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Bioethics and Informed Consent in Prenatal Diagnostics

Abstract

Innovative methods of prenatal diagnosis allow us to see the development of the fetus and to detect early disorders of fetal development, which may lead to an early diagnosis and possible treatment, or to a woman's decision to terminate the pregnancy. Therefore, it is very important to accurately inform a woman about the risks and consequences of this life-related issue, even before deciding to perform prenatal tests; and after the results, when a misinterpreted diagnosis may lead a woman to terminate her pregnancy. The obligation of doctors to inform patients is inseparable from the requirement to receive informed consent. The two parts are mandatory for any medical procedure and intervention. The main requirements for the informed consent include rationality, sufficient and clear information, free will, and the form of consent conforming to the legal acts. However, informed consent is not an absolute requirement, as the patient has a right to remain uninformed. Additionally, under certain circumstances, it might be impossible to inform patients, or to receive consent from patients or their duly authorized representatives. Prenatal testing is an integral part of ante-natal care that aims to verify the proper development of the fetus, or to identify potential hereditary or chromosomal diseases at the earliest possible stage. Prenatal testing can be classified as non-invasive or invasive measures, according to the types of procedures In addition to this,

according to the aim of the procedure, into diagnostic prenatal testing with the aim of prenatal therapy, and purely diagnostic prenatal testing. Purely diagnostic prenatal testing is closely connected with the problem of selective abortion.

Part of this article covers the main problems of informed consent in prenatal diagnostics, by outlining two stages of the process: conveyance before prenatal testing, and interpretation of the results alongside presentation of the possible choices. The legal implications we consider are based on information from other European countries: we name the main questions analyzed by courts, including cases of "wrongful birth" and "wrongful life"; inappropriate information regarding possibilities of abortion; the right of a woman to use all available diagnostic methods; and the allocation of damages to the claimants.

Keywords

Informed consent; bioethics; chromosomal anomalies; prenatal diagnostics.

1. Introduction

Accelerating advances in biomedical science, new treatments and evolving technologies are leading to ever-improving results in healthcare. As a result, the number of healthcare services is growing, which must be regulated by legal norms that ensure quality medical services; and establish the rights and obligations of doctors and patients, and the nature of the doctor–patient relationship. The once prevailing paternalistic doctor–patient relationship, in which the doctor made decisions for the well-being of the patient, evolved into the principle of personal autonomy, recognizing a partnership-based doctor–patient relationship, where the patient makes their own decisions. The basis for such decisions is the free and informed consent of the patient. By giving informed consent of his or her own free will, the patient is at the same time exercising his or her rights to integrity and self-determination regarding personal healthcare.[1]

[1] J. Baker, C. Shuman, D. Chitayat, S. Wasim, N. Okun, J. Keunen, R. Hofstedter, R. Silver, *Informed Decision-Making in the Context of Prenatal Chromosomal Microarray*, "J Genet Couns." (2018) Sep; 27 (5), pp. 1130–1147.

The decipherment of the human genome opened up a wide range of medical possibilities, including discovering one's predisposition to diseases, predicting the risks of hereditary diseases in unborn babies, and monitoring already developing fetuses at the prenatal stage. Parents may carry out such tests before planning to have a child, if they suspect they may be carrying hereditary genetic diseases with the risk of passing them on to their offspring. These advances in science have not only generated benefits, but they have also raised questions about its legitimacy and ethics. When it comes to interfering with human DNA, the only ethical intervention is to achieve therapeutic goals, and the sole purpose of such interventions may be to help the unborn baby develop naturally.[2] According to John Paul II, prenatal diagnostic techniques are morally acceptable "when they do not involve disproportionate risks for the child and the mother, and are meant to make possible early therapy, or even to favor a sense and informed acceptance of the child not yet born."[3]

Proper provision of information is particularly important in prenatal diagnosis because it involves not only the patient (pregnant woman), but also a new life. Prenatal diagnostics is not about one but two individuals, one of whom is particularly vulnerable. The doctor plays a very important role in such research, because a woman's self-determination, which may lead to termination of pregnancy, depends upon the interpretation of her research results, competence and ethical and moral values. Termination of pregnancy after prenatal testing is eugenic abortion and Pope John Paul II is clear on this matter: "since the possibilities of prenatal therapy are today still limited, it not infrequently happens that these techniques are used with a eugenic intention which accepts selective abortion in order to prevent the birth of children affected by various types of anomalies. Such an attitude is shameful and utterly reprehensible, since it presumes to measure the value of a human life only within the parameters of 'normality' and physical well – being."[4]

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[2] F. A. Chervenak, L. B. McCullough, *Professionally Responsible Counseling About Fetal Analysis*, "Obstet Gynecol Clin North Am." (2021) Dec; 48 (4), pp. 777–785.

[3] Pope John Paul II, *The Gospel of Life*. (Mar. 25,1995), no. 63, Origins 24: no. 42, Apr. 6, (1995), pp. 711.

[4] Pope John Paul II, *The Gospel of Life*, (Mar. 25,1995), no. 63, Origins 24: no. 42, Apr. 6, (1995), pp. 711.

2. Patient's informed consent

One of the basic principles of bioethics, which originated in the time of Hippocrates – *primum non nocere* – means first and foremost to do no harm. Hence the principles of non-harm, goodwill, duty to treat and respect for patient autonomy, which have long been considered the basis of medical ethics. Thus, informing the patient as an ethical requirement, is inseparable from respect for the patient and their autonomy. The principle of respect for patient autonomy guarantees five very important patient rights: the right to choose, the right to privacy, the right to information, the right to confidentiality and the right not to be discriminated against.[5] Accordingly, the doctor's obligation to inform the patient is inextricably linked to the obligation to obtain informed consent, which is necessary for the initiation of any medical procedure or intervention. Any action by a doctor without the free and informed consent of the patient is illegal, except in exceptional cases provided by law. In the field of healthcare, the style of doctor–patient relationship, based on mutual cooperation, is becoming more and more established, abandoning the previously prevailing principle of paternalism, when all decisions were made by the doctor. This change has been largely driven by the entrenched principle of autonomy, which promotes a person's ability to choose and act independently. Respect for patient autonomy in medical ethics is expressed in the requirement of free and informed consent.[6] In contrast to paternalism, autonomy essentially means that the subjects are the best representatives of their own interests, so that they can decide for themselves what is important to them, based on their values, free from outside influences and any coercion.

Autonomy consists of three elements:

- Self-expression in action;
- Freedom;
- Rationality.

Self-expression in action displays a person's values, desires and ability to implement them. Autonomy is perhaps the most crucial prerequisite, consisting of a person's internal and external freedom. Autonomy implies no outside

[5] K. Zerres, S. Rudnik-Schöneborn, W. Holzgreve, *Do non-invasive prenatal tests promote discrimination against people with Down syndrome? What should be done?*, "J Perinat Med." (2021) May 31; 49 (8), pp. 965–971.

[6] S. Huster, *Non-invasive prenatal diagnostics (NIPD) in the system of medical care*, "Ethical and legal issues. J Perinat Med." (2021) May 31; 49 (8), pp. 972–978.

coercion that may put pressure on one's decisions. These concepts apply in the form of conscious and voluntary decisions on the part of patients to allow or prevent doctors from taking certain actions.

Freely given consent is in no way incompatible with pressure, i.e. direct or indirect attempts to influence a patient's decisions. Indeed, the physician's opinion is a very important factor in helping the patient to make a decision, so the physician's insight and professionalism can largely determine a patient's choice. Rationality is related to a person's ability to understand and respond to the information provided to him, to determine what is right, to understand the current situation and to anticipate future consequences.

Informed patient consent can be understood as the process by which a person, having all the necessary information and being free to make their own decisions, consents to a procedure.[7] Informed consent should be seen as a process that involves mutual understanding and exchange of information between the doctor and the patient, while respecting the patient's autonomy.

The consent form is only one of the documents involved in the informed consent process, as informed consent is expressed not only in writing but also orally, and by implied action.[8]

Informed patient consent is a legal means of protecting a patient's rights against wrongdoing by his doctor(s) and of obtaining full information about the diagnosis of the disease, treatment options, alternative treatments, expected results and consequences of agreeing to or refusing treatment.

3. Prenatal Diagnostics

The fusion of male and female gametes is necessary for the formation of a human zygote. A zygote develops into an embryo and later into a fetus.

The time from conception to birth is called the prenatal period, *periodus prenatalis* (Latin: *prae* – before; *natus* – birth).[9] It is divided into two periods:

[7] H. Vikas, A. Kini, N. Sharma, N. R. Gowda, A. Gupta, *How informed is the informed consent?*, "J Family Med Prim Care" (2021) Jun; 10 (6), pp. 2299–2303.

[8] N. Sivanadarajah, I. El-Daly, G. Mamarelis, M. Z. Sohail, P. Bates, *Informed consent and the readability of the written consent form*, "Ann R Coll Surg Engl." (2017) Nov; 99 (8), pp. 645–649.

[9] C. M. J. Tan, A. J. Lewandowski, *The Transitional Heart: From Early Embryonic and Fetal Development to Neonatal Life*, "Fetal Diagn Ther" (2020); 47 (5), pp. 373–386.

1. Embryonic – the stage of human development from the moment of fertilization until the end of eight weeks;
2. Fetal – the stage of human development from the beginning of week 9 until birth.[10]

Prenatal diagnostics is an integral part of pregnancy healthcare: it is a set of different diagnostic methods and procedures that are used to diagnose diseases in an unborn baby. The purpose of prenatal diagnosis is to identify defects in the fetus and to treat them, if possible.[11] Prenatal diagnostics is an integral part of genetic counselling. The purpose of prenatal genetic counselling is to detect hereditary diseases or congenital malformations before birth. Prenatal genetic testing is justified when the desire is to cure the child or protect him or her from the consequences of defective genes. The purposes for which prenatal diagnosis is performed must always be in the best interests of the child and their mother, and the informed consent of the woman is therefore essential. Prenatal diagnosis would be clearly contrary to moral standards when, depending on its outcome, an abortion would be envisaged.[12]

It would be wrong to say that the main purpose of prenatal diagnosis is to detect embryonic or fetal diseases and birth defects, and consequently to terminate the pregnancy on that basis.[13] Advanced biomedical technology allows some treatments to begin in the womb; and in other cases, doctors can prepare to initiate treatment as soon as the child is born. Additionally, in such cases, proper choice of delivery method is very important to avoid as few complications as possible.

Prenatal tests can also help prevent abortions when a woman is considering one, due to anxiety about the future health of her child, as the baby's health may very well be better than the mother expects. For instance, a woman may

[10] J. Fry, R.M. Antiel, K. Michelson, E. Rowell, *Ethics in prenatal consultation for surgically correctable anomalies and fetal intervention*, "Semin Pediatr Surg." (2021) Oct; 30 (5), pp. 151102.

[11] A. K. Kiani, S. Paolacci, P, Scanzano, S. Michelini, N. Capodicasa, L. D'Agruma, A. Notarangelo, G. Tonini, D. Piccinelli, K. R. Farshid, P. Petralia, E. Fulcheri, F. Buffelli, P. Chiurazzi, C. Terranova, F. Plotti, R. Angioli, M. Castori, O. Pös, T. Szemes, M. Bertelli, *Prenatal genetic diagnosis: Fetal therapy as a possible solution to a positive test*, "Acta Biomed." (2020) Nov 9; 91 (13-S): e2020021.

[12] D. Schmitz, W. Henn, *The fetus in the age of the genome*, "Hum Genet." (2021) Aug 23. Epub ahead of print.

[13] S. Dukhovny, M. E. Norton, *What are the goals of prenatal genetic testing?*, "Semin Perinatol." (2018) Aug; 42 (5), pp. 270–274.

illogically wish to terminate her pregnancy due to the elevated risk of congenital defects with advanced maternal age, despite the chances of having a healthy baby still being high. In such cases, prenatal diagnostic methods can often destroy the fear and anxiety of the woman, rendering them the most appropriate solution. However, the results of tests can also reveal a more unfortunate situation than what the mother expected, so the diagnosis of a disabled child must be accompanied by adequate information about the severity, nature and treatment of the disease. Psychological help is also needed to assist mothers to prepare for, and accept, the difficulties of raising children with disabilities.

As mentioned earlier, it cannot be ruled out that the results of prenatal examinations will lead women to choose abortion. This is where the fundamental ethical problems of prenatal research arise. On the one hand, it is argued that it is a woman's right to choose whether or not to terminate a pregnancy. On the other hand, there is the position that upholds the fetus' right to live, whatever illness it may suffer, arguing that life is more important than all the trials and tribulations that a child's disability will cause. The state of such views depends upon society itself and its views on the beginning of life and its value, people with disabilities and social responsibilities. Genetic testing raises, and will continue to raise, moral issues for the family, for racial or ethnic groups, and for society as a whole.[14]

The following statements can be made to support the importance of prenatal diagnostics:

- Non-pathological or disease-free test results and normal ultrasound appearance should result in a calming effect;
- It should allow the choice of the most appropriate birthing tactic (e.g., Cesarean section after the fetus has had hemophilia A and B, or a spina bifida);
- The birth can take place in a specialized clinic, where the newborn is given the necessary care (e.g., in cases of heart defects or anterior abdominal wall defects);
- Early birth can be induced to minimize organ damage (e.g., progressive hydronephrosis or hydrocephalus);
- The family can be psychologically prepared for the birth of the child: information can be provided about the defect(s), treatment and corrective options.

[14] National Conference of a Catholic Bishops Science and Human Values Committee, *Critical Decisions: Genetic Testing and its Implications*, "Origins" 25: no 45 (May 2, 1996), pp. 770.

Prenatal diagnostics is an integral part of pregnancy healthcare, affecting a very vulnerable and sensitive group: women and their unborn babies. Therefore, the role of doctors, and their competence and professionalism when interpreting test results, are especially important in prenatal diagnostics. In medicine, no test can be 100% accurate.[15] Knowing this, physicians should inform patients very clearly and comprehensibly about possible false-positive test results. Physicians need to repeat tests and have consultations with colleagues; and only then, after using all possible testing methods and procedures, draw conclusions or take some action.

The goal of prenatal diagnosis is early, reliable and most importantly, geared towards the safe testing of pregnant women to detect fetal pathologies as early as possible and to select the best tactics for the families, women, and fetuses. Thanks to modern technology, when certain embryonic or fetal diseases are detected, it is possible to start treatment before the baby is born, or to prepare for treatment in advance. Modern NIPT tests (noninvasive prenatal testing) now can analyze free fetal DNA from maternal blood. NIPT, due to its high sensitivity, significantly reduces the need for an invasive testing, thereby reducing the risk of miscarriage and other complications.[16]

One of the major ethical issues in prenatal diagnostics is abortion. When asked whether abortion is morally permissible, two principles of medical ethics collide: respect for human autonomy and respect for individual human life. With regards to respect for human autonomy, proponents of her supremacy, in this case, argue that a woman has the right to choose to terminate or maintain a pregnancy because a mother cannot morally be forced to bear the burden of a child; therefore, for them, abortion is morally permissible when a woman so desires. The opposite view is prioritizing respect for human life, where abortion is seen as an immoral act that takes the life of a helpless person.[17] A primary disagreement though, is that to the latter group, the embryo is considered human from the moment of conception, making the termination of a pregnancy morally unacceptable.

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[15] N. Milinković, S. Ignjatović, Z. Šumarac, N. Majkić-Singh, *Uncertainty of Measurement in Laboratory Medicine*, "J Med Biochem." (2018) Jul 1; 37 (3), pp. 279–288.

[16] A. Kater-Kuipers, I. D. de Beaufort, R. H. Galjaard, E. M. Bunnik, *Rethinking counselling in prenatal screening: An ethical analysis of informed consent in the context of non-invasive prenatal testing (NIPT)*, "Bioethics" (2020) Sep; 34 (7), pp. 671–678.

[17] M. T. Brown, *The Moral Status of the Human Embryo*, "J Med Philos." (2018) Mar 13; 43 (2), pp. 132–158.

4. Informed consent in prenatal diagnostics

Proper provision of information is particularly important in prenatal diagnostics because it involves not only the patient, but a new human life. Prenatal diagnostics is no longer about one, but two individuals, one of whom is particularly vulnerable. The doctor plays a very important role in such research, because a woman's self-determination, which may lead to termination of pregnancy, depends upon the interpretation of her research results, her competence and her ethical and moral values. According to Pope John Paul II, "All scientific and technical progress whatever must therefore keep the greatest respect for moral values, which constitute a safeguard of the dignity of the human person. And since, in the order of medical values, life is man's supreme and most radical good, there is need for a fundamental principle: first prevent any damage, then seek and pursue the good."[18]

It is the responsibility of physicians to properly inform patients and their families of all possible consequences of maintaining their pregnancies in the presence of inherited genetic diseases or developmental abnormalities. The information should not just encompass the health consequences for the women who decide to carry their children to term, but also the lasting psychological impacts of choosing an abortion.

There are two important stages at which a doctor can influence patient's decision. The first is before the testing, at which time the doctor should inform the patient about the risks of the tests, such as the risk of miscarriage; the benefits and harms of them to her and the baby; and the diagnostic options and alternatives. The second stage is after the testing, when the doctor informs the patient about the results and further options. This is a very important task, as the doctor can influence the patient's choices with an interpretation of the results, as well as presentation of the options.

4.1. Informed consent prior to prenatal testing

The overall risk of having a child with congenital defects is about 3–4 percent.[19] It is very important that patients are properly informed from the very first

[18] Pope John Paul II, *The Ethics of Genetic Manipulation*, (Oct. 29, 1983). Origins 13: no. 23, Nov. 17, 1983, pp. 389.

[19] M. Dundar, A. S. Uzak, M. Erdogan, Y. Akbarova, *Prediction, prevention and personalisation of medication for the prenatal period: genetic prenatal tests for both rare and common diseases*, "EPMA Journal" (2011), Nr. 2, pp. 181–195.

consultation about the probabilities of diseases and developmental anomalies, indications for testing and possible alternatives to these tests. Providing patients with complete information will avoid indirect pressure on doctors to carry out all possible tests – who will often forget or fail to inform their patients of the tests' potential risks. For example, a study in Canada of 38 women who underwent prenatal invasive genetic testing found that the majority of women considered all tests to be routine and mandatory (they were not sufficiently informed about the purposes of these tests and the potential risks to the fetuses and themselves). In this situation, women could not give informed consent because they felt that their right was only to choose whether or not to terminate the pregnancy in the presence of fetal malformations.[20]

The first issue concerning the application of informed patient consent in prenatal diagnostics, is the provision of information to women about the risks involved in certain procedures or studies. Non-invasive prenatal tests, such as ultrasound, testing the maternal blood's biochemical markers and analyzing free fetal DNA, present minimal risks to both the woman and the baby. However, if invasive procedures such as amniocentesis, chorionic villi biopsy and others are being considered, the provision of proper and complete information to the woman is essential. The potential benefits and risks of these procedures to the woman and the baby should be considered. According to a study in Australia, as many as 31% of the 108 women who underwent amniocentesis and thought they were well informed about the procedure, did not realize that these studies could lead to miscarriage; their main focus was on the final diagnosis and the choice of whether or not to carry the baby to full term.[21] Studies conducted and summarized in different countries have shown that from 11% to 53% of women can be unaware of the possibility of miscarriage resulting from invasive prenatal testing.[22]

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[20] K. B. Potter, O. R. Reilly et. al., *Exploring informed choice in the context of prenatal testing: findings from a qualitative study*, "Health Expectations" (2008) Nr. 11, pp. 355–365.

[21] H. J. Rowe, W. R. J., Fisher, A. J. Quinlivan, *Are pregnant Australian women well informed about prenatal genetic screening? A systematic investigation using the Multidimensional Measure of Informed Choice*, "Australian and New Zealand Journal of Obstetrics and Gynaecology" (2006) Nr. 46, pp. 433–439.

[22] K. Dahl, U. Kesmodel, L. Hvidman, F. Olesen, *Informed consent: attitudes, knowledge and information concerning prenatal examinations*, "Acta Obstetricia et Gynecologica" (2006) Nr. 85, pp. 1414–1419.

4.2. Informed consent after prenatal testing

One of the most important steps in informed consent during prenatal diagnostics, is the interpretation and presentation of the test results to the patient. Whatever the outcome, it is important to emphasize the likelihood of a possible error. For example, an article in a Scandinavian journal for gynecologists and midwives, *Acta Obstetricia et Gynecologica*, covering 12 different countries, found that about half of the women in the study were unfamiliar with the possibility of false-negatives, and about a third were unaware of the possibility of false-positive test results.[23] A false-negative result means that the test did not find sufficient evidence of the abnormality/disease it targets, yet, in fact, the fetus had that abnormality/disease. A false-positive result is when an abnormality/disease was supposedly discovered, even though the child did not have that problem. False-positive results in prenatal diagnostics (serum biochemical screening) vary in frequency between 5 and 15 percent.[24] Therefore, it is important to inform the patients so that they do not rush into invasive testing or even termination of the pregnancy, as test results can be erroneous. Hence, ir is emphasized that healthcare professionals, whose opinions have a significant influence on patients' decision-making, must provide detailed information on the possible complications and the chances of false-negative and false-positive test results. Although patients receive information from a variety of sources (e.g., books, the Internet, magazines, friends and television), the greatest external influence on their choices is direct contact with physicians.[25]

It seems clear that non-invasive prenatal tests (e.g., biochemical serum screening) do not raise many ethical issues: in principle, they are safe for both mother and child. However, there are cases where even „innocent" investigations can lead to ill-considered decisions. The patient's informed consent and the right not to know the results, have become the focus for doctors at the very first stage

[23] K. Dahl, U. Kesmodel, L. Hvidman, F. Olesen, *Informed consent: attitudes, knowledge and information concerning prenatal examinations*, "Acta Obstetricia et Gynecologica" (2006) Nr. 85, pp. 1414–1419.

[24] K. Tobola-Wrobel, E. Wysocka, M. Pietryga, *The clinical usefulness of biochemical (free β-hCg, PaPP-a) and ultrasound (nuchal translucency) parameters in prenatal screening of trisomy 21 in the first trimester of pregnancy*, "Ginekol Pol." (2019); 90 (3), pp. 161–166.

[25] K. H. Geissler, J. Pearlman, L. B. Attanasio, *Physician Referrals During Prenatal Care*, "Matern Child Health J." (2021) Dec; 25 (12), pp. 1820–1828.

of prenatal consultation.[26] After high-risk prenatal test results from a serum test, it is advisable to perform non-invasive prenatal testing (rather than invasive) with free fetal DNA from maternal blood (NIPT), as the sensitivity of such tests is very high – 99% – and there is a chance of a low false-positive (0.1%).[27]

Regarding the doctor's influence on the patient's self-determination, it is important to emphasize that the doctor cannot directly or indirectly try to influence the patient's decision in one direction or another. The doctor simply has to tell the truth about the real nature of unborn as a human person, because it is the only safeguard against an imperative to choose an abortion. A woman who decides to maintain her pregnancy in the presence of a fetal pathology should be supported. If a mother does decide to keep the disabled child, it is then important to provide her and her family with as much information as possible about the child's future illness or disability, medical prognosis and treatment options, along with any other obstacles they may experience after the child is born.

5. European legal cases in prenatal diagnostics

A review of the relevant legal cases in European countries have revealed cases in which courts dealt with prenatal testing and informed patient consent. In cases of alleged negligence of doctors in relation to the birth or conception of disabled children when parents go to court for damages, judicial practice varies across the world. The concept of "wrongful birth" is used to regulate such cases. Women who have given birth to children with disabilities request pecuniary and non-pecuniary damages in these cases. Another related cause of action is called "wrongful life", where children make claims against their parents for their birth.[28] The physician's fault in these cases arises if the parents have been insufficiently or completely uninformed about possible prenatal testing or hereditary diseases,

[26] D. A. Jong, J. W. Dondorp, C. E. D. Die-Smulders, G. M. S. Frints, D. M. W. R. G. Wert, *Non-invasive prenatal testing: ethical issues explored*, "European Journal of Human Genetics" (2010) Nr. 18, pp. 272–277.

[27] M. S. Alberry, E. Aziz, S. R. Ahmed, S. Abdel-Fattah, *Non invasive prenatal testing (NIPT) for common aneuploidies and beyond*, "Eur J Obstet Gynecol Reprod Biol." (2021) Mar; 258, pp. 424–429.

[28] L. Berlin, *Wrongful life. Malpractice issues in radiology*, "American journal of roentgenology" (2003) Nr. 181, pp. 1181–1188.

and when there has been misdiagnosis. In any case, the plaintiff insists that the birth of the disabled person was unjust, and that complete termination of pregnancy or sterilization prior to conception was proper.[29]

Over the last 10 years, the Italian Supreme Court has taken a fairly united position on "wrongful birth" cases. The physician, knowing and not properly informing the patient about possible or existing fetal abnormalities, becomes responsible for "wrongful birth." Parents can ask for compensation if they could have terminated the pregnancy at the time of the doctor's violation. Damages can be property and non-property based. Property damages include medical expenses, increased maintenance costs for a disabled child and reduced working capacity due to the care required by a disabled child. Non-pecuniary damages include the psychological experiences of the parents and the deterioration of the family's social life.[30] In one case in Italy of a doctor's failure to inform, the Court upheld a woman's claim that she would have had her abortion if she had been properly informed by her doctor about the possible illness of her future child. The applicant was awarded compensation for "biological damage" and pecuniary damage.[31]

On October 13, 2011 Judgment of the Polish Supreme Court was on a case in which a woman, who had become pregnant, did not receive sufficient information from her doctor about her prenatal genetic tests. The applicant complained that she had not been given access to prenatal genetic diagnostic tests, that she had not been adequately informed by her doctor, that she had her decision delayed and that she had been provided with inaccurate information. After which, doctors refused to terminate the pregnancy. In 2003, the applicant gave birth to a baby with Turner syndrome (X chromosome monosomy). In this case, the Polish Supreme Court acknowledged that ambiguous medical information and advice on the possible risk of the genetic disease, and refusal to perform detailed prenatal examinations, which prevented the parents from having a legal abortion, should cause the doctor to provide damages (pregnancy and childbirth costs,

[29] S. M. Suter, *The routinization of prenatal testing*, "American journal of law and medicine" (2002) Nr. 28, pp. 233–270.

[30] G. Brüggemeier, A. C. Ciacchi, P. O'Callaghan, *Personality Rights in European* Tort Law, (2010), pp. 525–526.

[31] V. C. Bar, *Non-Contractual Liability Arising out of Damage Caused to Another*, 2009, pp. 352.

lost income and increased child support costs).[32] However, the case did not end there, and the applicant applied to the European Court of Human Rights ("the ECHR"). On May 26, 2011, the decision ruled that the applicant had received insufficient compensation from the Polish Supreme Court. The ECHR found that the superficial attention of doctors violated the prohibition on inhumane and degrading treatment, in breach of Article 3 of the Convention. The ECHR also recognized that each party has the right to determine the circumstances in which a pregnancy may be terminated. In the applicant's case, the ECHR stated that the necessary prenatal tests should have been carried out in time for a termination of the pregnancy to be possible under the country's legislation. The ECHR ruled that the Polish authorities had not taken due caution to respect the privacy of the individual, in breach of Article 8 of the Convention.[33]

All of these cases, like the concepts of the cases themselves, raise a number of legal and ethical issues and debates. Can life be the object of damages, and how is the value of a life calculated? The issue of persons with disabilities is also relevant, as the Court, by awarding compensation to a family for a child born with a disability, implicitly declares the harm of the birth and the right to eliminate such a person. The main legal ramifications, if the premises of the plaintiffs are granted, rest on whether the doctors involved have made mistakes.

To return to assessing the damage: what is the damage caused, how can one measure it and can it be assessed in monetary terms at all? The third question concerns the sequence of cause and effect. It can be probed by another question: who is really to blame if disability is a natural phenomenon? The main ethical issue though, is to assess how life is valued in principle, and relatedly, whether medical technology influences who has the right to be born. In cases of wrongful birth, the question arises as to whether the child born may be treated as an injury, rather than a gift that should bring joy. With regard to „wrongful living," the ethical question is two-fold: Should a disabled child have the right to blame his or her parents for his/her life? The second question is whether the life of a disabled person is less valuable than that of a healthy person[34]

[32] V. C. Bar, *Non-Contractual Liability Arising out of Damage Caused to Another*, 2009, pp. 352.

[33] Case 27617/04, R.R. v. Poland [2011] ECR.

[34] I. Giesen, *Of wrongful birth, wrongful life, comparative law ant the politics of tort law system*, "Tydskrif vir Heedendaagse Romeins-Hollandse Reg (THRHR)" (2009) Nr. 72, p. 257.

In summary, the treatment of "wrongful birth" and "wrongful life" cases in European courts varies considerably from country to country. On the one hand, there is the liberal case-law of the Netherlands, which accepts both "wrongful birth" and "wrongful life" claims for pecuniary and non-pecuniary damages. On the other hand, German courts generally do not recognize actions for "wrongful life" because, in their view, even if a woman is aware of her child's disability, she has no obligation to have an abortion, only a right to choose either way, so she cannot be blamed for not exercising her right.[35]

6. Conclusions

1. The basic requirements for informed patient consent are personal competence, sufficient and clear information, free will and consent in accordance with the formal requirements laid down by law.
2. The moral status of the embryo should be discussed at the stage of prenatal testing. That is why the only ethical intervention is to achieve therapeutic goals, and the sole purpose of such interventions may be to help the unborn baby develop naturally.
3. The issue of informed patient consent in prenatal diagnosis can be divided into two stages: the first involves informing the patient prior to performing certain tests, and the second involves interpreting the results obtained and presenting options. In the first stage, it is important for the patient to be properly acquainted with the types of tests available and their reliability; the potential risks of the tests to herself and the fetus; and the alternative tests. When interpreting the test results, it is important to provide comprehensible information to clarify the accuracy of the tests; the nature of any disease that is diagnosed and its potential impacts on the fetus; the possibility of additional or alternative tests. Thereby, ethical, safe and precise prenatal testing should be offered to pregnant women.

[35] I. Giesen, *Of wrongful birth, wrongful life, comparative law ant the politics of tort law system*, "Tydskrif vir Heedendaagse Romeins-Hollandse Reg (THRHR)" (2009) Nr. 72, p. 273.

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