



THE OFFICIAL POSITION OF THE POLISH SOCIETY OF REPRODUCTIVE MEDICINE AND EMBRYOLOGY (PTMRIe) AND OF THE FERTILITY AND INFERTILITY SECTION OF THE POLISH GYNAECOLOGICAL SOCIETY (SPiN PTG) CONCERNING THE PROPOSED LIMITATIONS IN INFERTILITY TREATMENT THROUGH IN VITRO FERTILISATION (IVF)

It is the position of the Polish Society of Reproductive Medicine and Embryology and the Fertility and Infertility Section of the Polish Gynaecological Society that attempts to further limit the number of fertilised oocytes and the potential prohibition of embryo freezing will deprive infertile patients of the access to safe and effective treatment of infertility by in vitro fertilisation, in accordance with the worldwide standards and good medical practice.

Because of biological and natural considerations, only about 3% of fertilised oocytes will end their development in pregnancy and result in the birth of a child. For this reason, hormonal stimulation and fertilisation of multiple oocytes are fundamental conditions for ensuring “acceptable efficacy” of the treatment, defined as 30–35% pregnancies per cycle. The current Act on Treatment of Infertility of 25 June 2015 in force in Poland limits the number of fertilised oocytes to 6 for women below the age of 35. This constitutes the most restrictive solution in Europe and in the world, albeit preserving the “acceptable efficacy”, as demonstrated by the results of the programme of the Ministry of Health (Programme – Treatment of Infertility Through the In Vitro Fertilisation Method for 2013–2016). The proposed further limitation of the number of fertilised oocytes **will dramatically reduce the efficacy of treatment**. As demonstrated by scientific studies, fertilisation of only one oocyte results in a birth rate of 4.7%. This represents a 5- to 7-fold decrease in treatment efficacy in comparison to a situation where no such limitation exists¹. As a consequence, the practice of limiting the number of fertilised oocytes dramatically reduces the chance for pregnancy, and sometimes eliminates it altogether because of the age factor which additionally naturally limits the woman’s fertility. The need for multiple repetitions of the procedures, including hormonal stimulations and ovarian punctures, unnecessarily increases health risks for the woman, including psychological risk, and also dramatically increases the costs borne by patients and the healthcare system.

¹ *Sesh Kamal Sunkara. Antonio LaMarca. Nikolaos P. Polyzos. Paul T. Seed and Yakoub Khalaf Live birth and perinatal outcomes following stimulated and unstimulated IVF: analysis of over two decades of a nationwide data. Human Reproduction Volume 31, Issue 10 Pp. 2261-2267.*



Cryopreservation of embryos is an integral and necessary stage of the in vitro fertilisation procedure and also constitutes a basic prerequisite for effectiveness and safety of the conducted treatment. In the practical aspect, it protects the woman's health when there are contraindications for embryo transfer to the uterus, ensures safety to the embryos in a situation where they cannot be delivered to the woman's body. Cryopreservation of embryos is the basis for securing fertility for the future in cases of cancer or any other significant risk of fertility loss. Absolute prohibition of embryo freezing will result in the need to transfer them to the uterus regardless of the circumstances. Consequentially, such an approach will put at risk the health and safety of women with imminent ovarian hyperstimulation syndrome and in other clinical situations where embryo transfer is contraindicated. It will also significantly increase the risk to embryos which will be transferred to the uterus in situations where such a transfer is contraindicated (e.g. inadequate endometrium in the uterus, luteal phase insufficiency, etc.). In the cases where transfer of the embryos to the uterus is impossible (e.g. misfortunes, an accident en route to the transfer, etc.), the prohibition of freezing will mean that embryos would inevitably die. Persons of childbearing potential who develop cancer or diseases that require a treatment associated with gonadal toxicity will lose their chances for using assisted reproductive technologies that defer fertility and require the cryopreservation of embryos.

The attempts of prohibiting the cryopreservation of embryos are incomprehensible from the point of view of contemporary medical knowledge. The available scientific reports confirm that neither cryopreservation of embryos itself nor the time of their preservation have a negative effect on their developmental potential². The clinical data on health of the children born from singleton pregnancies as a result of the transfer of defrosted embryos (the so-called cryotransfers) did not demonstrate any increase in the risk to their health and development in comparison with naturally conceived pregnancies³.

² Qinli Liu, Ying Lian, Jin Huang, Xiulian Ren, Ming Li, Shengli Lin, Ping Liu and Jie Qiao. The safety of long-term cryopreservation on slow-frozen early cleavage human embryos: *J Assist Reprod Genet.* 2014 Apr; 31(4): 471-475. doi: [10.1007/s10815-014-0197-0](https://doi.org/10.1007/s10815-014-0197-0).

³ Pinborg A, Loft A, Aaris Henningsen A-K, Rasmussen S, NyboeAndersen A. **Infant outcome of 957 singletons . born after frozen embryo replacement: The Danish National Cohort Study 1995-2006.** *Fertil Steril.* 2010 Sep;94(4):1320-7. doi:10.1016/j.fertnstert.2009.05.091; .S. Pelkonen, R. Koivunen, M. Gissler, S. Nuojua-Huttunen, A.-M. Suikkari, C. Hydén- Granskog, H. Martikainen, A. Tiitinen, A.-L. Hartikainen Perinatal outcome of children born after frozen and fresh embryo transfer: the Finnish cohort study 1995-2006 *Hum. Reprod.* (2010) 25(4): 914-923 first published online February 2, 2010 doi:10.1093/humrep/dep477.



Experts of the Polish Society of Reproductive Medicine and Embryology (PTMRIE) and of the Fertility and Infertility Section of the Polish Gynaecological Society (SPiN PTG) are of the unanimous opinion that the current Act on the Treatment of Infertility of 25 June 2015 enables access to safe and effective treatment of infertility, guarantees the legal rights to reproduction and the right to family development, and protects the safety of women and embryos.

Changes in the provisions of the Act that would lead to a dramatic decrease in the number of fertilised oocytes and the prohibition of cryopreservation of embryos will result in limiting the efficacy and safety of the treatment and will also limit access to state-of-the-art treatment methods and violate other legal rights of the patients.

Polish patients should have access to safe, modern medicine, and Polish physicians should have the possibility of using effective treatment consistent with evidence based medicine and decades of clinical experience documented in hundreds of thousands of scientific papers of Polish and foreign researchers.

Warsaw, 28 October 2016

/-/
Katarzyna Koziół, MD
President
of the Polish Society
of Reproductive Medicine and Embryology

/-/
Professor Waldemar Kuczyński, MD, PhD
Chairman
of the Fertility and Infertility Section
of the Polish Gynaecological Society