# Policy on Assisted Reproduction in Slovakia

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# **List of abbreviations**

- **ART** Assisted reproduction treatment
- **ER** Embryo-reduction
- **ESHRE** European Society of Human Reproduction and Embryology
- **EUTCD** The European Union Tissue and Cells Directives
- HLA Human leukocyte antigen
- ICSI Intracytoplasmic sperm injection
- IFFS International Federation of Fertility Societies
- IUI Intrauterine insemination
- IVF In vitro fertilization
- PGD Preimplantation genetic diagnosis
- PGS Preimplantation genetic screening
- **TESA** Testicular sperm aspiration
- **TESE** Testicular sperm extraction
- VšZP Všeobecná zdravotná poisťovňa

### Abstract

Aim of this paper is to give an overview of policy on assisted reproduction in the Slovak Republic. This paper can serve as guideline for couples looking for achieving offspring. Pointing out all advantages and disadvantages of infertility health policy, this analytical paper can help to policy and decision makers to perceive perspectives for policy and quality improvement.

Slovakia, likewise many European countries, is facing accelerated aging population problem with in the same time growing number of couples whose can not achieve offspring. Infertile couples can obtain assisted reproductive treatment in two public and six private hospitals in Slovakia. Slovak law, based on International declarations and European directives, allow in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI) method as well as donation, while prohibit surrogacy, experimentation on the embryo and cloning. As time consuming treatment of infertility, cryopreservation is allowed as one of the possibility to rich offspring in shorten time and more convenient way for woman. Possibility to apply pre-implantation genetic diagnosis (PGD) rang Slovak legislation as one of the liberal in Europe.

Confidentiality and anonymity are binding but Slovakia is among countries that on request provide offspring with identifying information. While couples can't expect that IUI treatment will be covered by their insurance, IVF treatment will be fully and ICSI partly reimbursed. Success rate and outcomes are still followed on the micro (hospital) and mezzo level (health insurance). Luck of national national register and reporting system are seen as one of the main problem in terms of measuring outcomes as important part of infertility health policy. Establishing these institutions would help to policy and decision makers to compare Slovak outcomes and regulations achievement in infertility health care with other European countries.

### Background

Assisted reproduction treatment (ART) is for many infertile couples the only way of pregnancy. Worldwide, the availability of ART is influenced by a complex combination of public and private health policies, as well as economic, political and social/cultural forces.<sup>1</sup> The Slovak Republic is country which, apart from accelerating the aging process, nowadays is facing the problem of infertility. Total population of Slovakia is 5.397.036<sup>2</sup>, where 80.7% declare their nationality as Slovak. The second nationality is Hungarian with 8.5%, Roma with 2% and other nationalities make together 8.8% of total population.<sup>3</sup> Population growth rate in the Slovakia Republic is positive 0.2% and birth rate is 11 births/1.000 populations while total fertility rate (total number of live births on one woman) is 1.4 children born per woman.<sup>4</sup> Those demographics facts show positive birth rate and slightly increasing trend of population.

Despite these data, increasing the number of infertile couples is a negative phenomena. Data from the 80<sup>th</sup> to 90<sup>th</sup> years reported 12–13% of infertile in Slovakia while now that number rise up to 15% of infertile couples. Estimation says that in Slovakia there are 121.631 infertile couples.<sup>5</sup> One of the six infertile couple solve the problem of infertility but for 9% of couples assisted reproduction treatment is the only way to achieve offspring.<sup>6</sup> As stated in the draft National Program on Protection of Sexual and Reproductive Health in Slovakia, there is still a low number of assisted reproduction interventions performed. In 2004 just 0.3%<sup>7</sup> of children were born after the performance of some of the assisted reproduction techniques.

The latest data for Slovakia show that an average of 50% of infertile couples is the cause of man infertility which is rising from year to year.<sup>8</sup> In the case of woman infertility in Slovakia, the main cause that 40% of women are childless due to is functional ovarian hormonal disorders. Large group of women are with positive antibodies on partner sperm and great importance is attributed

<sup>1</sup> Nachtigall, RD.: *International disparities in access to infertility services*. Fertil Steril 2006; 85:871–875 2 Statistical Office of the Slovak Republic: *Development in the number of inhabitants*, 2008 available at: <u>http://portal.statistics.sk/files/table-1.pdf</u>, Retrieved: April 3, 2013

<sup>3</sup> Ibid

<sup>4</sup> World Bank: *Population growth (annual %)*, available at: <u>http://data.worldbank.org/indicator/SP.POP.GROW</u>, Retrieved: April 3, 2013

<sup>5</sup> Extrapolation only! Not based on country-specific data sources, Right Diagnosis from Health Grades, available from <a href="http://www.rightdiagnosis.com/i/infertility/stats-country.htm#extrapwarning">http://www.rightdiagnosis.com/i/infertility/stats-country.htm#extrapwarning</a>, Retrieved: March 26, 2013 6 Gertler P. in "Support for assisted reproduction is a year chance for thousands of couples" (22.05.2007), available at: <a href="http://www.zzz.sk">www.zzz.sk</a>

<sup>7</sup> Ministry of Health of the Slovak Republic: Draft National Program on Protection of Sexual and Reproductive Health in the Slovak Republic, op. cit., part 8.8

<sup>8</sup> Dôvera, Interview April 5, 2013, Bratislava, Slovakia

to the age of the partners. Some estimation says that women who have been issued between 30 and 35 years of age, 20% of them still remain childless<sup>9</sup>. This is going in line with well-known medical fact that after 35 years the prospect of getting pregnant is significantly reduced. In addition, Slovakia is growing secondary infertility-the inability to conceive another child.

Regarding religious affiliation in 2011, most of the populations of Slovakia were Roman Catholics (62%). The members of the Evangelical Church of the Augsburg Confession (5.9%) and Greek Orthodox (3.8%) are the next biggest religious confession while 14.9% belonged to other religions and 13.4% of the population doesn't have any religious affiliation.<sup>10</sup> Slovakia signed a series of treaties with the Vatican by beginning in 2000 which oblige the country to codify certain treaty principles, such as a doctor's right to refuse to perform abortions, in national law. Christian churches, especially the Catholic Church, play a highly significant role in bioethical discussions in Slovakia, which also considerably influences Slovak biopolicy, which can be seen as fairly conservative.<sup>11</sup> If 70% of gynecologists in Slovakia refused to prescribe contraception, perform sterilization, abortion or assisted reproduction; the services would become practically unavailable.<sup>12</sup> It could lead to the situation when the state would provide only health care services and treatments in conformity with the Catholic teaching, which is not that case in Slovakia where assisted reproduction treatment is regulated by national legislation and is performed in medical indicated cases.

<sup>9</sup> Vargová V.: Bezdetných párov pribúda, (May 20, 2011) in sme.sk, available at:

http://korzar.sme.sk/c/5900588/bezdetnych-parov-pribuda.html#ixzz2OqHqfXHM, Retrieved April 8, 2013. 10 Statistical Office of the Slovak Republic:: *Census in 2011*, available at: <u>http://www.statistics.sk</u>, Retrieved: April 8, 2013

<sup>11</sup> Vilikovská Z.: *Catholic church believes Slovak Parliament will support Vatican treaties*, (June 23, 2010) in The Slovak Spectator, available at:

http://spectator.sme.sk/articles/view/39334/10/catholic church believes slovak parliament will support va tican treaties.html, Retrieved: April 10, 2013

<sup>12</sup> Lajčáková, J.: End of Women's Reproductive Health Freedoms in Slovakia: The Draft Treaty between the Slovak Republic and the Holy See on the Right to Exercise the Objection of Conscience op. cit., para. 18.

### **1. Legal policy**

The Slovak Republic is country where from the very beginning of biomedicine and bioethics' development, was recognized their importance. Country ratified many conventions on international and European level and implemented in its legislation. The importance of the bioethics in Slovakia has been seen on the beginning of 90's when the first serious health care reform attempt was fostered and prepared by the Slovak Ministry of Health between the years 1990–1992.<sup>13</sup>

At the international level, the Universal Declaration on the Human Genome and Human Rights was adopted unanimously and acclimated by the General Conference of UNESCO in 1997 and endorsed by the General Assembly of the United Nations in 1998 (*Table 1*). Convention, which is recognized as a standard in protection and promotion the rights of patients and users of health services, is Oviedo Convention on Human Rights and Biomedicine (1998). Thus, it's used for evaluation of the efforts and the progress made by the EU Member States. Slovakia have signed this Convention on April 4<sup>th</sup> 1997 and ratified on January 15<sup>th</sup> 1998 as the first Eastern European country. The Convention entered into force on 1<sup>st</sup> December 1999 and was published in National law under No. 40/2000 Coll.<sup>14</sup>

Access to infertility and sterility treatment is considered as fundamental human right in accordance with article 14 and article 8 of the *Convention for the Protection of Human Rights and Fundamental Freedoms* (1950) and of the *European Parliament resolution on the demographic future of Europe* (2008) where the principle of non-discrimination is highly lighted and respectful. Everyone can have equal access to infertility treatment without discrimination based on religion or belief, disability, age or sexual orientation. In Slovakia, there is still a low number of assisted reproduction interventions performed. Performing the assisted reproduction intervention is conditioned by intimate physical relationship between a man and a woman. This provision discriminates against single women who would like to get pregnant by means of assisted reproduction, as well as against women in homosexual relationships.<sup>15</sup>

<sup>13</sup> Oviedo Convention in Central and Eastern European Countries, Conference Medicínska etika & Bioetika – Medical Ethics & Bioethics Volume 16, 2009, Supplementum 1, Institute of Medical Ethics and Bioethics n. f., Bratislava, Slovak Republic, pages 1 – 32

<sup>14</sup> Defloor S. et al.: Patient Rights in the EU – Slovakia, European Ethical-Legal Papers N°14, Leuven, 2008, pg. 7 15 Spoločnosť pre plánované rodičovstvo: SRHR in Slovakia, available at:

http://rodicovstvo.wordpress.com/english/srhr-in-slovakia/, Retrieved: April 10, 2013

All these conventions had influence on internal legislative process in Slovakia. It has made more visible the existence of a common set of values based on human rights throughout Europe it has contributed to a deeper awareness of the necessity to reinforce these values by passing to national laws that are compatible with the Oviedo Convention. Moreover, it has stimulated the political debate and work on a legal policy in Slovakia.

Slovakia ratified Additional Protocol to the Convention Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998) came into force on March 1<sup>st</sup> 2001. Article 1 of the Protocol states: "Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited."<sup>16</sup> Furthermore, Slovakia ratified Additional Protocol on Biomedical Research (2005) which emphasizes the importance role of ethics committees, evaluation on merits of the research, duty of care and patient consent which, according with the Article 14 of this document has to be "informed, free, express, specific and documented."

Year	International/European Document	Notification
1950	Convention for the Protection of Human Rights and Fundamental Freedoms	<ul> <li>Signature 2/21/1991</li> <li>Ratification 3/18/1992</li> <li>Entry into force 1/1/1993</li> </ul>
1997	Universal Declaration on the Human Genome and Human Rights	<ul> <li>adopted unanimously</li> </ul>
1998	The European Convention on Human Rights and Biomedicine, Oviedo	<ul> <li>first Eastern European country</li> <li>Act No. 40/2000 Coll.</li> </ul>
1998	Additional Protocol to the Convention Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings	• came into force March 1st 2001.

#### Table 1. Overview of International and European Acts recognized from the Slovak Republic

<sup>16</sup> United Nations Educational, Scientific and Cultural Organization (UNESCO), National Legislation: Concerning Human Reproductive and Therapeutic Cloning, Paris, July 2004

2004	European Parliament and Council Directive 2004/23/EC of 31 March 2004 (OJ. L 102, 7 4 <sup>th</sup> 2004)	<ul> <li>setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells</li> </ul>
2005	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research	<ul> <li>ratified September 25th 2005</li> <li>enter in force September 1st 2007</li> </ul>
2006	Commission Directive 2006/86/EC of 24 <sup>th</sup> October 2006	<ul> <li>Implementing Directive of the European Parliament and Council Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ. L 294, 25 10th 2006)</li> </ul>
2008	European Parliament resolution on the demographic future of Europe	• principle of non-discrimination

Source: Author

Based on documents above, Slovak law makers defined national law framework. Precisely, the national legislation framework in Slovakia on the assisted reproduction is made by the Act No. 576/2004 Coll. on Health Care, which was amended by Acts No. 350/2005, 282/2006, 662/2007, 345/2009 Coll. (*Table 2*).<sup>17</sup> Law No. 576/2004 Coll. on health care (as amended later) covers biomedical research in general, including genetic research. This Act regulates informed consent, biomedical research (including "special situations"), ethics committees, question about transplantation, organ/tissue donation as well as patients' rights. Some bioethics issues were excluded (e.g. assisted reproduction, some issues in genetics, cloning).

Human reproductive and therapeutic cloning is prohibited according to the Health Care Act No. 277/1994 and the Slovak Criminal Code (2003): "Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited."<sup>18</sup> Therapeutic cloning is implicitly prohibited by Article 42, sub-paragraph 3c of the same act which states: "Research without medical indication is not permitted on human embryos and fetuses." For

<sup>17</sup> Act No. 576/2004 Coll. on Healthcare, Healthcare-related Services and on the Amendment and Supplementing of Certain Laws, Available at:

http://www.privireal.org/content/rec/documents/Slovakia\_ActNo576\_Healthcare\_2004.pdf, Retrieved: April 10, 2013

<sup>18</sup> The Health Care Act No. 277/1994, Article 46

person who performs any intervention seeking to create a human being shall be sentenced from 3 to 8 years of imprisonment or shall be punished by a prohibition of activity or by a pecuniary penalty.<sup>19</sup> It is clear that cloning of human being is seen as criminal act and became subject of criminal sanction.

No explicit regulations on the use of predictive genetic tests could be found in Slovak medical law. Genetic testing in Slovakia is mainly regulated by the legal framework that applies to health services as a whole. Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counseling.<sup>20</sup> The lack of national legislation however doesn't mean that the use of predictive genetic tests is not regulated since article 12 of the Biomedicine Convention is directly applicable.

National Act	Regulated issues
Health Care Act No. 277/1994 and	Human reproductive and therapeutic
Slovak Penal Code (2003)	cloning
Act No. 576/2004 Coll. on Health Care amended by Acts No. 350/2005, 282/2006, 662/2007, 345/2009 Coll.	<ul> <li>informed consent,</li> <li>biomedical research (including "special situations") covers biomedical research in general, including genetic research.</li> <li>ethics committees</li> <li>question about transplantation</li> <li>organ/tissue donation</li> <li>patients' rights</li> </ul>
Government Regulation no. 20/2007	<ul> <li>details of donations</li> <li>the donation of tissues and cells</li> <li>the criteria for donors of tissues and cells of laboratory tests required for donors of tissues and cells</li> <li>procedures for procurement of cells or tissues and reception health care providers</li> </ul>
	• ART conditioned by intimate physical relationship between a man and a

#### Table 2. National Legal Framework on Assisted Reproduction in Slovakia

<sup>19</sup> Slovak Penal Code, article 246a, introduced on September 1, 2003 20 Convention on Human Rights and Biomedicine, article 12

	woman.
Act No. 428/2002 Coll. on Protection of Personal Data	<ul> <li>processing of personal data</li> <li>protection of the rights of data subjects</li> </ul>
Act No. 577/2004 Coll. of Laws on the Scope of Health Care Covered by the Public Health Insurance and on Payment for Services Related to Health Care Provision as amended	• Limited on 3 cycles up to 39 years

Source: Author

Ministry of Health of the Slovak Republic<sup>21</sup> and Institute of Medical Ethics and Bioethics<sup>22</sup> are the relevant authorities on the assisted reproduction issue in Slovakia. An active role in preparation and commenting on the new health legislation has Central Ethics Committee of the Ministry of Health. Slovakia does not have own registry established yet, consequentially no registration of treatments. The curiosity is that Slovakia is the one of two EU Member States (with Poland) which at once has implemented The European Union Tissue and Cells Directives (EUTCD) and has not established a Competent Authority. Thus, ethical committees on regional level play important role. Regional ethics committees are appointed by the regional state authority while local ethics committees are appointed by directors of health care facilities or research institutions. No centralized authority currently supervises or audits ethics committees, or checks for their quality.<sup>23</sup> There are 8 regional ethics committees, and about 60 "local" ethics committees. According to the law, each inpatient health care facility in Slovakia should have an ethics committee<sup>24</sup> which is in charge to give opinion and decision on many ethical dilemmas that can be raised on questions about assisted reproduction based on ethical guidelines. On supranational level, Slovakia also started to take part in the regular work and other activities of the Council of Europe committees, including the present the Committee on Bioethics (DH-BIO).

Confidentiality and informed consent as well as legal and ethical issues on collecting and protecting information is defined by national law. The right of a patient to consent to diagnostic

http://www.iss.it/ecet/scie/cont.php?id=85&lang=2&tipo=23#stop

<sup>21</sup> On Slovak: *Ministerstvo zdravotníctva Slovenskej republiky* is competent authority for tissues, HPC and ART, available from: <u>http://www.health.gov.sk/</u> and

<sup>22</sup> Institute of Medical Ethics and Bioethics, n. f., Bratislava, Slovakia, see more on: <u>http://www.bioethics.sk/</u> 23 EFGCP: *The EFGCP Report on The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe* (April 2011), available at:

http://www.efgcp.eu/Downloads/EFGCPReportFiles/Slovakia%20interim.pdf, Retrieved: March 18, 2013 24 For more information see:

http://www.health.gov.sk/redsys/rsi.nsf/0/1F79D6C7C9726858C12574C7004104A7?OpenDo cument&ID=&TYPE=U&LANGUAGE=S&LENGTH=S or at the web page of SIDC: http://www.sukl.sk/sk/klinickeskusanie-liekov/pokyny/zoznam-etickych-komisi-va0slovenskej- republike

procedures (such as genetic tests) is one of the basic patient rights in Slovakia.<sup>25</sup> "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time".<sup>26</sup> Right to medical secrecy/confidentiality says that everyone has the right to respect for private life in relation to information about his or her health.<sup>27</sup> The processing of personal data and the protection of the rights of data subjects are regulated by the Act No. 428/2002 Coll. on Protection of Personal Data.

The Slovak Republic, as secular country allow many procedures and treatments on assisted reproduction but it seems that some issues are not précised in national law (*Table 3*). Soft regulations on clinical and good laboratory practice guidelines are having big impact on performing treatments that are not regulated by law.

Slovakia	IUI IVF ICSI	Assisted Hatching	Oocyte maturation	TESA/TESE	IVF Surrogacy	Other Micromanipulation
Allowed by Law	Yes	Yes* in some hospitals	Yes	Yes	No	Not mentioned

Source: Author

National Slovak Law doesn't obligate clinics to report performance and outcomes. European Society of Human Reproduction and Embryology (ESHRE) in its Annual Report (2009) was missing Slovak data on this issues due to the fact of lacking reporting system. Outcomes are followed on hospital (micro) level measuring its success rate and health insurance companies (mezzo) level which collect data from providers about outcomes for its insurers.

26 Convention on Human Rights and Biomedicine, article 5

27 Ibid., article 10

<sup>25</sup> Defloor S. et al.: *Patient Rights in the EU – Slovakia*, European Ethical-Legal Papers N°14, Leuven, 2008, pg.33

In Slovak Republic there are eight active centers in Bratislava, Košice and Martin and each of these Hospitals supposed to meet the criteria given for performing assisted reproduction treatments by Ministry of Health. Performed number is about 2000 to 2500 per year in facilities which are mostly private, two centers are state-owned (Univerzitné centrum reprodukčnej medicíny in Bratislava and Univerzitná nemocnica L. Pasteura, Košice) and six are private. For the first time private clinics have been involved in providing AR treatment from the year 2000 due to the fact that public clinics in that time weren't well equipped.<sup>28</sup> These private clinics represent contract partner of health-insurance companies in Slovakia. Currently, there is one state health insurance (Všeobecná zdravotná poisťovňa -VšZP) and 2 private (Dôvera and Union) which are covering the treatment of *in vitro* fertilization under certain conditions.<sup>29</sup>

Treatment is open to all citizens without any restriction regarding marital status, number of cycles, embryo's<sup>30</sup> either in public and private institutes. As the society becomes more familiar with all aspects of ART, the requirements concerning the marital status in ART is more liberalized.<sup>31</sup> Couples who aren't married but leaving in stable union need to have signed notary notification as a proof of their relationship.<sup>32</sup> Therefore, there are not criteria that supposed to be met in order to be eligible for assisted reproduction treatment if couples are going to pay out of pocket. Couples that for certain time can't achieve offspring, must have referral from gynecologist. Women (infertile couples) are sent to Centers of assisted reproduction on the basis of recommendations of the attending gynecologist where they will get suggestion about certain procedure.<sup>33</sup> Examinations and treatments are without registration fees.

<sup>28</sup> Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013

<sup>29</sup> Slovakia is going to return to have a single, state-run health insurance system and nationalize two private insurers from 2014.

<sup>30</sup> ESHRE: Final Report-Comparative Analysis of Medically Assisted Reproduction in the EU: Regulation and Technologies, 2010, pg 21

<sup>31</sup> Dostál J., *Specific Ethical and Legal Aspects of ART practice in Eastern European Countries* (63-86) in book: Ethical Dilemmas in Assisted Reproductive Technologies edited by Schenker G. J, (2011), De Gruyter, Berlin, pg.67

<sup>32</sup> Gyn-Fiv, Bratislava, Interview April 15, 2013

<sup>33</sup> Všeobecná zdravotná poisťovňa, Interview 10<sup>th</sup> April 2013, Slovakia

#### Table 4. Reimbursement of assisted reproduction

	Intrauterine insemination (IUI)	Number of cycles IVF/ICSI	Embryo- reduction (ER)	Decision makers to allow reimbursement
Slovakia	No	up to 2-3	No	According to decision of health insurance company

Source: Author

National program in Slovak Republic for IVF does not exist<sup>34</sup> and treatment is not fully covered from the national health insurance fond either from private insurance company (*Table 4*). There are differences across the Europe regarding the number of cycles reimbursed and minimum criteria for reimbursement are the criteria that apply to access to assisted reproduction treatments.

Using IVF treatment (as well as other health care), to the extent and in the manner specified by the competent is generally paid for by the applicable legal standards. In particular, the conditions for its payment shall be laid down in contracts concluded between the Health Insurance Company and Health care provider – the Center of assisted reproduction.<sup>35</sup>

In general, centers of assisted reproduction can have contracts with insurance company for three types of performances due to the specificity of the treatment. Unfortunately, it is possible that woman under hormonal stimulation will not produce eggs with good quality or not produce at all which can implicate nonperformance of embryotransfer. There are three options. First option is that health insurance will pay for cycle prior to oocyte collection. Second performance is cycle of the oocyte collection *in vitro* fertilization without the transfer embryos and third one complete cycle with embryo transfer.

In Slovakia, couples that are undergo intrauterine insemination (IUI) can expect that will not be reimbursed at all while for IVF/ICSI treatment they can expect partly reimbursement.<sup>36</sup> Data in *Table 5* represent the percentage of reimbursement in public centers. Consultations, blood analysis and ultrasound examinations are fully covered by insurance.<sup>37</sup> The second part of treatment program, when woman start with hormonal stimulation is covered by 70% while the rest is covered by patients out of pocket. Drugs per one cycle can cost up to 1.200 euros where lowest patient co-payment can range between 150-350 euros.<sup>38</sup>

<sup>34</sup> Ibid

<sup>35</sup> Ibid

<sup>36</sup> Fertility Europe: Equality of Access to Medically Assisted Reproduction across Europe – May 2012, pg.12 37 Všeobecná zdravotná poisťovňa, Interview 10<sup>th</sup> April 2013, Slovakia

<sup>38</sup> Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013

#### Table 5. Reimbursement of IVF treatment in Slovakia

	Consultations	Blood analysis	Ultrasound examinations	Drug (total cost)	Laboratory IVF	Laboratory ICSI
Slovakia	100 %	100 %	100 %	Up to 70 %	100 %	75 %

Source: Author

Furthermore, laboratory phase of IVF will be covered 100%. The performance of IVF method (including embryotransfer) based on the public health insurance (VšZP) is paid in full according to the law no. 577/2004 and will cover up to 3 IVF/ISCI cycles.<sup>39</sup> IVF procedure (embryo-transfer included) costs around 1.100 euro and ICSI laboratory phase would be covered partly since that this method is more complex and require additional labor work.<sup>40</sup> Payment for treatment is an individual in each center and for illustration cost of IUI goes from 50 to 150 euros, ICSI 200-660 euros, IVF up to 1.100 euros and cryopreservation from 30 to 150 euros.<sup>41</sup>

What are than medical reasons that allow patients to undergo treatment? According to the law no. 777/2004<sup>42</sup> IVF treatment expenses are reimbursed by health insurance company in the following indicated cases: absent or damaged Fallopian tubes, endometriosis, absent or damaged ovaries, sterility with a non-recognisable cause, low quality sperms of a partner, immune conditional sterility, inherited diseases, endocrine and others.<sup>43</sup> Treatment will be also reimbursed the due to the male factor infertility as well such are: azoospermia, asthenospermia, ejaculatory dysfunction and disease associated with chemotherapy or traumatic conditions that are verified by andrology, immunological causes of sterility, certified laboratory.<sup>44</sup> In all other cases that are not mentioned above, it is necessary to ask VšZP for authorization and reimbursement for certain IVF cycle by using separately form "Application for reimbursement of IVF performance by public health insurance"<sup>45,</sup> which lists assisted reproduction center in Slovakia. However, the insurance company pays 3 cycles (ie, ovarian stimulation, egg collection and embryo transfer) for woman under 39

41 Beňová Z.: Čo robiť, keď má bocian dovolenku, in Nový čas (January 11, 2009), http://lesk.cas.sk/clanok/83147/co-robit-ked-ma-bocian-dovolenku.html, Retrieved April 2, 2013
42 Insuring the List of Diseases, in case of which the health interventions are partially covered or not covered based on the public health insurance, annex no. 2, Scope of Payment for Medical Interventions in Case of Diseases Listed in the Disease Registry in Compliance with Section 1 para. 1 of the Decree.
43 VŠZP: Kedy platiť za zdravotnú starostlivosť a kedy nie, Available at:

https://www.vszp.sk/poskytovatelia/zdravotna-starostlivost/zdravotna-starostlivost/kedy-platit-za-zdravotnustarostlivost/, Retrieved: March 13, 2013

44 Vargová V.: *Bezdetných párov pribúda*, (May 20, 2011) in sme.sk, available at: <u>http://korzar.sme.sk/c/5900588/bezdetnych-parov-pribuda.html#ixzz2OqHqfXHM</u>, Retrieved April 8, 2013

<sup>39</sup> According to Government Regulation no. 777/2004

<sup>40</sup> Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013

years. According with the data from VšZP more than 3 times the performance of assisted reproduction will be paid by the person who requested the performance.<sup>46</sup>

In Dôvera, private health insurance company, there are two steps of procedure. First is that partners visit physician and after doing necessary tests, they are getting referral from one of the Clinics.<sup>47</sup> Clinics send request for authorization for certain couple and in 90% of overall cases it will be allowed for these couples to start with the treatment. The second step is related on what kind of drug protocol (short or long) will be used for certain couple and calculation of the expense that will be covered from health insurance (while the rest will be covered by patients out of pocket). Couples supposed to fill application for the request of payment of the performance of assisted reproduction for health reasons and submit it to health insurance. The cover of each cycle must be requested separately. Along with the application it is needed to submit request for payment assisted reproduction method IVF for health reasons. Request lists the center of assisted reproduction in which proposed treatment will be carried out. Review medical health insurance application assessing and meeting all conditions approved. Dôvera is covering two cycles for sure while decision about third will be made after looking into the patient medical documentation from previous cycles. That means that the patient has a legitimate claim for maximum three cycles but the law doesn't require reimbursement all three cycles. Dôvera has the criteria on woman age which is 38 years (before she reaches 39 years). This insurance company will cover fully IVF procedure with embryo transfer together with a partial payment for the drugs needed for in vitro fertilization (70% drug price is paid by insurance).<sup>48</sup> Apart from the basic cycle elongated culturing, part of ICSI procedure, storing reproductive cells, cryo-preservation, per-implantation genetic diagnosis (PGD) and other examinations and procedures beyond the basic cycle supposed to be covered by patients' out of pocket. Likewise, if patients decide to undergo the treatment of IVF with frozen embryos, than the case cycles will not be included in payments by health insurance companies.

Nevertheless, patients in Slovakia whose are going under assisted reproduction treatment are seen as patient under the risk and they are going to be monitored. The standardized procedure that would be done is amniocentesis (in first trimester of pregnancy) and, thus, would be covered

<sup>46</sup> As well as performance of medical abortion and sterilization (except if is because of medical reasons) 47 Dôvera: Časopis zdravotnej poisťovne Dôvera, 2010, Available online at: www.dovera.sk, Retrieved on March 29, 2013 48 Ibid

by health insurance.<sup>49</sup> Costs associated with treatment (travel, compensation time, discomfort) will be paid after the end of treatment and will be paid regardless of the outcome of treatment.<sup>50</sup>

Situation with reimbursement in Slovakian hospitals where treatment and drugs are partly covered can be possible confusing for the patients who are undergoing IVF treatment. In these cases, it's up to the hospitals to accurately calculate final price and provided to the patients. Patients supposed to be informed about the expenses covered by their health insurance company and how much they have to cover by themselves prior to the start stimulation in any case.

Regarding administrative procedures, patients do not need to pay on place the part that will be covered by insurance. They supposed to pay the amount that hospitals calculate that will not be covered by insurance. Contract between hospitals and health insurance companies regulate this issue on a way that hospitals administrators will send the invoice to the health insurance companies which will be reimbursed to the hospitals.<sup>51</sup> Reimbursement of IVF treatment starts with health insurance company request on behalf of the patient to the Center of assisted reproduction. Together with the application for reimbursement, Center of assisted reproduction submits also medical documentation of patient, which confirms the health indication of treated IVF patient. Doctor from insurance company will comprehensively verify and confirm the application for IVF reimbursement and issue on its opinion. His opinion validates the competent head worker of Health Insurance Company. Then the request is sent with the opinion of the Insurance Company back into the Center of assisted reproduction.<sup>52</sup>

Recently a major study ranked Britain near the bottom of a European league table on spending for fertility treatment. Even Serbia, Montenegro and Slovakia are paying more to help childless couples.<sup>53</sup> Numbers of cycles that Dôvera has covered in 2012 were 462 where success was in 182 cases what means 39.39% success rate.<sup>54</sup> This needs to be taken with reserve, since these dates are clinical and still miss dates from the maternity ward due to the fact that some pregnancies are biochemical or are not finished with delivering baby. Thus, some estimation says that one new life born trough IVF procedure cost between 10.000-12.000 euro what is money

53 Borland S.: *Third of women with right to IVF rejected by GPs who don't know enough about fertility treatment*, (August 27, 2012), Available at: <u>http://www.dailymail.co.uk/health/article-2194476/third-women-right-ivf-rejected-clueless-gps.html#ixz2nkywk1tj</u>, Retrieved March, 12 2013 54 Dôvera, Interview April 5 2013, Bratislava, Slovakia

<sup>49</sup> Dôvera, Interview April 5, 2013, Bratislava, Slovakia

<sup>50</sup> Centrum Asistovanej Reprodukcie ISCARE: *Darovanie vajičok*, Available at: <u>http://www.iscare.sk/liecba-a-vysetrenia/darovanie-vajicok/</u>, Retrieved March 25, 2013

<sup>51</sup> Dôvera, Interview April 5, 2013, Bratislava, Slovakia

<sup>52</sup> Všeobecná zdravotná poisťovňa, Interview April 10, 2013, Slovakia

obtained just for the procedures where are calculated failures plus 3.000 euro for drugs per case.<sup>55</sup> Health insurance companies observe outcomes of IVF treatments in terms of born babies number due to the fact that they are paying per performance.

In Slovakia is not known that some labor organization or local municipality is having kind of social program of financial support for its workers or citizens<sup>56</sup> like in Serbia as an example. Currently, there are no waiting lists for treatment by means of assisted reproduction created by IVF, treatment takes place smoothly, without waiting, and depends on current health status of the patient. This is a planned health care, which is performed in accredited Centers of assisted reproduction.<sup>57</sup>

55 Ibid

<sup>56</sup> Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013

<sup>57</sup> Všeobecná zdravotná poisťovňa, Interview April 10, 2013, Slovakia

# 3. Embryo transfer, Cryopreservation and Donation issues

There are some other issues of high importance for health infertility policy such are embryo transfer, cryopreservation and donations and their regulations in the Slovak Republic.

After laboratory phase decision about embryo-transfer is coming, precisely how many embryos to put into the woman's womb. That sensitive question in Slovakia is regulated by guidelines and usually it's one or two embryos<sup>58</sup> and maximum number is 3 embryos that can be transferred.<sup>59</sup> The final decision is based on the doctor's opinion on patient's health conditions, woman's age and patient's preference.<sup>60</sup> Even implementing 2 embryos brings risk off multiply pregnancies. New International and European guidelines emphasis the importance of single embryo-transfer and ongoing efforts to limit the number of embryos transferred in each assisted reproduction treatment. The goal is to minimize possible adverse maternal and child health effects associated with multiple pregnancies.<sup>61</sup> In case of high order multiple pregnancies (HOMP), or to selectively terminate an abnormal pregnancy or an ectopic pregnancy, fetal reduction is the technique used to reduce the number of fetuses. Slovakia is among these countries which legislation did not mention this technique but is practiced in order to reduce possible adverse event that can appear for mothers and babies. Additionally, this technique is based on women guaranteed right in Slovakia to decide does she want to have child or not.<sup>62</sup>

#### Table 6. Emryo-transfer and Embryo-reduction in Slovakia

Number of transferred embryos	Embryo-reduction
Usually 1-2	Allowed and practiced

Source: Author

From previous decision raise another question: what to do with the rest of the embryos that aren't used in certain cycle? One of the possibilities is to cryopreserve it for another cycle or to donate. Cryopreservation is allowed in Slovakia in some extend (see *Table 7*). While fertilized eggs

<sup>58</sup> Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013

<sup>59</sup> Dostál J., *Specific Ethical and Legal Aspects of ART practice in Eastern European Countries* (63-86) in book: Ethical Dilemmas in Assisted Reproductive Technologies edited by Schenker G. J, (2011), De Gruyter, Berlin, pg.71

<sup>60</sup> Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013

<sup>61</sup> Howard W. Jones Jr. M.D. et all: *International Federation of Fertility Societies Surveillance 2010: preface, American Society for Reproductive* Medicine, 2010, Available at: <u>http://www.iffs-reproduction.org</u>, Retrieved: March20, 2013

<sup>62</sup> Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013

and ovarian/testicular tissue are allowed by statute and seems practiced in hospitals in Slovakia, oocytes cryopreservation is not mentioned in Statute but is practiced. When couple decides not to keep frozen embryos further, they need to send signed confirmation of their decision and verified by layer.<sup>63</sup>

#### Table 7. Cryopreservation- regulation by Law in Slovakia

Cryopreservation in Slovakia	Allowed /Practiced
Fertilized eggs	Yes/ Yes
Oocytes	Not mentioned/Yes
Ovarian/testicular tissue	Yes/Yes

Source: Author

The cryopreservation is one more chance for the couples to conceive child. Cryopreserved embryo transfer is less stressful process for the couple which can be done in natural cycle (without woman's hormonal stimulation). That is one of the reasons why couples choose cryopreservation option in certain clinics in Slovakia. Duration of cryopreserved embryos is not defined and it's up to the patients wish whether they want to preserve embryos for the next year or not since that these is yearly payable service.<sup>64</sup>

Therefore, there are some special cases when couples after many years of trying, because of some health reasons can't get baby and need to look for third party for donation. In case when problem is man infertility, *donation of sperm* is one of the possibilities which are allowed in Slovakia by national law and practice in IVF and in non IVF donation cases (*Table 8*).

#### **Table 8. Sperm Donation in Slovakia**

Slovakia	Allowed	Used
IVF Sperm Donation	+	+
Non-IVF Sperm Donation	+	+
Post-mortem sperm retrieval	-	/

Source: Author

In order to avoid some adverse event that can appear, in Slovakia is practiced that every man could be a donor only once. Recipients can be only married and heterosexual couples.

<sup>63</sup> Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013 64 Ibid

However, couple with IVF donor, the donor remains anonymous, and therefore it is not possible to turn to him with the determination of paternity according with law. Nevertheless, in Slovakia there is no national biobank that IVF centers have based its sperm bank.<sup>65</sup> Doctor on biological criteria and recommend with couples choose a suitable donor from stored frozen sperm samples of voluntary donors. Question of anonymity is following donation issue. Sperm donation is anonymous, and the beneficiaries are the legitimate parents of newborn child. Post-mortem sperm retrieval for assisted reproduction treatment is not mentioned in legislation or guidelines.<sup>66</sup>

Likewise, *egg donation* is not prohibited and consent for egg cell donations is explicitly included in the law or government rules as well as in national or international organization guidelines.<sup>67</sup> In Slovakia, egg donation is one of the possibilities of assisted reproduction where one woman-the donor donates her eggs to a couple-the recipients, to enable them to conceive. The method of donating eggs for fertility treatment deemed legal method in Slovak legal framework (*Table 9*).

#### **Table 9. Oocite and Embryo Donation in Slovakia**

Slovakia	Allowed/Used
Oocite Donation	+/+
Embryo Donation	+/+

Source: Author

Only people whose ovaries do not produce any eggs or whose eggs cannot be used to attain healthy pregnancy can apply for egg donation. This is applicable for those women whose suffering from ovarian failure (ovaries aren't functional) and are unable to produce eggs due to genetic, after surgery or chemotherapy, menopausal reasons.<sup>68</sup> Thus, might be woman produce eggs of lower quality, which is difficult to fertilize and often lead to unsuccessful fertility treatment or woman have a poor response to stimulant drugs produce a small number of eggs. All these women will need donated eggs to have a child. First, it can be voluntary oocytes donors based on sharing of eggs: woman undergoing fertility treatment has voluntarily decided to share the produced eggs with another woman (after she passes all the tests which have considered her as

<sup>65</sup> Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013.

<sup>66</sup> Dostál J. et all: *Post-mortem sperm retrieval in new European Union countries: Case report, Human Reproduction*, Vol.20, No.8 pp. 2359–2361, 2005, pg. 2360

<sup>67</sup> Report on the regulation of reproductive cell donation in the European Union (2006), European Commission, Health & Consumer Protection Directorate-General, available on:

http://ec.europa.eu/health/archive/ph\_threats/human\_substance/documents/tissues\_frep\_en.pdf, Retrieved March 18, 2013

<sup>68</sup> Krajkovič P.: *Cena umelého oplodnenia*, (May 2009), Available from: <u>http://baby-</u> web.topky.sk/clanky/a2118-Cena-umeleho-oplodnenia.aspx Retrieved March 13, 2013

suitable oocytes donor). Women who had previously undergone oocyte donation cycles are not allowed to donate oocytes. Thus, donor can be registered in an IVF program during which woman (future donor) obtained higher quality eggs than she wants for her own pregnancy and she is ready to donate (case of hyperstimulation).<sup>69</sup>

Program egg donation in the centers for assisted reproduction in Slovakia has been prepared in accordance with the guidelines, rules and ethics of egg donation in the world.<sup>70</sup> Usual procedure is that donor (between 21-34 years) after successfully completing the entry form and for inclusion in the program undergoes hormonal stimulation of the ovaries.

Donors that plan to donate oocytes have the right to obtain any information about their treatments, their opportunities and risks. Donor is informed during the procedure on how many eggs were obtained and how much was donated, but not about how many eggs were provided by a single pair.<sup>71</sup> Donor can change her consent to the donation of oocytes but not later than one day before collection of oocytes and complete the donation cycle. Donor consent for egg cells - informed consent must be given by the donor and approved and signed by notary and/or a witness.<sup>72</sup>

According to the EU Tissue Directive donors in EU may only receive compensation, which is strictly limited on travel expenses and inconveniences related to the donation. Given that the patient is not paid in Slovakia inconveniences related to the donation of eggs, it may only be reimbursed the costs associated with the donation, such as travel. That is why there are few donors and generates waiting lists for IVF treatment.<sup>73</sup>

Donation of embryo is indicated as only possible solution for achieving offspring for some couples. Donated embryo could come from a pair who have already successfully undergone embryo transfer, have pair frozen embryos and have decided to donate them. The eggs are consequently fertilized with sperms from a donor. Developed embryos are cultivated until the 5th day and the highest quality blastocysts are frozen and stored. In one Slovak clinic woman has decided after a hyperstimulative eggs retrieval process to donate at least 5 eggs.

<sup>69</sup> Centrum asistovanej reprodukcie ISCARE: Darcovstvo, Available at:

http://www.darovanie.sk/print.php?go=2, Retrieved April 10, 2013

<sup>70</sup> Ibid

<sup>71</sup> Ibid

<sup>72</sup> International Federation of Fertility Societies (IFFS): *International Federation of Fertility Societies Surveillance 2010, Fertility and Sterility,* Available at: <u>http://www.iffs-</u>reproduction.org/documents/IFFS\_Surveillance\_2010.pdf, Retrieved 17 April 2013

<sup>73</sup> Krajkovič P.: *Darovanie vajíčok (oocytu): Na Slovensku je málo darkýň* (09. 05. 2009) in cas.sk, Available from: <u>http://lesk.cas.sk/clanok/79898/darovanie-vajicok-oocytu-na-slovensku-je-malo-darkyn.html</u>, Retrieved April 13, 2013

Ethical issues that rise with the donation are that in what extent the anonymity of the donor should be preserved. The ability of human beings to know their genetic roots is universally important and the issue of anonymity (gamete and embryo donation) is considered as question of big importance as core of self-determination (*Table 10*).

#### Table 10. Donor Anonymity in Slovakia

Slovakia	Offspring provided on request with donor <b>identifying</b> information	Offspring provided on request with donor <b>non-identifying</b> information
Allowed by Law	Yes	Yes

Source: Author

Precisely, confidentiality and anonymity are binding. However, Slovakia is among 15 countries with statutes and guidelines that on request provide offspring with identifying information.<sup>74</sup> All information concerning donors undergoing egg donation program remain in strict confidentiality and this also applies to all the medical procedures and results. Other donors involved in the process of donating eggs don't have access to information on the treatment of the donor or its results. All parties involved in donating eggs remain in mutual anonymous to each other, what means that some receiving or donor eggs will not find the mutual identity.<sup>75</sup> The only limitation is the case for disclosure if the information provided might be in conflict with the rights and interests of the recipient couples undergoing the same treatment and when couple provides its donor.

None of the IVF Clinics in the Slovak Republic provides reproductive cells for the import or export.<sup>76</sup> The status of egg cell imports/exports issue is unclear and there are no reports of unauthorized imports or exports of reproductive cells. No sperm either egg imports/exports in Slovakia according with the evidence.<sup>77</sup>

- 74 International Federation of Fertility Societies (IFFS): International Federation of Fertility Societies Surveillance 2010, Fertility and Sterility, Available at: <u>http://www.iffs-</u>
- <u>reproduction.org/documents/IFFS\_Surveillance\_2010.pdf</u>, Retrieved: 17 April 2013 75 Centrum asistovanej reprodukcie ISCARE: *Darcovstvo*, Available at:
- http://www.darovanie.sk/print.php?go=2, Retrieved: April 10, 2013

76 Report on the regulation of reproductive cell donation in the European Union (2006), European Commission, Health & Consumer Protection Directorate-General, available at: http://ec.europa.eu/health/archive/ph\_threats/human\_substance/documents/tissues\_frep\_en.pdf, Retrieved:March 18, 2013 According to Article 35 Section 8<sup>78</sup> of the Health Care Act in line with European and national ethical principles and legislation, as well as taking account of the related provisions of the Oviedo Convention, human tissue and cells may only be donated on an unpaid, voluntary basis in Slovak Republic. Therefore the Health Care Act declares that the procurement and transfer of the organs, tissues and cells with the aim of financial or any other profit are forbidden. The organ, tissue or cell donation is voluntary and free. The donor can be granted with the financial compensation of the declared travel, room and board expenses, according to the individual prescription connected with the procurement of the organs, tissues or cells. Non-remuneration is explicitly binding by law in Slovakia. Reproductive cell donors are receiving compensation and it is regulated in the law or government rules (explicitly included).

<sup>78</sup> Sándor J., Schvéger J. and Bárd P: *The Legal Regulation of Biobanks, National Report: Slovakia*, 2010, Center for Ethics and Law in Biomedicine (CELAB), Budapest, Hungary, pg.7, See more: Zákon č. 576/2004 Z. z. o zdravotnej starostlivosti, službách súvisiacich s poskytovaním zdravotnej starostlivosti a o zmene a doplnení niektorých zákonov. Available at (Slovak): <u>http://www.vyvlastnenie.sk/predpisy/zakon-o-zdravotnej-starostlivosti/</u>, In English: Act no. 576/2004 Coll. on health care, adopted by the National Council of the Slovakian Republic, with effect from: 01/11/2004, effective from: 06/01/2006, in force: 12/31/2007.

# 4. Preimplantation genetic diagnosis, Surrogacy,

### **Experimentation on the Embryo and Cloning**

Preimplantation genetic diagnosis (PGD) is a method that allows genetic testing of embryos before their transfer into the uterus within IVF cycle. In Slovakia is allowed and used PGD as well as PGS for embryo screening (aneuploidy) (*Table 11*).

#### Table 11. PGD in Slovakia

Slovakia	PGD	PGD for embryo screening (aneuploidy)
Allowed	Yes	Yes
Used in practice	Yes	Yes

Source: Author

There are six general categories for which PGD testing is used: Autosomal single gene disorders (thalassaemia, cystic fibrosis, Tay-Sachs disease, and sickle cell disease); Chromosomal rearrangements (inherited chromosomal abnormalities); Aneuploidy; X-linked diseases; Non-medical sex selection and Human leukocyte antigen (HLA) typing.<sup>79</sup> Gender selection is allowed just in case of medical reasons when family is genetically predisposed to passing on a sex-linked genetic disease, not due to the personal reasons.<sup>80</sup>

Surrogacy is seen as prohibited act by law makers. The law rigidly sets that "The woman who delivers a child is its mother". The aforementioned provision does not take into consideration medical methods of assisted reproduction (e.g. surrogacy in cases when a woman is not able, due to health problems, to carry the fetus). At the same time, the provision discriminates against women who cannot get pregnant in a natural way. This decision was not preceded by an open discussion of both the professional and general public.<sup>81</sup> Experimentation on the embryo and embryonic stem cell (ESC) research is banned in Slovakia. This decision is closely interconnected

80 Gyn-Fiv, Bratislava, Slovakia, Interview April 15, 2013

<sup>79</sup> International Federation of Fertility Societies (IFFS): *International Federation of Fertility Societies Surveillance 2010, Fertility and Sterility,* Available at: <u>http://www.iffs-</u> <u>reproduction.org/documents/IFFS\_Surveillance\_2010.pdf</u>, Retrieved: 17 April 2013

<sup>81</sup> Joint Submission: *Shadow Report to the Committee on the Elimination of Discrimination against Women for the Slovak Republic*, (41st Session 30 June to 18 July 2008), OKAT PLUS s.r.o., Bratislava, 2008, Available at: <u>http://www2.ohchr.org/english/bodies/cedaw/docs/ngos/IWRAW Asia Pacific Slovak41.pdf</u>, Retrieved: March 15, 2013

with the issues of the moral status of the embryo based on Christian doctrine. In line with this, cloning is not allowed by law as agreed on international level.

## 5. Cross-border cooperation

The International Federation of Fertility Societies (IFFS) has been working with the European Society of Human Reproduction and Embryology (ESHRE) in support of the ESHRE Good Practice Guide for Cross Border Reproductive Care.

It is not rare that some patients coming in Slovakia to obtain some of AR treatments. Some coupes are coming from Germany in Slovakia since that in Germany is forbidden egg donation. A shortage of egg donors in the UK prompts many women to travel abroad, particularly to countries such as Spain and Slovakia where egg donors are paid and donation is more plentiful.<sup>82</sup> For the couples that are traveling from Slovakia to some other country there are possibility for reimbursement of the treatment abroad within the meaning of the provisions of the legislation into force, concerning the way of payment and treatment abroad.<sup>83</sup> People who are coming in Slovakia are mostly Slovak people who are leaving abroad.

<sup>82</sup> Guy S.: *Restrictive IVF Access Prompting Thousands to Travel Abroad for Treatment*, BioNews 515, 06 July 2009, Available from: <u>http://www.bionews.org.uk/page 45492.asp</u>, Retrieved: April 13, 2013 83 Všeobecná zdravotná poisťovňa, Interview 10<sup>th</sup> April 2013, Slovakia

### Conclusion

Trend of childless couples, like in many other countries all over Europe, is increasing in Slovakia. From year to year is accumulating more and more couples who have trouble with conceiving. Once and for most of them the only way to become a parent is assisted reproduction treatment. This paper tends to present current legal framework and analyze health and financial policy on infertility care in Slovakia which can be used in future policy and decision making process.

While according to analysis, Slovakian law is considered as liberal regarding donation of eggs, sperm and embryos (allowed and practiced), regulations on donor compensation and import/export of reproductive cells are in some extend unclear defined by law. Conditioning performance the assisted reproduction by intimate physical relationship between a man and a woman makes Slovak health policy more rigid than in other countries. Consequently, this provision discriminates single women who would like to achieve offspring as well as women in homosexual relationships. One of the suggestions would be the principle of non-discrimination of singles, so that they can have equal access to infertility treatment. According to Slovak legal system is not possible to preform artificial insemination after husband's death, which can raise social questions in the future.

From the financial side, there is no option that IUI can be reimbursed from the health insurance and this makes intrauterine insemination treatment inaccessible for many couples in Slovakia. The insurance company pays a basic choice of three cycles of assisted reproduction. If it fails even once, further attempts to parents must pay for themselves. Patients paid procedures beyond the basic cycle support medications, prolonged cultivation, storage of reproductive cells, cryopreservation, per-implantation genetic diagnosis, and others which is not different from the policy from other European community countries. Additionally, we have to bear in mind that infertility treatment can be time consuming and financially difficult especially when national law does not provide opportunity for the treatments and when patients need to pay additional amount which can be equal to double of amount of the minimum wage for one cycle in Slovakia. Nevertheless, Slovakian insured patients whose have undergone assisted reproduction treatment are followed as patient under the risk and insurance will covered the early amniocentesis treatment. Slovakia shows high achievement legal policy regarding informed consent as well as legal and ethical issues on collecting and protecting information. With approximately 2.000-2.500 cycles per year, eight IVF centers are quite responding on the market demands. According to the data, there is not waiting list or, if so, it is solved very quickly. Having centers in different part of Slovakia seems that citizens are having quite good possibility to access to the service.

It is not possible to give precise national data about outcomes as an important part of health policy due to the fact that Slovakia do not report details and quantified data on assisted reproduction. Recommendation for Slovak national health infertility policy is to establish national institutions which will collect the data from all fertility clinics in Slovakia and calculates standardized success rates for each clinic. This would give to potential users of assisted reproductive technology an idea of their average chances of success. Likewise, it will help policy and decision makers to compare its outcomes and regulations achievement with other European countries.

Like all medical procedures, assisted reproduction has the potential for benefits and harms. It is in the interests of individual and society to make regulations as precise as possible in order to maximize benefits and minimize harms that can appear. It is necessary to work on benchmarking and involving all stakeholders in developing health policy on regulating assisted reproduction practices. Reporting system on national level should be one of possibilities. Improving monitoring systems and putting it on higher national level should lead to long term goal- reducing cost by improving quality of service, patient safety and outcomes.

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