

Different perspectives on regulation of assisted reproduction treatments in Serbia and Hungary: Comparative analysis ¹

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Introduction

According to World Health Organization (WHO) infertility is defined as a disease which requires complex approach (medical, legal and ethical), analysis and treatments. The treatment which is used to overcome infertility is assisted reproduction (AR) and the most applied methods are IVF/ICSI. The application of the assisted reproductive technologies (ART) gives chance to many people to get offspring. "Five million babies are a clear demonstration that IVF and ICSI are now an essential part of normalized and standardized clinical therapies for the treatment of infertile couples."² Nevertheless, getting offspring in this way is not just a question of individuals but it is question of society and state. Numerous religious, ethical, legal, and socio-cultural dilemmas are raised by this global problem.

The question of application of IVF/ICSI methods is important both Serbia and Hungary, and these are the countries which will be examined in this article. With more or less similar demographic structures, pro-natalist social-cultural norms, and adopted post-communistic health care systems, we found interesting to examine the current situation in these countries by reviewing some of the currently available data and experts' opinions.

The comparative approach applied here is looking at socioeconomic, religious and legal context of this problem in order to achieve a greater understanding of the dynamics behind some policy choices and their perspectives.

I Glimpse on socio-economic indicators

The Republic of Serbia³ is a parliamentary democracy with population of 7.276.195 million according to the recent Census in 2011.⁴ Serbs represent 82.9% of the population and the Hungarians are the second largest ethnic group (3.9%).⁵ According to data from 2010, population growth rate is -0.47% and birth rate is 9.4 births/1,000 populations which is 0.2 less than in 1999. Total fertility rate which represents the total number of live births on one woman is 1.4 children born/woman.⁶

In Hungary was registered 9.985.722 population in 2011. The population growth rate was -0.40 % and birth rate was 9.0 births/1,000 populations.⁷ From Table 1, we can observe that Serbia and Hungary share the same size of population and the same demographical trend of negative population

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- 2 Dr. Anna Veiga, chairman of the European Society of Human Reproduction and Embryology, in ESHRE news release: *The world's number of IVF and ICSI babies has now reached a calculated total of 5 million*, Retrieved February 23, 2014. Available from: <http://www.eshre.eu/Press-Room/Press-releases/Press-releases-ESHRE-2012/5-million-babies.aspx>
 - 3 Serbia is a member of the Council of Europe since the year 2003. In 2010, the Serbian Government submitted the initiative for the candidate status with the European Union. Hungary is full member of EU from 2004.
 - 4 Statistical Office of the Republic of Serbia, Retrieved February 24, 2014, from ww.stat.gov.rs
 - 5 Data available from Census 2002
 - 6 Statistical Office of the Republic of Serbia, Retrieved February 24, 2014, from ww.stat.gov.rs
 - 7 Hungarian Central Statistical Office (KSH), Retrieved February 24, 2014, from <http://www.ksh.hu/?lang=en>

growth rate and the same birth rate.

Table 1: *Comparative data between Serbia and Hungary*

	Serbia	Hungary
Population in millions	7.276.195	9.985.722
Population growth rate %	-0.47	-0.4
Birth rate per 1.000 populations	9.4	9.0

Moreover, data shows that fertile population (women aged 15 to 49) is 23.01% of the total population in Serbia (1.677.562) while the optimal fertile contingent, consisting of women aged 20 to 34, is 10,07% (734.188).⁸ The exact number of women and men who have infertility problems isn't possible to precise. Some estimation says that every sixth couple in Serbia, (around 200.000 couples) and between 70.000 and 100.000 women have this problem. The situation in Hungary is the same, infertility affecting about 150.000 couples in Hungary. This means that one in seven couples have problems in conceiving.⁹

Total health expenditures in Serbia in 2010 was 10.4% of GDP¹⁰ and in Hungary was 7.3¹¹ which is noticeable under average EU's 8.3%.¹² Nevertheless, data show that out-of-pocket health expenditure as a proportion of total health expenditure, 2009 in Serbia was 35% and in Hungary was 24%.¹³ It looks that Serbian citizens have to pay more out of pocket than Hungarian for the health services.

How much state will allocate for health determine which services will be available to the population. We can identify the main drivers creating health expenditure policies toward infertility treatment that are common for Serbia and Hungary. One of the strongest is surely the demographical change, dominant trend of negative birth rate and raised problem of infertility which has been existed for a long time but started to get more attention in the last few decades. Apart from health-social we can identify economical drivers as infertility treatment is considered among expensive in the concerned countries. Serbian and Hungarian policy makers are aware of importance to treat infertility by AR technologies therefore they create national legislation and budgets for supporting assisted reproduction interventions.

8 Statistical Office of the Republic of Serbia, Retrieved February 24, 2014, from [ww.stat.gov.rs](http://www.stat.gov.rs)

9 Hungarian Central Statistical Office (KSH), Retrieved February 24, 2014, from <http://www.ksh.hu/?lang=en>

10 WHO, 2012, *Global Health Expenditure Database*, available at: http://apps.who.int/nha/database/StandardReport.aspx?ID=REP_WEB_MINI_TEMPLATE_WEB_VERSION, Retrieved February 14, 2014

11 WHO (2012) *Table of Key Indicators, Sources and Methods by Country and Indicators*. Available at: <http://apps.who.int/nha/database/StandardReport.aspx>

ID=REP_WEB_MINI_TEMPLATE_WEB_VERSION&COUNTRYKEY=84701, Retrieved July 16 2013

12 OECD Health Data 2010, (data from 2008), Retrieved January 13, 2014, from OECD: www.stats.oecd.org

13 WHO *Global Health Expenditure Atlas*, WHO, 2012 (based on data 2009) pg.12. Available at: <http://www.who.int/nha/atlas.pdf>, Retrieved on July 10, 2012.

Both countries with communistic past had extensive public welfare system where free healthcare was made available to all citizens. Recently, both countries started with reforms to administer the health insurance system by involving private insurance companies to avoid national insurance funds. The main aim of introducing supplement health policies is to ensure the efficient operation and cost-effective control of the health insurance systems. Serbian Republic Fund of Health Insurance (RFHI)¹⁴ and Hungarian National Health Insurance Fund Administration (NHIFA)¹⁵ took purchasing role, having chance to decide what (e.g. service, medicine, device), from who and how much to buy.

In Serbia we can notice that private sector is excluded and exists separately from the public health sector. Patients in Serbia see that as a big issue which is mostly result of lack of good organization expressed through long waiting lists. Only in few areas public health system allowed private sector to be cooperant and assisted reproduction is one of regulated area.¹⁶ Serbian NFHI started with funding IVF in end of 2006. From 2008 till June 2011 National Fund of Health Insurance made a contract with 6 private IVF clinics. In 2010, 4 public and 6 private hospitals carried out 1.484 rounds of treatment in total. The percentages of rounds of treatment performed in public and private institutions show that 60% (877) of total performed rounds in 2010 was performed in public and 40% (597) in private sector within National financed program.¹⁷ Some of those are large-sized clinics (> 199 cycles/year) because they are performing a big number of treatment rounds for those couples who unmet criteria for the National program. Some patients are complaining that administrative procedures for National program in Serbia take a lot of time to be complied. This is also one of the reasons why patients decide to pay out-of pocket for this service and go to private sector to obtain the service. Nevertheless, the result showing that in last 5 years within National Health Program financed by NFHI were treated 3.500 couples and were borne more than 1000 babies.¹⁸

Data for Hungary reveal that in 2002 there were 11 IVF Clinics and in total 6.814 treatments have been performed.¹⁹ In 2006 there were 10 clinics registered but only 5²⁰ were reporting to National

14 In Serbian – Republički fond za zdravstveno osiguranje (RFZO) former name RZZO

15 In Hungarian - Országos Egészségbiztosítási Pénztár (OEP)

16 Karajičić, Slavica and Mužik, Roman (2013) *Serbia: An Overview of the Health System*, Health Policy Institute, Bratislava, Slovak Republic. Available at: <http://hpi.sk/hpi/sk/view/10480/srbsko-prehľad-zdravotneho-systemu.html>, Retrieved on February 24, 2014

17 Republička stručna komisija za VTO, (2011). *Izveštaj o rezultatima programa vantelesne oplodnje finansiranog od strane RZZO za 2010.godinu*, Beograd. (In English: Annual Report of Results of Assisted Reproduction Treatments Financed by RFHI for 2010)

18 Su. J. (May 6, 2012) *Banka jajnih ćelija: bebe mogu i po želji*. Novosti newspapers realise. Available at: <http://www.novosti.rs/vesti/naslovn/aktuelno.290.html:378591-Banka-polnih-celija-Bebe-mogu-i-po-zelji>, Retrieved on February 16, 2014. (In English: Bank of gametes: Babies can and if desired)

19 Sorenson C. and Mladovsky P. (2006) *Assisted reproduction technologies in Europe: an overview*. Available at: http://ec.europa.eu/employment_social/social_situation/docs/rn_assisted_reproduction_technology.pdf, pg. 3. Retrieved on February 20, 2014.

20 In 2006 it was voluntary based evidence.

Registry with 3.280 treatments in public and private clinics²¹ and in 2009 there were 6.721 conducted cases reported.²² Administrative procedure in Hungary is less complicated due to the existing electronic health cards which allowed five IVF/ICSI attempts. In Serbia procedures are still based on required papers, and patients who are going under AR treatment, need to bring the whole paperwork with themselves every time they see the doctor during whole procedures. The project of introduction E-health card in Serbia is planned to be realized in the beginning of 2013, unfortunately it is still not realized. Hungarian example of using e-card in domain of assisted reproduction can be good example how to make less complicated administrative procedures and initiate to use advantage of E-health in Serbia.

Governments of both countries with the similar sociodemographic challenges support assisted reproduction through their national policies and see private sector as crucial partner in this domain. Private sector in both countries with developed infrastructure capacities helps efficient utilization of the existing capacities in both sectors. Hungarian reported data on conducted cases show tendency of increasing number of IVF treatments and in comparison with Serbian data, give us a clue that Hungary "over-support" assisted reproduction treatments. This conclusion is due to the fact that Hungary, with the similar sociodemographic and economical indicators like Serbia, conducted 4 times more couples than Serbia did in one year. Nevertheless, this should be used with cautions that in Hungary within 5 covered attempts are counted not just IVF/ ICSI but also treatment with frozen embryos transfer.

II Religion versus assisted reproduction

Religion is the one of the strongholds for believers, giving answers on many questions concerning secular life. Christian people base their confession on Bible and answers on ethical dilemmas are found in religious learning which are mostly similar. That is why bioethics²³ has aim to find a consensus about what will and what will not count as a legal issue.

Both Christian countries, Serbia (Orthodox) and Hungary (Catholic and Protestants)²⁴ have their own opinion regarding assisted procreation and bioethics. The attitude toward reproductive practice varies among Christian groups. The practice of assisted reproduction isn't accepted by the Vatican, but it may be practiced by Protestants, Anglicans and other Denominations.²⁵

21 ESHRE (2010), *Final Report-Comparative Analysis of Medically Assisted Reproduction in the EU: Regulation and Technologies*. Available on European Society of Human Reproduction and Embryology:

http://ec.europa.eu/health/blood_tissues_organs/docs/study_eshre_en.pdf. pg. 45, Retrieved on February 25, 2014

22 *Jelentés asszisztált reprodukciós eljárásokról*, GYEMSZI, 2009 (In English: Report on assisted reproductive procedures)

23 Potter's definition of bioethics is "Biology combined with diverse humanistic knowledge forging a science that sets a system of medical and environmental priorities for acceptable survival" in book Sateesh M.K., *Bioethics and Biosafety*, I.K. International Publishing House, New Delhi, India, 2008., pg. 3

24 Representatives of Vatican and Protestant churches regularly attend meetings of the Committee on Bioethics of the Council of Europe, while other religious communities, for now, don't show interest in this subject.

25 Schenker, J.G., *Women's reproductive health: monotheistic religious perspectives*, International Journal of Gynecology &

There is a recently published article where Pope Benedict XVI called infertile couple to shun 'arrogant' IVF treatment and insisted that sex between a husband and wife was the only acceptable way of conceiving and matrimony is the only place worthy of the call to existence of a new human being.²⁶ Procreation is deprived of its proper perfection when it is not a result of the conjugal act and spouses' unification.²⁷ Pope called for resistance to 'the fascination of the technology of artificial fertility', warning against 'easy income, or even worse, the arrogance of taking the place of the Creator.' Sperm or egg donation and methods such as in vitro fertilization are banned for members of the Catholic church but he added that the Church encourages medical research into infertility.²⁸ Consequently, the Vatican's instructions is: "do not accept the donation of gametes to an infertile couple as an act of generosity due damaging personal family relations, as the offspring and society."²⁹

Protestants accept traditional treatment of infertility based on disagreement with other Christians regarding the relationship between humanity and God.³⁰ Mainline Protestant traditions generally assume a more liberal view, taking into account not only tradition, scripture, and reason, but also the experience and moral agency of the individuals contemplating ARTs.³¹ Assisted reproductive technologies are acceptable only if the gametes are from the married couple and the procedure avoids damage to the preembryo.³² The practice of surrogate motherhood is not accepted by the Roman Catholic and Protestant church with the objection based on that surrogate motherhood is contrary to the unity of marriage and to the dignity of the procreation of the human.³³

While Catholic Church has unique statement, Orthodox attitude can be considered through several Orthodox churches.³⁴ The Eastern Orthodox Church supports medical and surgical treatment

Obstetrics 70, 2000, 77-86, pg. 77

26 From Vatican conference on infertility in Rome

27 Reynolds, E. (2012, February 25). *Pope tells infertile couple to shun 'arrogant' IVF treatment as sex between husband and wife is the 'only acceptable' way to conceive*. Retrieved on February 20, 2014, Available on: <http://www.dailymail.co.uk/news/article-2106392/Pope-Benedict-XVI-tells-infertile-couple-shun-arrogant-IVF-treatment-sex-husband-wife-acceptable-way-conceive.html>

28 Ibid.

29 Schenker, J.G., *Religious Views Regarding Treatment of Infertility by Assisted Reproductive Technologies*, Journal of Assisted Reproduction and Genetics, Vol. 9, No. 1, 1992, pg. 6

30 Shenker, J.G., *Women's reproductive health: monotheistic religious perspectives*, International Journal of Gynecology & Obstetrics 70, 2000, 77-86, pg. 79

31 Ott M. Kate, *A Time to Be Born, A Faith-Based Guide to Assisted Reproductive Technologies*, Religious Institute, USA, 2009, pg. 21

32 Schenker, J.G., *Religious Views Regarding Treatment of Infertility by Assisted Reproductive Technologies*, Journal of Assisted Reproduction and Genetics, Vol. 9, No. 1, 1992, pg.4. See also Dunstan GR, In-vitro fertilization: the ethics, Human Reproduction 1, 1986, 41—48.

33 Schenker, J.G., *Religious Views Regarding Treatment of Infertility by Assisted Reproductive Technologies*, Journal of Assisted Reproduction and Genetics, Vol. 9, No. 1, 1992, pg.6

34 In favor of the existence of different opinions within the Orthodox Church, as discourse, we can see the Bulgarian Orthodox Church's governing body, the Holy Synod, has spoken out against in vitro fertilization and surrogate motherhood which is clearly at odds with the interpretation of the Serbian Orthodox Christian understanding of the origin and meaning of human life. It didn't deny the scientific achievements involved, but said that it was clear that assisted reproduction showed that families with fertility problems had lost their Christian hope and it represents "impiety and blasphemy.", The Sofia Echo (January 2, 2012) *Bulgarian Orthodox Church speaks out against in vitro fertilisation*,

of infertility. While IVF and other assisted reproductive technologies are not absolutely rejected, the Church opposes gamete donation as an adulterous act.³⁵

In Orthodox culture, it's not acceptable to conduct any diagnostic or therapeutic method that would, in part or in full, or in any way compromise the biological survival of the human personality. The embryo is considered as a "leaving creature", having personal identity, like the fetus, newborn, child and every person is. Since the Fathers do not observe marital infertility as God's punishment (St. John Chrysostom: "We can not say that infertility is a result of sin..." Sermon on Genesis XLIX 1-2), the position of the Serbian Orthodox Church is to overcome this problem by treatment. In any case, in accordance with the Orthodox ethos is that biomedical assisted reproduction is allowed and to be performed only on married couples. Churches are excluding the participation of a third party (such as donor cells or surrogate mothers), and prefer fertilization of no more than three egg cells before embryo transfer (return of the embryo in the womb). Freezing embryos is still in debate while the freezing of sperm and egg cells is acceptable because they are considered as tissue.³⁶

However, Christian churches are concurrent on the main principle that procreation should be linked with conjugal act, as expression of spiritual union of the spouses and not just biological. Christian Churches also agree about seeing embryo as "leaving creature" but it looks that Serbian Orthodox Church and Protestants has less strict attitude on treating infertility by assisted reproduction. According to Christian view, especially the one of the Catholic Church, gender preselection even for medical indications is forbidden.³⁷ We can see that oocyte donation as well as surrogate motherhood are forbidden by three main branches of Christianity: Roman Catholic, Eastern Orthodox and Protestant.

At least three factors determine the influence of religious viewpoints: the size of the community, the authority of current viewpoints within a particular community, and the unanimity and diversity of opinion present. The weight and authority of specific religious viewpoints will influence the number of adherents who draw on these views when considering public policy issues.³⁸ With regard on these

surrogacy, Available on: http://sofiaecho.com/2012/01/02/1737079_bulgarian-orthodox-church-speaks-out-against-in-vitro-fertilisation-surrogacy, Retrieved on January 25, 2014

- 35 Schenker, J.G., *Religious perspectives in assisted reproduction*, Reproductive BioMedicine Online, vl 10. No 3. 2005 310-319, 2005, pg. 6, Available on: <http://content.ebscohost.com/pdf9/pdf/2005/KTS/01Mar05/16386095.pdf?T=P&P=AN&K=16386095&S=R&D=aph&EbscoContent=dGJyMNHr7ESeqLY4zdnyOLCmr0qep7JSs6i4TbaWxWXS&ContentCustomer=dGJyMPGqtkivr7JRuePfgex44Dt6fIA>
- 36 Лазиф, С., *Новине српске патријаршије, Слово о биоетичким дилемама, интересу са њаконом др Петром Дабичем*, бр. часописа 1053, Available on: <http://pravoslavije.spc.rs/broj/1053/tekst/slovo-o-bioetickim-dilemama/print/lat> – this is according with interview from the official newspapers of Serbian Orthodox Church, Retrieved January 16, 2014. (In English: Letter about bioethics dilemmas)
- 37 Schenker JG., *Gender selection: cultural and religious perspectives*. J Assist Reprod Genet. 2002 Sep;19(9):400-10. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12408533>, Retrieved on January 28, 2014
- 38 Schenker, J.G., *Religious perspectives in assisted reproduction*, Reproductive BioMedicine Online, vl 10. No 3. 2005 310-319, 2005, pg.1

facts, we can find the influences of dominant churches in Serbia and Hungary in some extends. Nevertheless, those countries are secular and they are following new achievements in domain of assisted production. Even if religious viewpoints have influence on public mind, it looks like individual right given by the universal declaration of human rights to make decisions regarding his/her reproduction in those communities have stronger impact on policy-makers. Law on assisted reproduction in both countries is strongly tied to the community opinion and personal choices than to religious domain. In comparison with more liberal assisted reproduction laws from other countries, we can see that regulations in both countries, such as regulation of prohibition of achievement offspring in homosexual couples, are much more associated with moral and religious dogmas.

III Legal Framework: Serbia and Hungary

Infertility is recognized as a disease process by the World Health Organisation³⁹ and calls for equity of access and safety between and within nations. From the moment society and medicine have recognized infertility as not just a “woman” problem, International Federation of Fertility Societies is suggesting that all men and women who are affected by infertility should have access to advice, diagnosis and, where possible, treatment, irrespective of race, social background or financial status. This federation is setting up standards which have to ensure that reproductive health programmes and policies respect, protect and fulfill human rights and promote gender equity and equality.⁴⁰

The complexity of issues involved in assisted reproduction led me to make a connection with the two concepts of liberty of Isaiah Berlin and the distinction between positive (freedom from internal constraints) and negative liberty (freedom from external restraints). Positive liberty, in terms of assisted reproduction, can be understood as the possibility of every citizen to have equal access to health care without excessive burden and right to decision that affects their future life with emphasis on human integrity without discrimination. In this sense, couples who have taken all possibilities to become parent or in single woman case, want to feel free to rich their rights to have offspring and consider it as their fundamental human right. Nevertheless, society and (bio)ethics are establishing set of standards, particular conditions and norms exposed in national law and international convention. Affected groups can understand this as a negative freedom in terms of not being able to exercise their own right to achieve offspring, therefore, these stipulated legal and social norms are kind of external restraints. Even if regulations are trying to give answers and solutions on such complex ethical questions, some

39 It's not surprising that World Health Organization recognizes infertility as a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse' in: Raper Dr Vivienne, *World Health Organisation recognise infertility as disease*, BioNews 536, 30 November 2009, Available on: http://www.bionews.org.uk/page_51799.asp

40 International Federation of Fertility Societies, *Policy Statement 1, Access to infertility care*, September 2010. Available at: http://c.ymcdn.com/sites/www.iffs-reproduction.org/resource/resmgr/practice_standards/iffsaccesstoinfertilitytreat.pdf, Retrieved January 21, 2014.

ethical questions are still under consideration in Serbia and Hungary.

Hungarian legal system is based on the civil law model where statutes and decrees are main sources of legislative power. Hungarian assisted reproduction law is based and created on very important international declaration and convention such are: UNESCO Universal Declaration on Human Genome and Human Rights 1997; Convention on Human Rights and Biomedicine, Oviedo, 1997 and two UNESCO declarations International Declaration on Human Genetic Data in 2003 and Universal Declaration on Bioethics and Human Rights 2005. Oviedo Convention entered in force in May 2002 in Hungary and in Serbia very recently 1st of Jun 2011 even if it was signed already in 2005. Serbia was waiting for more than 6 years to enter in force this Convention.⁴¹ One of the reasons might be that assisted reproduction wasn't recognized in that time as priority topic by the politicians as well as lack of organizational structure that could enforce this issue. As EU country, Hungary in 2007 finished transposition of document The Tissues and Cells Directive EU from 2006. The main aim of this Directive was to harmonize ART regulations within EU.⁴²

Serbia enacted *Law on the treatment of infertility by biomedically assisted fertilization procedures* launched in 2009 and started slowly with implementation in January 2010.⁴³ This law brought new national organization *Directorate for Biomedicine* which has to have the highest authority together with Ministry of Health. Directorate of biomedicine makes decisions on approval for the procedure of assisted reproduction⁴⁴ with donated reproductive cells.

Hungary has longer legislative tradition in regulating ART issue than Serbia. Before 1997, Hungarian law didn't deal with the legal questions of assisted reproduction, except for decrees dealing with artificial insemination. Decree on artificial insemination specified an upper age limit for women of age 45.⁴⁵ The regulation of ART in Hungary started with the *Hungarian Act on Health Care (Act CLIV/1997)* which is considered as one of the most liberal once, since it authorizes gamete donation, even embryo donation and surrogacy.⁴⁶ This act was amended⁴⁷ in 1999 regarding the regulation of surrogate motherhood and from than surrogate motherhood is illegal in any form in Hungary. Before

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- 41 UNESCO, <http://www.unesco.org/shs/ethics/geo/user/?action=Geo4View&db=GEO4&id=10&type=TREATY&lng=en&criteria=Tjs%3D>. Retrieved on February 20, 2014
- 42 *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells*, Official Journal of European Union. Available on: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:EN:PDF>. Retrieved on February 25, 2014
- 43 Karajičić, Slavica; Radović Tripinović Gordana and Krstić Aleksandar (2013) Legal Policy on Assisted Reproduction in Serbia. In Judit Sándor (ed.), *Studies in Biopolitics*. Central European University, CELAB, Budapest, 103-112
- 44 In Serbian law it is named as Biomedical Assisted Reproduction (BAR)
- 45 Ordinance No.7 of March 22, 1989 issued by the Minister of Health and Social Affairs
- 46 Sandor, J., Anonymity in Assisted Reproduction: Gender Equality and a Pronatal Reproductive Policy in Hungarian Law, Chapter 12 in book *Who is My Genetic Parent? Donor Anonymity and Assisted Reproduction: A Cross-Cultural Perspective*, edited by Feuillet-Liger B., Orfali K., Callus T., Bruylant, Bruxelles, 2010.
- 47 Act on Health Care (Act CLIV/1997, Hungary. The amendment repealed Art.166(1)/e and the Articles 183 and 184 (in Hungarian: 1997. évi CLIV. Törvény az egészségügyről)

this Act was altered by amendment, the law allowed gestational surrogacy in cases when the surrogate was closely related to the mother or father, was between ages 25 and 40, and had at least one child. Hungary has specific regulation for AR treatments called *Act on Health, Chapter IX., 20/2007. (IV.19.) Ministerial Decree (EüM), 30/1998 (VI.24) Ministerial Decree (NM)*. In accordance with the Report that ESHRE made about the legal situation present in 2009 in EU countries, Hungary has implemented the *EU Tissue and Cells Directive (EUTCD)* and has Competent Authority installed.⁴⁸ The Hungarian Competent Authority is Committee of Human Reproduction of the Hungarian Research Council and its Ethics Committee of the Ministry of Health (see Table 2). Soft regulation is not law but is defined as guidelines which help countries to act in the most appropriate way such as good clinical practice guidelines, good laboratory practice and ethical guidelines. In Hungary, no good clinical/laboratory/ethical guidelines exist except preimplantation genetic diagnosis (PGD) guidelines.⁴⁹

Table 2: *Serbia and Hungary- national legal frame and soft regulations*

	Serbia	Hungary
Key organizations	<ul style="list-style-type: none"> • Ministry of Health • Directorate for Biomedicine • Republican Fund of Health Insurance • National Expert Commission of the Ministry of Health 	<ul style="list-style-type: none"> • Ministry of Health • Committee of Human Reproduction of the Hungarian Research Council • Ethics Committee of the Ministry of Health
Legislation and Regulations	Law on the treatment of infertility by biomedically assisted fertilization procedures, 2009	Act on Health, Chapter IX., 20/2007. (IV.19.) Ministerial Decree (EüM), 30/1998 (VI.24) Ministerial Decree (NM)
Guidelines-soft regulations	No, except PGD guidelines	No, except PGD guideline

In Serbia and Hungary wide range of methods of assisted reproduction are applied (see table 3). Hungarian law has some specificity that post-mortem use of embryos/gamets are allowed only if the use AR process was started before the partner died and this should be registered in National MAR Registry. Even after couples divorce or separate, if the egg has been already inseminated, the assisted reproduction procedures may still continue by the woman on her own.⁵⁰ The law recognizes that from a medical ethics perspective, sperm donation differs considerably from egg donation, which presents much more serious intervention for the donor and is often preceded by hormonal therapy.⁵¹

48 ESHRE. (2010). *Final Report-Comparative Analysis of Medically Assisted Reproduction in the EU: Regulation and Technologies*, pg. 4

49 Ibid., pg.12

50 Sandor, J., "A terápiától a szelekcióig: Jogi es etikai viták a reprodukciós beavatkozások új módszereiről" (From Therapy to Selection: Legal and Ethical Debates on the New Methods of Assisted Reproduction) (2005) *Acta Humana*, vol 16, No.4, p 3-20

51 Sandor, J., Anonymity in Assisted Reproduction: Gender Equality and a Prenatal Reproductive Policy in Hungarian Law,

According to Serbian Law, if the donor have been given written consent before death, after his death productive cells can be used in AR.⁵² That means before every AR procedures, medical workers are obligated to verify whether donor is alive or not. Performing the AR requires the written consent of all persons undergo the AR procedure and may be revoked in writing until the seminal cells, unfertilized eggs or early embryos do not enter the woman's body.⁵³

In both legal systems we can find that, apart from giving chance heterosexual, married and unmarried couples to go under AR treatment, single women are entitled for these procedures. In Hungary this issue is regulated since 2006⁵⁴ and in Serbia is allowed in special cases with justifiable reasons.⁵⁵ Donation of human embryos in AR as well procedures with simultaneous application of donated eggs and donated sperm cells are forbidden by the Serbian law.⁵⁶ Moreover, legislators have conciliated that procreation of children of same-sex partners should be absolutely forbidden.

Research work on embryos is one of the most debating questions as embryos in Christianity are defined as human beings. Research work on those early embryos which aren't of suitable quality to be implemented in the woman's body or for freezing, as well on those embryos that would have to be let to die is allowed by Serbian legislation.⁵⁷ In Hungary research work on embryos can start after 14 days.⁵⁸

Hungarian law allows different AR procedure but not pre-implantation genetic diagnosis (PGD) and surrogacy. Serbian legislator predicts PGD only in case of risk of transmitting genetic diseases, chromosomal and genetic diagnostics disease or if they are necessary for the success of the procedure AR.⁵⁹ The use of PGD for non medical purposes isn't accepted in Hungary either is not recommended the use of PGD for diseases that are relatively frequent in the Hungarian population (monogenic genetic disorders and chromosomal abnormalities).⁶⁰ However, applying guidelines as non-binding instruments for PGD procedure are enormous help in practice for medical workers in these countries (Table 3). This is especially important since that exist data about pre-implantation

Chapter 12 in book *Who is My Genetic Parent? Donor Anonymity and Assisted Reproduction: A Cross-Cultural Perspective*, edited by Feuillet-Liger B., Orfali K., Callus T., Bruylant, Bruxelles, 2010., pg 201

52 Law on the treatment of infertility by biomedically assisted fertilization procedures 2009, paragraph (3), article 53

53 Ibid., paragraph (1, 3), article 37

54 Sandor, J., Anonymity in Assisted Reproduction: Gender Equality and a Prenatal Reproductive Policy in Hungarian Law, Chapter 12 in book *Who is My Genetic Parent? Donor Anonymity and Assisted Reproduction: A Cross-Cultural Perspective*, edited by Feuillet-Liger B., Orfali K., Callus T., Bruylant, Bruxelles, 2010.

55 Law on the treatment of infertility by biomedically assisted fertilization procedures, paragraph (3), article 26. Ministar of Health and Ministar of Family Realtionship have to approve that procedure.

56 Ibid., article 56

57 Ibid, paragraph (3), article 60

58 Sándor, J., *International Encyclopedia of Laws*, Kluwer Law International, 2003. paragraph 560.

59 Law on the treatment of infertility by biomedically assisted fertilization procedures 2009, article 54

60 *Praeimplantációs genetikai diagnosztika, a humán reprodukciós bizottság állásfoglalása*, elfogadva a hrb 2008. november 17-i ülésén, 6. (In English: Preimplantation Genetic Diagnosis, The opinion of Hungarian Committee for Human Reproduction (HRB) adopted at the HRB session of 17 November 2008), pg 6.

genetic testing in Hungary reported in 16 cases in 2009.⁶¹

Table 3: Summary of current national regulations on ART in Serbia and Hungary

	Serbia	Hungary
Marital status	Married and unmarried couples	Married and unmarried couples
Single woman	Allowed in special case with justifiable reason ⁶²	Allowed if infertility is legally proven
Lesbians	Not allowed	Not allowed ⁶³
Registers for MAR-treatments National/local	National ⁶⁴	National
IUI	Allowed	Allowed
ICSI	Allowed	Allowed
IVF	Allowed	Allowed
IVF/ET	Allowed	Allowed
OI	Allowed	Allowed
Assisted hatching	Allowed	Allowed
PGD	Not allowed ⁶⁵	Not allowed
Surrogacy	Not allowed	Not allowed
IVM	Not mentioned	Not allowed ⁶⁶
Post-mortem use of gametes and embryos	Allowed with written consent	Allowed
Number of embryos transferred (usual practice)	2-3	3-4
Use of embryos/gametes in case of divorce and separation	Not allowed	Allowed
Cryopreservation Seminal cells, unfertilized eggs and early unused embryos (usual practice)	5 years	10 years
Research work on embryos	Allowed on embryos not suitable quality	Allowed after 14 days

Establishment of Registries for AR treatments is compulsory on national level in Hungary and Serbia (National Registry) and reporting data is under legal obligation, without defined sanctions for no reporting.

Society changed its reflection about infertility as only a “woman problem”, and legislators in

61 *Jelentés asszisztált reprodukciós eljárásokról*, GYEMSZI, 2009, pg .6 (In English: Report on assisted reproductive procedures)

62 Law on the treatment of infertility by biomedically assisted fertilization procedures, paragraph (3), article 26. Minister of Health and Minister of Family Relationship have to approve that procedure.

63 Lesbian woman are treated as single women even if they live in a partnership in Hungary. Available at: <http://scmedicaltravel.co.uk/faq1.html>, Retrieved on February 20, 2014.

64 Register is predicted according to National law, but not established yet.

65 Allowed only in specific cases

66 In Vitro Maturation (IVM) is allowed in 26 of 27 EU Member States and is forbidden in Hungary.

both countries are aware of contemporary medical facts, therefore, they have included male fertility in defining possible solutions when the problem is caused by male partner's infertility.

Main hurdle that is facing legislation in Serbia is lack of legislative decrees, regulations and legal acts of lower legal power. More additional regulations issued to implement this law and are in process. Serbia is still waiting for more regulations and additional instruments that should be created and issued in the name of governmental administrative bodies. From Directorate for Biomedicine is expected to participate in the preparation of guides for good practice and standards for AR procedures and procedures for conducting sampling, processing, distribution, and consumption of reproductive cells or embryos.⁶⁷

Legislation has a tendency to cover different aspects of assisted reproduction: whether patient will be included in AR process, in which conditions, and in which circumstances embryos can be used for purposed of research. Some issues are not regulated by law but exist as common practice in case, for example, of number of embryos transferred and how long frozen embryos can be preserved and storage. Serbia and Hungary are considered liberal countries since they are allowing in vitro fertilization but they are less liberal comparing to other countries which regulations allow surrogacy, IVM or AR for homosexual couples, for example. Surely, these treatments will be new challenges in the future for policy and decision makers in both countries and their introduction into legal system will depend on the many factors: public, political, religious attitude as well as social-cultural influences.

IV (Non) anonymous donations

Cases with more sever medical problems when donor of sperm, eggs and gamete/embryo are needed for the performance of AR treatment, are subjects of legal regulations in Serbia and Hungary.

Legislation in Hungary allows gamete/embryo donation and in any case donors should be less than 35 years old. Anonymous sperm donation is allowed with financial compensation, but it isn't allowed otherwise (Table 4). "This formulation is based on idea that if anonymity does become suppressed, sperm donation will decrease. First, donor may fear the consequences from a family law perspective or as second, may fear that the child, when reaches legal age, will want to contact her/his biological father".⁶⁸

67 Law on the treatment of infertility by biomedically assisted fertilization procedures 2009, article 67

68 Sandor, J., Anonymity in Assisted Reproduction: Gender Equality and a Pronatal Reproductive Policy in Hungarian Law, Chapter 12 in book *Who is My Genetic Parent? Donor Anonymity and Assisted Reproduction: A Cross-Cultural Perspective*, edited by Feuillet-Liger B., Orfali K., Callus T., Bruylant, Bruxelles, 2010, pg. 205

Table 4: *Sperm, oocyte and embryo donation in Hungary*

Hungary	Sperm donation	Oocyte donation	Embryo donation
Anonymous	Allowed	Allowed	Allowed
Non-anonymous	Forbidden	Allowed ⁶⁹	Forbidden
Imports and Exports	Forbidden	Forbidden	Forbidden

Egg donation in Hungary in the beginning was stipulated as anonymity but from 2006 exclusive anonymity for egg donation has ended and donation between friends is permitted. Explanation for the reason of acceptance friends to be oocyte donors is that close family members are few and far between and there were risk of pressure to put on only one sister to be donor.⁷⁰ It is interesting that different from sperm donation, Hungarian legislation allows both types of egg donation without compensation. The roots for a non compensation decision for donation, lay down in Oviedo Convention where is defined that the human body and its parts shall not, as such, give rise to financial gain.⁷¹ A fact from the practice in 2009 says that donations in Hungary are applicable and fruitful. For IVF/ICSI/ ET process, 50 cases were egg donation, 7 cases were donated embryo transfer, and sperm donors were in ICSI in 103 cases and 46 cases in IVF.

In sense of understanding donation as altruistic not entrepreneurial act, Serbian Law allows sperm donation with regard that giving own reproductive cells or embryos with any compensations is defined as the act of crime (Table 5).⁷² In both countries, is predicted to reimburse costs of donors which are necessary and justified. Reimbursement, according to the decree, includes the donor's loss of salary which is linked to the donation.

Table 5: *Sperm, oocyte and embryo donation in Serbia*

Serbia	Sperm donation	Oocyte donation	Embryo donation
Anonymous	Allowed	Allowed	Forbidden
Non-anonymous	Forbidden	Forbidden	Forbidden
Imports and Exports	Forbidden	Forbidden	Forbidden

Sperm donations in Serbia didn't still perform in practice since that the first bank of sperm, due the lack of devices, prolonged the opening. However, anonymity is highlighted in case of sperm and oocyte donation and personal data are professional secrecy. According to Serbian Law, information (but not personal data) about donors can be obtained only on doctors' or child's request (child who was conceived with AR procedure with reproductive cells of donor). That information is in charge of

69 Close family member can be donator of oocytes from 2006.

70 Ibid, pg. 203

71 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*, Chapter VII, article 21

72 Law on the treatment of infertility by biomedically assisted fertilization procedures 2009, paragraph (1), article 71

Directorate for Biomedicine and it is not allowed to give any personal data of donors, except the data of the medical importance.

Both countries are consented on prohibition import or export of embryos and reproductive cells for making embryos in the biomedical AR. Difference between Serbia and Hungary lays down in regulation on non-anonymous egg donation and embryo donation in favor of Hungary. From this perspective, we can consider that Hungarian lawmaker (on experience based practice) define certain liberal legal norms in order to provide greater conditions for childless couples to achieve offspring.

V Cross-border cooperation and health tourism

Prominent phenomena of crossing border to obtain some medical services, is embodied in Directive on cross-border health care adopted.⁷³ Directive is facilitating access to safe and high-quality cross-border health care within EU community and promotes cooperation on health care between member states of affiliation. Thus, the operational principles that should be considered include equity, safety, efficiency, effectiveness (including evidence-based care), timeliness and patient centeredness with equal importance.⁷⁴

Since that in Serbia donation of oocytes and sperm is allowed by law but not practiced yet, some patients are looking to obtain service in some of the neighboring countries. Nevertheless, certain numbers of couples are coming to obtain IVF/ICSI treatment in Serbia and Hungary since these countries have cheaper prices, experts, high quality of service, and good results as common factor that attract people to come. Hungary gives precise information that in 2010, 4.5% of total foreign visitors (or every tenth foreign visitor) that came in Hungary had medical and health purpose.⁷⁵ Even if official data aren't available, for sure, Serbia is part of health ART tourism.

Hungary as member of EU is in advantage taking possibilities given by membership such is easy flow of people. Even though reimbursement is allowed in EU, Hungary doesn't reimburse AR treatment expenses if treatment is performed outside of Hungary. The same case is in Serbia – only treatments performed in Serbia can be reimbursed. Reimbursements and patients' mobility are just some of the aspects of possible cross-border cooperation and mobility of medical workers, devices and health services by using e- health should be taken under consideration in the future.

Successful example of cross-border cooperation between these two countries is seen in

73 *Directive on Cross-border Healthcare adopted, Council of the European Union, 28 February 2011, Brussels.* Available at: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/119514.pdf, Retrieved on February 24, 2014.

74 F. Shenfield, G. Pennings, J. De Mouzon, A.P. Ferraretti and V. Goossens, *ESHRE's good practice guide for cross-border reproductive care for centers and practitioners*, Human Reproduction, Vol.0, No.0 pp. 1–3, 2011. Available at: <http://www.eshre.eu/~media/emagic%20files/Task%20Forces/Cross%20Border/Good%20practice.pdf>. Retrieved on February 24, 2014

75 *Hungary in Figures 2010*, Hungarian Central Statistical Office, 2011, pg, 36

GynEndo project⁷⁶ where General Hospital in Subotica (Serbia) and Hungarian University of Szeged cooperate with the aim to solve the problem of infertility with gynecological endoscopy. Gynecological endoscopic equipment and laparoscopic surgery simulator are obtained to plan for both partners. Equipment is used in the daily work of professionals and it is expected that new medical equipment would significantly improve the work and achieve better scientific results in the investigation of infertility in this region with the straightening professional relations. Cooperation between patients' association would be worth full for those patients who are going under AR treatment.

Regarding management- medical worker- patient relation, professionals should take into consideration the specific circumstances of foreign patients by adapting their practical management. Since Serbian and Hungarian language are basically different, professionals need to pay additional attention to ensure that patient understands clearly the conditions given by consent. With these precautions, some legal risk factors can be avoided with optimal patients' access to opportunities for achieving offspring.

Concluding remarks

In this work we compare different perspectives on regulation on assisted reproduction treatments in Serbia and Hungary. On the policy level, both countries, with almost the same demographic structure and pro-natalist policies, recognized the importance of applications of ART. The comparative approach based on socioeconomic, religious and legal perspective give us greater understanding of the dynamics behind some policy choices and their perspectives.

As Christian countries, Serbia and Hungary, agree in consideration embryo as a "living creature" and matrimony as the best place for giving a birth of new human being. While Serbian Orthodox Church allows assisted reproduction on married couples, freezing of sperm and egg, Catholic Church is calling infertile couples to shun 'arrogant' IVF treatment and doesn't support sperm and egg freezing. Furthermore, remarkable results, that affect policy making from religious prospective in both countries, are found in domain of prohibition using ART for achieving offspring in case homosexual couples and absolute forbidden surrogacy.

Nevertheless, in those countries assisted reproduction is performed and national policies, defined trough national law, show that assisted reproduction is understood as a dynamic issue. That dynamics can be seen especially in Hungarian law which has been changed very often in order to follow population's needs and ethical norms. Serbian law on assisted reproduction doesn't have such

⁷⁶ Project was realized in April-March 2011 and was 302 057 Euros financed by IPA Cross-border Co-operation Program Hungary-Serbia; Opšta bolnica Subotica, Available at: <http://www.bolnicasubotica.com/tekstovi/id.58/> also see: <http://www.youtube.com/watch?v=MQ0yzzcLZ1w>, Retrieved on February 27, 2014

a long history but for sure Serbian legislation is following recent trends on assisted reproduction and is adapting own legislation in accordance with regulations of European Union.

Comparing to Serbia, Hungary has some specific differences in legislation. For a very short time, surrogacy was allowed in Hungary but very soon it was forbidden, considering this treatment as very liberal for the social circumstances. Contrary to Serbia, Hungarian law gives the opportunity for infertile woman to find a non-anonymous eggs donor (such as relative or a friend) and childless couples to obtain anonymous embryo donation. The curiosity of Hungarian law is post-mortem use of embryos/gametes in case when assisted reproduction treatment started before the partner died while in Serbia that applies just for reproductive cells (with the written consent), but not for embryos/gametes. Pre-implantation genetic diagnostics (PGD) isn't allowed in Hungary while Serbian legal policy allows PGD just in case of risk of transmitting genetic diseases. However, soft regulations on PGD exist in both countries.

In time of expanding rationalization, cross-border cooperation can be seen as a great opportunity for Serbia and Hungary to develop cooperation through exchanging experiences in AR field, devices and easy flow of health workers and patients. People, who are living in north part of Serbia (Vojvodina), probably travel in Hungary and vice versa for obtaining IVF/ICSI treatment or treatments which aren't allowed in their countries. In order to reduce unmet needs in subfertile populations from this bordering area, both countries should consider idea about reimbursement policies for treatments performed outside of their countries. For Serbia, constitution of the key organizations in regulating AR is the first step, however, needs to put more effort to create sub-acts which would have to bring clearer picture about regulation on biomedical assisted reproduction.

For Serbian and Hungarian policy-makers, as dominant Christian countries, the big challenge in the future might be getting offspring in homosexual couples as well as to be ware of potential misuse of the rights provided for a single woman. Bearing in mind increased number of social and individual needs, expectations and demands directed to the health system, this research opening question of patients' access to ART. The results from this research can be used in the future in the field of legal regulations, health policy and analysis.

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