particularly due to the fact that children conceived in this way will inherit traits from three parents[5].

There are also significant legal and bioethical obstacles preventing the use of such methods for human embryos and, therefore, attempts to cancel out and bypass these restrictions.

The safety and relevance of such technologies is reasonably denied by many experts.

For example, the position of the Swedish National Council on Medical Ethics seems to be considerable. The Council states, in its special report on the issue, that, generally thinking positively (complementarily), under certain conditions, about such manipulations in the long term, today it is ethically unacceptable to use the methods of replacement of

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[3] These technologies are schematically shown here: **J**. **GALLAGHER**, *Three-person babies "in two years"*, cit.

[4] **S**. **BURNS**, *Three-parent babies: the legal and ethical issues*, *Halsbury's Law Exchange* (*http://www.halsburyslawexchange.co.uk/three-parent-babies-the-legal-and-ethical-issues/*).

[5] **T**. **STANLEY**, *Three parent babies: unethical, scary and wrong*, *The Telegraph* (*http://www.telegraph.co.uk/news/health/11380784/Three-parent-babies-unethical-scary-and-wrong.html*).

mitochondria in embryos by donor mitochondria in view of current uncertainty of medical risks. However, some members of the Council say that the use of such technologies can not be justified in principle[6]. The Swedish National Council on Medical Ethics gives the following arguments against the use of these methods:

– the genetic modification of human germ cells is associated with too high and, most importantly, uncertain medical risks of adverse effects in the future since there are significant gaps in knowledge about medical risks for the health of the planned child itself and for future generations (the offspring of the child); other unforeseen and undesirable consequences of the use of such technologies are also possible;

– the replacement of mitochondria poses an ethical conflict between the interest of the potential child to be free from diseases (and related sufferings) and the interest of parents to have healthy children, genetically related to them, on the one hand, and the principles of respect for human dignity and humane treatment of individuals, on the other hand, in view of possible long-term consequences that such techniques might have for the whole society;

– such technologies may constitute a threat to human dignity and humane treatment of individuals;

– there are more acceptable alternative ways in which parents may solve problems associated with a high probability of mitochondrial diseases in their potential children, for example, through the adoption[7].

In our opinion, the legitimation of artificial creation (both in vitro and (probably, later on) in vivo) of the human embryo using genetic material from more than two persons (three or more persons[8]) is unacceptable and unlawful for the following reasons.

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[6] Mitochondria replacement in cases of serious diseases – ethical aspects 2013:2 (Summary of the original report «Mitokondriebyte vid allvarligsjukdom – etiskaaspekter, 2013:2» published in November 2013), The Swedish National Council on Medical Ethics, (*http://www.smer.se/wp-content/uploads/2013/11/Mitochondria-replacement-sammanfattning-eng2.pdf*, 14 p. – P. 5).

[7] Mitochondria replacement in cases of serious diseases – ethical aspects 2013:2 (Summary of the original report «Mitokondriebyte vid allvarligsjukdom – etiskaaspekter, 2013:2» published in November 2013), The Swedish National Council on Medical Ethics, (*http://www.smer.se/wp-content/uploads/2013/11/Mitochondria-replacement-sammanfattning-eng2.pdf*) 14 p. – P. 5, 8).

[8] This is not about progenitor genes naturally transmitted to subsequent generations.

3 - A number of technologies of artificial creation (conception) of the human embryo using genetic material from more than two persons (at least one of the two technologies legitimated in the UK) lead to the destruction of human embryos (in addition to the primary embryo) which are deliberately used, in a planned manner, as a consumable for each operation.

Human embryos used as a raw material cannot principally survive after such manipulations, meaning that they are intentionally and knowingly produced for such procedures only.

The use of this technology directly depends on the supply of human eggs or embryos as some kind of "spare parts" and is originally aimed at increasing the viability (real or imaginary) of one child and reducing (real or imaginary) genetic risks for the child by eliminating the potential life of one or more other children (at the pre-embryonic stage of development). Therefore, this approach is based on the deliberate direct acceptance of possible use of human embryos as a "consumable" ("raw material", source of "spare parts") and the industrial use of human embryos.

In our opinion, such manipulations are totally unacceptable neither in terms of law nor in terms of bioethics (as a normative regulatory system) since the human embryo may be positioned as a "consumable" or "raw material" under no circumstances.

4 - Even if we exclude the destruction of human embryos when using such technologies, the legalization of the use of these technologies will certainly lead to further dilution and reduction of the significance of dignity and rights of the child at the prenatal (in this case, pre-embryonic) stage of development since the embryo here is subjected to high-risk medical (in fact, experimental) manipulations with humans.

The use of these technologies creates significant somatic and genetic risks for the conceived child who will be genetically modified.

The position of the World Health Organization set forth in the "Genomics and World Health" report (2002) prepared by the Advisory Committee on Health Research shall be taken into account. It states that gene therapy of embryo cells, in view of its potential harmful effects for future generations, shall be prohibited today, even in the case of existence of severe genetic diseases. It is noted that the ratio between risks and

potential benefits from such interventions will be even less favorable in case of not too severe genetic diseases[9].

Moreover, there are significant concerns about potential consequences of the use of the donor mitochondrial DNA in the primary cell since partial replacement of mitochondria in the cell by donor mitochondria (which is possible) will likely lead to that the child conceived in this way will transmit mitochondrial diseases to its offspring. The current fundamental issue is that it is impossible to fully simulate and accurately predict the consequences of the use of such methods for those not yet born.

Such methods harshly change the human genetic line transmitted through generations.

Today there is no comprehensive and completely reliable method of monitoring and verification of the consequences of such changes for the good reason that children conceived using genetic material of a third person and the offspring of these children cannot subsequently be surely involved (far less, forced) to participate in scientific researches positively confirming the anticipated result of such experiments. Moreover, according to the British organization that argues against the legitimation of mitochondrial donation, no relevant non-human primate tests and researches have been conducted to determine the consequences for future generations[10]. And this is the case when it was impossible to use alternative methods and, thus, it was absolutely necessary to carry out non-human primate experiments.

As explained by David J. Clancy, expert in genetics and biology of aging at the University of Lancaster, the area of using of genetic material from a third person in child conception process is topical also for the reason that, without determining the genetic compatibility between the donor and the parents of the child, it is highly probable that an individual with genetic defects may be born[11]. But no preliminary researches are offered and performed prior to using these technologies.

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[9] *Genomics and World Health* (Report of the Advisory Committee on Health Research) / World Health Organization (*http://www.who.int/rpc/genomics_report.pdf*, 2002, – 241 p. – P. 113).

[10] *Why are we opposed to mitochondrial donation? / STOP GM 3 Parent Babies* (*http://www.stopgm3parentbabies.com/why-are-we-opposed-to-mitochondrial-donation/*).

[11] Expert reaction to House of Lords parliamentary vote on mitochondrial donation (*http://www.sciencemediacentre.org/expert-reaction-to-house-of-lords-parliamentary-vote-on-mitochondrial-donation/*).

As a result, the natural rights of the child, i.e. to human dignity (at the pre-embryonic stage the child is only treated as a test subject) and to health and health protection, are seriously violated. There is a huge difference when the child is naturally born with some abnormalities and when the child is artificially conceived with very high risks of defects knowingly permitted (including long-term defects).

Obvious insecurity of the introduction of these technologies into medical practice by preliminary referential medical experiments verifiable by claimed results, failure to scientifically prove statements of supporters of these technologies about their safety and positivity and, most dangerously, about long-term somatic and genetic consequences of their use – all of this do not allow us to consider these statements reliable and these technologies – safe.

5 - Conception of the child using the above technologies supposes that a third person interrupts strictly pair (by its nature and essence) reproductive relationships between man and woman and, thus, directly contributes to the destruction of the social institutions of parenthood, fatherhood, motherhood and family.

The child has the inalienable natural right, constitutionally and internationally guaranteed, to know his/her parents and grandparents.

Since, according to the UK legislation, donor mitochondria will be transferred anonymously, children conceived in this way will not be principally able to exercise this right (i.e. to know their parents). The argument of supporters of these methods that mitochondria are not so important for the personal identity is questionable since a third person who made a genetic contribution to the conception of the child shall also be considered as his/her parent. This position is defended by many experts, including Tim Stanley[12].

The elimination of anonymity in the use of these technologies will raise other, more serious issues of uncertainty of genealogical identity and self-identification of the child produced using these technologies from three "genetic participants" of the process. Such manipulations (conception using genetic material of a third person) will certainly undermine the genealogical identity and self-identification of the child conceived in this way, will result in contradictory or confusing vision of the child of himself/herself and social roles of others in relation to

[12] **T. STANLEY**, *Three parent babies: unethical, scary and wrong*, cit.

himself/herself, and make it really difficult (even exclude the possibility) for the child to determine his/her personal and family (genealogical) identity.

The use of mitochondrial donation technologies, in fact, involves the construction of a new (another) egg from the material of two women rather than significant adjustment, "repair" of a defective egg. This produced new egg do not genetically belong to either of these two women alone, so we can say that the child born as a result of such manipulations is "distanced" from the two women and, as aptly stated by Tadeusz Pacholczyk, "orphaned" from both women who participated in the process[13].

Moreover, the use of such technologies may subsequently (and will very likely) adversely, even devastatingly affect the relationships between the children and their official parents. This may lead to a serious negative impact on public morals and to negative social distortions.

6 - The use of these technologies will create significant and currently unpredictable genetic risks for future generations, i.e. for the offspring of the child conceived using such technologies. Related risks are very likely not restricted by the first (present) generation, and manipulations made within such procedures have an indirect impact on subsequent generations.

Therefore, it is highly risky to legitimate and introduce these technologies into practice. Not only the child conceived in this way but also all his/her offspring will be genetically modified. However, the child himself/herself and his/her [future] off spring are totally deprived of the possibility of giving his/her informed consent to the use of such (in fact, experimental) technologies (technologies of genetic modification) against him/her.

7 - The technologies in question, in fact, represent hidden forms of eugenic manipulations (i.e. methods of improvement of the "human breed" aimed at creating humans with new qualitative characteristics).

Although it is claimed that technologies aimed at preventing the birth of children with genetic defects are mainly used for fundamental

[13] **T. PACHOLCZYK**, *The Ethics of Correcting Mitochondrial Disease*, Catholic Education Resource Center (*http://www.catholiceducation.org/en/science/ethical-issues/the-ethics-of-correcting-mitochondrial-disease.html*).

humane reasons, such as compassion and care, the technologies in question, in their essence and according to their real objectives, are quite clearly traceable to the eugenic practice, and the legitimation of these technologies will set a dangerous precedent in this area.

Using of technologies of implantation of foreign mitochondria (of a third person) do not represent methods of treatment or adjustment of mitochondrial diseases, and therefore the legitimation of "mitochondrial donation" is not a panacea or tool preventing mankind from mitochondrial diseases.

These technologies are used to create a completely alternative system of child conception, which obviously contradicts with the natural (authentic) human reproduction procedure and, in fact, is aimed at the eugenic selection of certain "artificially engineered" ("designer") children and, in the long term, at making it technologically possible to "construct" children with predefined characteristics.

As a matter of fact, these methods do not treat mitochondrial diseases but greatly reduce impetuses and motivation for scientific researches aimed at developing new methods of treatment of such diseases.

Instead of focusing on helping those suffering from such diseases, the above-mentioned regulatory act adopted in the UK, in fact, is aimed at preventing the birth of children with such diseases, no matter whether real or imaginary concerns about future genetic defects underlie such decisions and no matter to which extent such defects can be treated.

The use of these technologies is expressly prohibited or negatively assessed in a number of international instruments. When analyzing the legitimacy and ethics of the use of the above technologies, the international human rights instruments shall be considered first.

According to Article 13 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) dated April 4, 1997[14],

> "any intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants".

[14] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997, *http://conventions.coe.int/treaty/en/*(*Treaties/Html/164.htm*).

Article 5(a) of the Universal Declaration on the Human Genome and Human Rights (1997)[15], which is advisory, states that

> "research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law".

According to Article 11 of the Declaration, "practices which are contrary to human dignity … shall not be permitted". Article 24 of the Declaration seeks to identify "practices that could be contrary to human dignity, such as germ-line interventions".

As reasonably stated by Tim Stanley, society has always avoided the use of genetic engineering techniques in relation to infants since it is very dangerous to give humans the opportunity to select "characteristics" of their children. According to this author, in addition to relevant ethical issues, such ability to "design" may reduce the amount of natural variations within the human race, which, in turn, will generally reduce its adaptation abilities necessary to survive. If the need to eliminate some features of embryos will depend on the 'trend', it will have a significant adverse impact on future generations[16].

It should be emphasized that human conception using these technologies may have other unforeseen, highly significant, adverse medical and social, including demographic, moral and legal consequences in future.

8 - Conclusions

Thus, the construction of human embryo using "mitochondrial donation" technologies is unacceptable, in terms of bioethics, and illegal and clearly and materially contradicts with a number of international instruments on human rights, human health protection, and bioethics.

[15] Universal Declaration on the Human Genome and Human Rights of 11.XI.1997 (*http://portal.unesco.org/en/ev.php- URL_ID=13177&URL_DO=DO_ TOPIC&URL_SECTION =201.html*).

[16] **T. STANLEY**, *Three parent babies: unethical, scary and wrong*, cit.