Legal framework for the use of assisted reproductive technology in Poland

Michał Stec¹, dr n. med. Monika Sadowska², mgr Piotr Wójcik¹, dr n. med. Artur Wdowiak²

¹ Student scientific association Laboratory of Diagnostic Procedures, Faculty of Nursing and Health Sciences, Medical University, Lublin, Poland

² Laboratory of Diagnostic Procedures, Faculty of Nursing and Health Sciences, Medical University, Lublin, Poland

Abstract

To summarize these considerations should be noted the indispensability of detailed statutory regulation issues ART techniques. The existing legal solutions are superficial and inadequate. This causes a lot of problems not only to be confronted with the disease of infertility, but most of all doctors who perform ART. What more regulation in this regard requests the Polish EU. Treatments legislation must have regard to standardize medical practice and prohibit activities that in the opinion of the legislature agree on the value of human life which is. The future legal regulation should resolve issues determine the conditions and symptoms for the use of ART techniques, medical duties and sanctions for their failure, and the establishment of centers authorized, in which the techniques discussed can be applied. An important issue is also to regulate the legal status of the human embryo. In addition, the legislature must decide in which direction they will go different legal solutions, bearing in mind that they have an impact on the effectiveness of ART techniques. Restrictive solutions introduced in some countries under the banner of respect for human dignity brought negative consequences for the effectiveness of treatment, the incidence of complications, limitations in the availability of certain services and benefits as well as discrimination against individuals and groups.

European Journal of Medical Technologies

2014; 2(3): 50-55 Copyright © 2014 by ISASDMT All rights reserved www. medical-technologies.eu Published online 28.04.2014

Corresponding author:

dr n. med. Artur Wdowiak Laboratory of Diagnostic Procedures. Faculty of Nursing and Health Sciences, Medical University, Lublin, Poland ul. Staszica 4/6 Lublin wdowiakartur@ gmail.com

Key words:

surrogate motherhood, assisted reproduction technologies, reproductive health

Introductory remarks

WHO has defined infertility as a social disease that affects 10 to 18% of couples of reproductive age worldwide [1]. In Poland, the problem of infertility is observed in approximately one million pairs, of which 4% are infertile, and 15% are persons with reduced fertility. Based on epidemiological data, it was assumed that equally, ie about 40% of cases, the cause of infertility is male factor and female, the remaining 20% relates to both partners. In determining the liability for infertility couples should be equal distribution – 50% – of both partners [2,3].

The response of medicine at assisting couples treated for infertility are assisted reproductive technology (ART). ART is a group of diverse methods for getting pregnant without one or more stages of natural conception. Among these methods is the method in vitro, considered one of the most effective [4].

Assisted procreation produces a lot of excitement and discussion both in the medical and legal professions. At the same time it is worth noting that the development of medicine in this area undoubtedly entails legislation-despite the fact that issues such as the responsibilities of doctors using the above technique or surrogacy are multidimensional and difficult to assess, also in terms of legislation [5]. Although ART techniques are used in Poland for a long time (the first successful IVF treatment was carried out in 1987) is still in our legal system is not functioning legal act that completely regulate this matter. Therefore, the discussion de lege lata in connection with the use of ART techniques appears appropriate action.

Polish legal system does not have detailed solutions to the issue of assisted reproductive techniques application hence valid view that the doctor on the occasion of application techniques, ART should be guided by the general medical and legal premises located in the Act about the profession of doctor and dentist (uzl) [6], the Code medical Ethics (kel) [7], positions of Polish Gynecological Society for assisted Reproductive Technology in the treatment of infertility [8], as well as the Polish Society for Reproductive Medicine ws ART [9], the Scientific Council of the Section of Fertility and infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society and the Polish Society for Reproductive Infertility Polish Gynecological Society for Reproductiv

tive Medicine [10]. In four recent cases dealing with non-statutory acts and standards contained therein are extralegal, are moral standards and professional rules by which you can judge the professionalism, diligence, and this approach can be applied in relation to the techniques of ART [11]. Moreover, given the nature of the relationship between the patient's doctor also apply the provisions of the civil law in the context of contractual liability.

Duties of a doctor

The analysis of the rules, in the absence of specific regulations should begin with the Code of Medical Ethics [7], and more specifically of art. 38-39a beneath the title of Procreation. Article 38, paragraph. 1 indicates that the physician should with a sense of special responsibility to refer to the transmission of human life. This provision applies to both natural conception and conception by assisted procreation. Haberko [12] indicates that the term with a sense of special responsibility to be interpreted like the term of the due diligence of art. 355 § 1 and § 2 of the Civil Code. It is about the highest degree of care, higher than average.

Given the standard of care can be assessed must verify the conditions and symptoms, the occurrence of which will allow applications to join the ART. At present there are no specific rules that specify those conditions because the doctor who uses ART should be guided by the general medical premises contained in the positions of the Scientific Council of the Section of Fertility and Infertility Polish Gynecological Society and the Polish Society for Reproductive Medicine, Polish Gynecological Society for Assisted Reproductive Technology in the treatment of infertility and the Polish Society for Reproductive Medicine ws ART, and general legal prerequisites contained, inter alia, in the Act on the medical profession. Among these conditions are min. determine whether the majority of infertility couples.

Article 38, paragraph 2 and 3 of the Code of Medical Ethics says physicians should give consistent with medical knowledge, information concerning the processes of fertilization and birth control methods, taking into account their efficacy, mechanism of action

and risk, and patients must be familiar with the capabilities of modern medical genetics, as well as prenatal diagnosis and therapy including information about the risks associated with conducting research anatenatal. In discussing this provision should pay attention to art. 31 of the Act on the medical profession. This article points out the obligation to provide information. The physician should inform the patient about the health, the nature and purpose of the treatment and all its consequences, which are usually the result of surgery, it is desirable effects and about the so-called side effects [13]. In the case of the use of ART techniques gynecologist is obliged to detailed, accurate information on the methods used and any consequences that these methods can have on the health of the patient. The information obligation should be fulfilled in a clear and legible, ie, the physician should use the language that is comprehensible to patients. In addition, part of the information obligation is to alert the cost of the procedure associated with the use of ART, if the treatment occurs in centers other than those financed by the state.

Correct fulfilling of the obligation of information by a doctor has a huge influence on the decision by the patient as to the use of ART techniques, and thereby consent to such a process through a declaration of intent. The obligation to obtain consent for the use of ART comes from art. 32 section 1 of the Act on the medical profession. On the basis of this provision, the doctor may perform a test or provide other health benefits, subject to the exceptions provided for in the Act, the consent of the patient. Consent pursuant to Art. 32 paragraph. 7 u.z.l. can be expressed verbally or by other conduct of the patient, which unequivocally points to the willingness to submit to the proposed medical operations. In contrast, art. 34 paragraph. 1 of that Act says that a doctor can perform surgery, or use a method of treatment or diagnosis posing an increased risk to the patient, after obtaining the written consent of [7].

Particular importance in the case of the use of ART techniques is required to maintain the confidentiality doctor in connection with art. 40 u.z.l. This article requires the doctor's duty to maintain the confidentiality of information related to the patient, and obtained in connection with the exercise of the profession. This

obligation includes all the information that you gave to your doctor during treatment, as well as information not directly related to the treatment process, as well as those that the doctor concluded delegated to him by the patient's information. It should be emphasized the importance of this obligation in the case of heterologous fertilization ie semen donor. In this case it is necessary to strictly maintain the anonymity of both donor and steam uses this type of insemination.

Analyzing the law in force in relation to the application of assisted reproduction techniques one can not invoke the provisions of the Civil Code. Between a pair of bidding for the offspring and the doctor comes to the contract. Such an agreement is concluded on the basis of Art. 750 of the Civil Code to which the relevant provisions of the order – art. 734 et seq. Civil Code The doctor is responsible for the general rules for default and shall be liable for damage caused to patients tort (Art. 471 CC or 415 CC). The correctness of performance of the obligation, any action taken by the doctor and his diligence shall be subject to control by the courts of law.

Surrogacy

Among the techniques of ART is also surrogacy (surrogate motherhood called) [16]. Surrogacy is based. Mary Warnock Report of 1984 the practice of the fact that a woman is pregnant for another woman with intent to transfer her child after birth [17]. On the other hand, some experts describe as "an agreement pursuant to which a woman carries a child that the birth will be forwarded to another woman" [18].

Tokarczyk [19] indicates that a typical surrogacy contract obliges the husband to fertilize the egg cell that is not his foreign wives, recognition and acceptance of the child having been born; wife to accept the conception and adoption of the child; surrogate to consent to the insemination, wearing pregnancy, child birth and delivery to parents who are trying to have a baby under this agreement.

The Polish legal system there is no provision that would ban the use of surrogate motherhood. However, surrogacy agreements are contrary to the principles of social coexistence and pursuant to Art. 58 § 2 of the Civil Code are invalid [20]. Contradiction with

the law of the above is argued primarily that violate the inherent dignity of the person, making the life of a human subject of legal action. [20] The Constitution of the Polish Republic in art. 30 speaks of the inherent and inalienable dignity of man. In contrast, the Constitutional Court in its case law indicates that the word dignity is valid from the moment of conception [21]. Besides the legal transactions are excluded goods such as child and parental rights.

As part of this problem remains a question that woman by. Polish law is the mother of the child. He talks about art. 611 of the Civil Code, "the mother of the child is the woman who gave birth to him." Explains Dr. Marta Soniewicka (Department of Philosophy of Law and Legal Ethics at the Jagiellonian University in Cracow): mother, from the point of view of Polish law, a woman who gave birth to a child. In this connection, the authority, even if that is the donor of the genetic material of a child has no rights to the child and no substantive basis for a claim for return of the child after birth. Under current law, the surrogate mother bear all the consequences of being a mother in law" [22].

However, there is a possibility that your child has become a surrogate mother for a child struggling to pair with them. This is an indication of adoption. Surrogate mother waives rights to the child, and then identifies a specific pair of parents who at the same time apply for the full adoption of the child [23].

Research on human embryos and the prohibition of trade

Another problem associated with ART techniques is the fact that the legal status of the human embryo is not directly regulated. Linked to this is the problem of the use of fertilized ova min. to stem cell research, therapeutic cloning and reproductive cloning also.

The act of retrieval, storage and transplantation of cells, tissues and organs from 1 July 2005, does not apply to the collection and transplantation of germ cells and gonadal tissues of embryonic and fetal and reproductive organs and their parts. In the absence of any regulatory framework concerning genetic engineering should be used general provisions on medical

treatments and experiments, the European Convention on Bioethics in 1997 and the recommendations of the Council of Europe [24]. Physicians should also comply with kel, which in art. 45 paragraph. 2 and 3 prohibits research experiments on embryos, and only allows therapeutic experiment. Next Article. 51 h section 3 and 4: the doctor can make interventions within the human genome only prophylactic or therapeutic purposes and can not participate in activities aimed at causing heritable genetic changes in humans. In addition, the need to cite art. 39a, which indicates that a doctor can not participate in the procedures of human cloning for reproductive or therapeutic purposes. It is also important at this point to recall the most important provisions of the European Convention on Bioethics. Although it has no legal effect because it was not ratified it sets standards for the protection of the human genome prevailing in Europe.

Article 13: An intervention seeking to make changes in the human genome may only be undertaken for preventive, diagnostic or therapeutic only if its aim is not to heritable genetic changes in the offspring.

Article 14: Use of medical techniques assisted procreation is forbidden, if the goal of these techniques is the choice of sex of the future child, except when such a choice to avoid a serious hereditary disease depends on the sex of the baby.

Article 15: Research in the field of biology and medicine are carried out freely, subject to the provisions of this Convention and other rules ensuring the protection of the human person.

Article 18 para. 1 and 2: If the law permits carrying out research on embryos in vitro, it shall ensure adequate protection of the embryo. Creation of human embryos for research purposes is prohibited.

At the end of the debate on this issue should be noted that the law on the collection, storage and transplantation of cells, tissues and organs prohibits trafficking in cells, tissues or organs. Moreover introduces the obligation to obtain a permit to conduct activities related to cell and tissue banks and prohibits the dumping of Polish territory or bring in its territory a cell tissue or organ. Also mentioned regulation penalizes the actions listed above. It is therefore not possible sale or purchase of the male sperm, ova, or human embryos.

Conclusion

To summarize these considerations should be noted the indispensability of detailed statutory regulation issues ART techniques. The existing legal solutions are superficial and inadequate. This causes a lot of problems not only to be confronted with the disease of infertility, but most of all doctors who perform ART. What more regulation in this regard requests the Polish EU.

Treatments legislation must have regard to standardize medical practice and prohibit activities that in the opinion of the legislature agree on the value of human life which is [25]. The future legal regulation should resolve issues determine the conditions and symptoms for the use of ART techniques, medical duties and sanctions for their failure, and the establishment of centers authorized, in which the techniques discussed can be applied [26]. An important issue is also to regulate the legal status of the human embryo.

In addition, the legislature must decide in which direction they will go different legal solutions, bearing in mind that they have an impact on the effectiveness of ART techniques. Kuczynski [27] points out that: Restrictive solutions introduced in some countries under the banner of respect for human dignity brought negative consequences for the effectiveness of treatment, the incidence of complications, limitations in the availability of certain services and benefits as well as discrimination against individuals and groups. Liberal approach in creating reproductive rights marked by pragmatism and concern for others, we found positive effects (reducing the number of multiple pregnancies, increasing efficiency, and improving demographic indicators, reducing individual treatment costs and expenses system).

An example to prove the above words is the Italian legislation. According to official data of the Italian Ministry of Health issued in June 2007 (comparison of state from 2003 - before the introduction of the Act of 2005 - the first two years of the Act), the new regulation resulted in a decrease in vitro efficacy (with the 24.8% to 21.2 %), an increase of nearly 80 % of multiple embryo transfers, the increase in multiple pregnancies (22.7% of the value to 24.3 %), an

increase in pathological cases in the form of spontaneous abortions, obumarć fetus inside the uterus, ectopic pregnancies (the value of 23.4 % to 26.4%), widespread phenomenon of "reproductive tourism "for the purpose of in vitro fertilization – (32 % of Italian couples) [28].

References

- Łepecka-Klusek C, Pilewska-Kozak AB, Jakiel G. Niepłodność w świetle definicji choroby podanej przez WHO. Med Og Nauk Zdr. 2012; 18(2): 163-166.
- Olajossy-Hilkesberger L, Pawłowska B, Studzińska--Niedoborek A, Tkaczuk-Włach J, Jakiel G. Obraz siebie u kobiet leczonych z powodu bezpłodności. Annal Univ M Curie-Skłodowska, Sect. D, (suppl.14), 2004; 59: 236-240.
- Studzińska-Niedoborek A, Tkaczuk-Włach J, Jakiel G: Subiektywna ocean stanu zdrowia pacjentek leczonych z powodu niepłodności. Annal Univ M Curie-Skłodowska, Sect. D, (suppl.14), 2004.
- 4. Zob. więcej Pisarski T, Szamatowicz M, Niepłodność. Warszawa 1997, s. 311-333.
- Haberko J. Obowiązki lekarza ginekologa stosującego techniki prokreacji wspomaganej medycznie. Gin Prakt 2005; 83: 11-18.
- 6. Ustawa o zawodzie lekarza z dnia 5.12.1996 roku (Dz.U. 1997 nr 28 poz. 152 ze zmianami).
- Przyrzeczenie Lekarskie i Kodeks Etyki Lekarskiej z dnia 2 stycznia 2004 roku – dostępne na stronie internetowej: http://www.nil.org.pl/dokumenty/ kodeks-etyki-lekarskiej.
- Stanowisko Polskiego Towarzystwa Ginekologicznego dotyczące technik wspomaganego rozrodu w leczeniu niepłodności – http://www.libramed. pl/wpg/NumeryArchiwalne/05/03.html.
- Stanowisko Polskiego Towarzystwa Medycyny Rozrodu, Towarzystwa Biologii Rozrodu, Sekcji Płodności i Niepłodności Polskiego Towarzystwa Ginekologicznego oraz Komisji Medycyny Rozrodu Komitetu Biologii Rozrodu Zwierząt Polskiej Akademii Nauk w sprawie leczenia niepłodności i jej skutków metodami rozrodu wspomaganego medycznie – http://rozrodczosc.pl/ptmr/index. php?page=stanowisko-PTMR-SPiN-TBR-i-KMR--ws-ART.

- 10. Stanowisko Rady Naukowej Sekcji Płodności i Niepłodności Polskiego Towarzystwa Ginekologicznego oraz Polskiego Towarzystwa Medycyny Rozrodu w sprawie zakresu i kształtu regulacji prawnych odnoszących się do metod wspomaganego rozrodu oraz postępowania z komórkami rozrodczymi i zarodkami ludzkimi powstałymi w wyniku zapłodnienia pozaustrojowego (in vitro) u człowieka z 1 maja 2009r. http://rozrodczosc.pl/ptmr/uploads/docs/Stanowisko_SPiN_PTMR_ws_prawa_reprodukcyjnego.pdf.
- 11. Por. J. Haberko, Obowiązki lekarza ginekologa stosującego techniki prokreacji wspomaganej medycznie. Gin Prakt 2005: 83: 11-18.
- 12. Zob. szerzej: J. Haberko, jw. str. 13, 14.
- 13. A. Dyszlewska-Tarnawska art. 30–57a, w: Ustawa o zawodach lekarza i lekarza dentysty. Komentarz, red. L. Ogiegło, Warszawa 2010, str. 291.
- 14. A. Dyszlewska-Tarnawska, jw. str. 299.
- 15. Ibid. J. Haberko, Obowiązki lekarza ginekologa... str. 15.
- W październiku 2009 roku Światowa Organizacja Zdrowia (WHO) zaliczyła do technik wspomagania prokreacji ludzkiej instytucję zastępczego macierzyństwa.
- W Wielkiej Brytanii Mary Warnock prowadziła rządową komisję, która miała zbadać szeroki aspekt skutków rozwoju w dziedzinie technik ART; por. M. Wałachowska, Macierzyństwo zastępcze, SP 1993, z. 1, s. 99.
- 18. R. Baker, Seks w przyszłości. Spotkanie pierwotnych popędów z technologią jutra, Rebis, Poznań 2002. s 108.
- 19. R. Tokarczyk, Prawa narodzin, życia i śmierci: podstawy biojurysprudencji, Zakamycze, Kraków 2006, s. 180.
- W tej kwestii w piśmiennictwie panuje zgoda. Zob. m.in. M. Safjan Prawo wobec ingerencji w naturę ludzkiej prokreacji, Warszawa 1990, s. 436; M. Nestorowicz Prawo medyczne, Poznań 2005, s. 218.
- 21. Zob. orzeczenie TK z 28 maja 1997 r., K 26/96 i orzeczenie TK z 30 września 2008r., K 44/07.

- 22. Por. M. Tomczyk. Macierzyństwo za pieniądze, artykuł dostępny na stronie internetowej: http://www.sluzbazdrowia.com.pl/artykul.php?numer_wydania=3994&art=2.
- 23. Por. P. Rutkowka, Macierzyństwo zastępcze czy wynajem brzucha w Polsce jest dopuszczalny? artykuł dostępny na stronie internetowej: http://prawoprosto.pl/prawo-cywilne/prawo-rodzinne/519-macierzystwo-zastpcze-czy-wynajembrzucha-jest-w-polsce-dopuszczalny.html.
- 24. M. Nestorowicz Prawo medyczne, Poznań 2010, s. 322.
- M. Działyńska, Postępowanie lekarza przy dokonywaniu wspomaganej prokreacji w: Wspomagana prokreacja ludzka, Poznań 1996, str. 139.
- Ibid. J. Haberko, Obowiązki lekarza ginekologa... str. 17.
- 27. W. Kuczyński, Medyczne, społeczne i ekonomiczne konsekwencje prawa reprodukcyjnego w: Materiały prasowe z konferencji prasowej: Regulacje prawne in vitro w Polsce w świetle włoskich doświadczeń, dostępne na stronie internetowej: http://darek1.home.pl/user_files/In%20vitro%20-%20wrzesien%2009%20-prasowe.pdf.
- 28. Komunikat prasowy wydany przez organizatorów konferencji prasowej Regulacje prawne in vitro w Polsce w świetle włoskich doświadczeń, która odbyła się 17 września 2009 roku. Komunikat został przygotowany w oparciu o materiały przygotowane przez Prof. dr hab. Emanuele Turillazzi – Dyrektora Wydziału Kształcenia Podyplomowego Medycyny Prawnej na Uniwersytecie Medycznym w Foggi, we Włoszech, Prof. dr hab. med. Waldemara Kuczyńskiego- Przewodniczącego Sekcji Płodności i Niepłodności Polskiego Towarzystwa Ginekologicznego i Prof. dr hab. med. Sławomira Wołczyńskiego- Przewodniczącego Polskiego Towarzystwa Medycyny Rozrodu; Komunikat dostepny na stronie: http://darek1.home.pl/user files/In%20vitro%20-%20wrzesien%2009%20-prasowe.pdf.