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# Inwazyjna diagnostyka prenatalna w Polsce. Postulaty modyfikacji w infrastrukturze medycznej

### Streszczenie

Realizowana w Polsce inwazyjna diagnostyka prenatalna (IDP) obejmuje 3 procedury pozyskiwania materiału biologicznego płodu (amniopunkcję, biopsję kosmówki i kordocentezę), a następnie jego biochemiczną, cytogenetyczną i molekularną analizę. Umożliwia to bardzo wiarygodną weryfikację kilku tysięcy wad genetycznych, a w konsekwencji zaplanowanie odpowiedniej opieki i ewentualnej terapii dziecka. Niestety, w procedurę inwazyjną wpisane jest zawsze zagrożenie dla życia płodu i zdrowia kobiety ciężarnej. Drugim istotnym problemem etycznym jest częste wykorzystywanie niepomyślnej diagnozy jako podstawy do legalnej terminacji ciąży.

Celem artykułu jest przypomnienie warunków koniecznych dla godziwego przeprowadzenia IDP oraz wyznaczenie kierunków działania w obrębie polskiej diagnostyki prenatalnej służących autentycznej „humanizacji medycyny”. Płaszczyzną przeprowadzanych analiz jest personalizm ontologiczny charakteryzujący się realizmem epistemologicznym i etycznym. W tym ujęciu podstawowe kryterium sądu moralnego stanowi integralne dobro osoby. IDP jest więc godziwa, gdy jej jedynym celem jest równoczesne działanie dla dobra poczętego dziecka oraz jego matki. Postulaty dotyczące poszczególnych etapów diagnozowania streszczają się w czterech ogólnych nakazach: zagwarantowanie realnego dostępu do badań; zachowanie maksymalnych środków ostrożnośc, empatia lekarza, integracja z terapią i opieką paliatywną.

**Słowa kluczowe:** badania genetyczne, diagnostyka prenatalna, etyka, humanizacja medycyny, konsultacja genetyczna, opieka paliatywna, osoba, personalizm.

# Invasive prenatal diagnosis in Poland. Postulates of modification of the medical infrastructure

### Abstract

The implemented invasive prenatal diagnosis (IPD) in Poland includes three procedures of obtaining biological material of the fetus (amniocentesis, chorionic villus sampling, percutaneous umbilical cord blood sampling) and its biochemical, cytogenetic and molecular analysis. This enables a reliable verification of several thousands of genetic defects, and in consequence leads to planning appropriate care and treatment of the child. Unfortunately, the invasive prenatal diagnosis may turn out to be deadly for the fetus and may cause health loss of the pregnant woman. Sadly, all invasive procedures include risks of life or health loss. Another important ethical issue is the frequent use of the unfavorable diagnosis as a basis for a legal termination of the pregnancy.

The aim of the article is to remind the conditions, necessary for an ethical conduction of the IPD and the establishment of the directions in the Polish invasive diagnostics that will lead to a true “humanization of medicine”. The plane on which the analysis will be conducted is the ontological personalism, characterized by epistemological and ethical realism. In this perspective, the basic criterion for the moral judgment is the integral wellbeing of the person. IPD is thus ethical, when its main goal is to aid the unborn child and its mother. The postulates of each stage of the diagnosis can be summarized in four general orders: ensuring access to the test, taking maximum precautions, physicians’ empathy, integration of therapy and palliative care.

**Keywords:** genetic test, prenatal diagnostics, ethics, humanization of medicine, genetic counseling, palliative care, person, personalism.

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## INTRODUCTION

Invasive prenatal diagnosis (IPD) has been implemented in Poland for over thirty years. Within the Prenatal Testing Program [1] founded by the National Health Fund, in 2010 there were as many as 5623 of such procedures conducted. This type of diagnosis, however, raises two important ethical dilemmas: inscribed in this type of invasive procedure life-threat to the fetus and health hazard for the mother and providing legal basis for terminating a pregnancy. In 2010, 1645 fetal abnormalities have been diagnosed and 614 abortions carried out [2].

Personalistic ethics (PE) refers to the basic criterion, which is the promotion and protection of the integral (physical, psychological and spiritual) wellbeing of a person. Above all, the concern for the person signifies the protection of the fundamental value which is the physical life and secondly the protection of secondary values which are health, integrity and freedom [3]. PE always includes equal and simultaneous care for both, the unborn child and its mother. IPD is thus ethical when the physician's and parents' aim is purely "therapeutic", understood as the desire to find out the state of health of the unborn child in order to plan appropriate care and treatment. Another necessary condition for the ethicality of IPD are medical premises that justify taking the risk of performing the tests. The second condition is precisely defined by the recommendations of the Polish Gynecological Society from 2009 [4].

The article aims to answer the question of what can be done for IPD in Poland so that the procedure would be carried out with more benefit for the patients (the unborn child and its mother). Here PE specifies four general orders:

1. Guarantee of access to the test;
2. Taking maximum precautions;
3. Physicians' empathy;
4. Integration of therapy and palliative care.

These imperatives require further detailing, taking into account the realities of Polish medical infrastructure. Postulates, formulated by the author, discussed in detail in the monograph [5], are not ready solutions waiting to be automatically implemented in clinical practice. They are proposals of actions that physicians and other persons responsible for IPD should include in their daily work in order to maintain authentic sensitivity to the dignity of human life.

### Accessibility of IPD

Reports of the Council of Ministers on implementation of the Family Planning Act [6] repeat alarming information on the lack of access of the State's Program of Prenatal Testing [1] in the Podkarpackie voivodeship. The report from 2010 reads, "There were no medical benefits provided because there was no provider who would meet requirements in the field of medical personnel qualifications and appropriate medical equipment. Patients from the Podkarpackie voivodeship had to travel to various centers for prenatal tests including Warszawa and Łódź" [2]. Pregnant women must therefore drive hundreds of kilometers to reach the center, which carries out IPD. This is connected with additional stress and sometimes results in abandoning the trip and the overall procedure.

PE by referring to the principles of social justice and subsidiarity, calls for the necessity to create conditions for a real accessibility of IPD. Every woman with medical indications and a will to undergo this procedure should be able to do so relatively easy. A significant facilitation for women living in the South-Eastern part of Poland would be the establishment of such a medical center in that region. It is also important that the country constantly increase the pool of financial resources for prenatal diagnosis and training professionals in this field of genetics [7].

### Consultation preceding testing

The obligation to precede IPD with a conversation between the physician and parents, or at least with the pregnant woman, is confirmed by virtually all legal and deontological documents including Recommendation (90) 13 issued by the European Council [8]. Given the nature of IPD, only in exceptional cases the conversation does not end in "genetic counseling". The primary goal of the consultation is to provide accurate information necessary for making informed decisions as to conducting the test. This goal, however, faces a number of problems that concern mutual communication and the inability to eliminate the "directiveness" of the advice [9].

Recalling the principle of solidarity, PE calls for the aforementioned consultation to be more than just strictly informational. It should take on the form of "help" provided to parents and the unborn child. This however does not exempt the physician from the obligation to provide professional and comprehensive information, but to sensitize him to the manner in which the information is given. The first step in changing consultation into a help based relationship is the attitude of the physician providing advice. The physician is called for:

- empathy (the ability to capture the emotional state of others and to communicate adequately to the situation);
- heartfelt respect (respecting the dignity and value of the interlocutor as a person);
- authenticity (coherence between verbal and non-verbal communication, not trying to hide behind the role of a consultant);
- precision (limiting the conversation to essential matters);
- confrontation (presenting the differences between what the interlocutor says and what is implied by his behavior, between what he says now in comparison to what he said earlier);
- directness (being aware of the relationship between the physician and the patient in this particular situation hit et nunc) [10].

Other important factors are the external conditions in which the consultation takes place. For the comfort of the discussion, it is necessary to provide a discreet place, which will allow for parent's verbalization of their concerns and a calm analysis of the existing situation. What is more, the parents should be devoted as much time as they need. The practice of carrying out the consultation and examination on the same day, which sometimes occurs in the Polish reality, seems to be rather undesirable. What is more, PE states that the physician's empathy should embrace not only the parents but also the unborn child. Physicians sensitive to the dignity of human life from the moment of conception should also pay attention to the vocabulary and instead of using the word “fetus” should use the word “child.” This personalistic terminology does not contradict the “indirectiveness” of the consultation. It does not force parents to comply with the decision of undergoing/abandoning tests, but allows the consultant to adopt a genuine attitude without concealing his personal relation to the unborn child.

Physicians’ empathy and care for maintaining maximum precautions should be particularly visible when a woman requests IPD without medical justification. Such a request is an expression of deep fears. Often, pregnant women fear the challenges that would appear with raising a disabled child and the only “reasonable” solution to this tragic situation seems to be selective abortion. Due to the evil that a termination of pregnancy is, and taking into account research results, which suggest that even a negative result is not able to resolve all of the mother’s concerns [11], physicians should discourage women who do not belong to the “genetic risk” group from wanting to undergo IPD and try to direct them to seek the assistance of psychotherapy [9].

### Collecting biological material

The ambulatory procedure of biological material acquisition is one of the most essential stages of IPD. It is the moment of direct life threat to child’s life and the mother’s health. Contemporarily, in Poland there are no official data concerning the percentage of miscarriages and other complications of this invasive procedure. The only sources of information on the high quality of IPD are scientific articles written by employees of various diagnostic centers [12-16].

Considering the procedure of obtaining biological material of the fetus, EP analyses two morally-relevant elements: maintaining highest precaution measures and using this time to strengthen family bonds. In carrying for the “technical” quality of the test, a special apparatus should be provided and sterility of the place kept. What is more, the physician is obliged to provide the highest medical standards e.g. prior verification of contraindications for surgery, careful choice of the place of the injection and cautious trajectory of the needle. Considering strengthening of the family bonds, it is essential to mention the strengthening of the bonds between parents and between parents and the conceived child. The first morally essential duty of the physician is fulfilled by allowing the father of the child to participate in the procedure. The partner’s presence is a significant psychological support to the woman and positively reduces the stress level. The stress experienced in solitude can result in psychosomatic ailments, which adversely affect the procedure and the pregnancy [9]. Prenatal testing involving the father is no longer a “woman’s problem” and becomes a family event. The physician may implement second moral obligation by using the ultrasound equipment. After taking a sample, the physician may show the conceived child on the screen, explaining to the parents its appearance, presentation and movement. This strengthens the relationship with the child, which is especially important in the case of a lethal defect. Paradoxically a strong emotional bond helps parents go through mourning caused by the child’s premature death.  The picture of their son or daughter seen on the screen becomes a reference point for explaining the mourning. It protects the parents from pushing out memories of this tragic event into the “subconscious” [17].

### Analysis of the biological material

The stage equally important as collecting the biological material of the fetus is its subsequent analysis. Although the procedures carried out in the laboratories do not pose a direct threat to the life and health of neither of the participants, their results may be fateful. In order to ensure the desired quality of the results, Polish laboratories apply standards of the International Organization for Standardization (ISO). Until 2004 they introduced a general standard PN-EN 17025:2001, and since 2005 a standard concerning medical laboratories EN 15189:2003 [18,19]. Unfortunately, there are no official statistics concerning the reliability of the test results obtained in individual diagnostic centers.

PE also raises concerns for the reliability of biochemical, cytogenetic, and molecular analysis. This requires laboratories to obtain appropriate certificates and to perform tests in the highest standards. Of similar importance is conducting internal and external audits. Based on special projects on quality control, the following issues should be continuously assessed: the conditions of tissue storage, cell cultures, the analysis of chromosomes and individual fragments of the DNA chain, documentation of results and data protection.

### Delivering results

The results of IPD are always awaited with great tension. The parents’ attitude towards the conceived child may change depending on the diagnosis itself as well as on the manner in which it is presented. Receiving a diagnosis is not ordinary information on the health status of the child but a serious existential experience, especially if the result is positive. A signal confirming that the painful information on the genetic defect of the child delivered in Poland is done so in the spirit of empathy comes from the study of doctor D. Kornas-Biela [9].

The main demand set by PE before this stage of IDP is as following: results of the test should be provided within the shortest time from examination if there is a rational certainty of their correctness. The physician should give the diagnosis during a conversation with both the parents as from the psychological point of view the most favorable situation is when parents confront the information on the health problems of the child together. It is also important to remember that there exists a possibility of the results being falsely positive or falsely negative thus the rational certainty as to the variability of the result is extremely important. In case of a positive result, the physician should only provide the diagnosis when he is able to determine the probable consequences of the discovered defect. It is also necessary to remember that particular genetic defects will not always be correspondent with the same clinical picture, especially in the case of chromosomal mosaicism.

A positive IPD result makes it especially important to call for the physician’s empathy and concern for helping the parents build an emotional bond with the sick child. Giving unfavorable diagnosis should always be done in a calm, peaceful and secluded place. It is important that the presence of others does not “block” parents from expressing their feelings and asking questions. The atmosphere of the conversation should be characterized by cordiality and respect. The physician is encouraged to deliver all information without hurry, in an understandable manner, omitting technical terms if possible. The content of the conversations should be general. In this tragic moment, it is more important to "be" with the parents than to provide them with details. The physician should have adequate illustrations and other aids to help parents recognize specific aspects of the predicted illness. He should explain what is certain about the health of the fetus, what is still unknown and show possible therapeutic methods. The physician should encourage parents to ask questions, listen to their needs and "follow" them through the whole course of conversation. All explanations and answers should be adapted to their level of perception, conditioned by their emotional state and education level. It is also important to leave as little room as possible for parent's imagination, which causes them to see the situation as more dramatic than it really is. The physician proclaiming the dignity of human life from the moment of conception is required not only to pass the diagnosis but also show his personal attitude towards the unborn child. The main objective is for the parents to understand what is happening to their child and to understand that the detected illness does not lesser its human dignity. The length of the meeting should depend on the parents [20,21]. Apart from a written diagnosis, the physician should provide information on the child's illness and addresses of any institutions that may prove useful in the future. In fact, giving the diagnosis should mark the beginning of the child's health program and comprehensive support for the parents. It would be ideal if prenatal diagnosis centers would not reduce their mission to carrying out medical procedures but functioned as institutions that offer complex support for prenatal patients and their families.

## Therapy of the unborn and the newborn child

IPD helps in planning possible prenatal and postnatal care, as well as the time and delivery method. Sometimes there exists a possibility of carrying out the therapy in utero using pharmacological means and/or surgery. It is worth noticing that free access to medical benefits including prenatal care is guaranteed among others by the Act on Publicly Funded Healthcare Benefits [22]. The Polish Mother's Memorial Hospital – Research Institute is currently implementing a comprehensive Program for complex diagnostics and intrauterine therapy in the prevention of the consequences and complications of developmental defects and fetal diseases – as an element of improving fetal and newborn health for 2009-2013 [23].

In reference to the only morally right goal of prenatal testing which is the broadly understood "therapeutic objective", PE requires a close integration of IPD and treatment. A manifestation of such integration is creating interdisciplinary teams supervising the entire diagnostic and therapeutic process. Such teams could and should be created in centers prepared for both IPD and perianal therapy. Effective help provided for both the unborn child and the mother requires the integration of various fields of medical knowledge, thus the team should consist of gynecologists, radiologists, obstetricians, neonatologists, cardiologists and surgeons. Depending on the circumstances, representatives of other medical fields should also be invited to cooperate. A person who should always be a part of such a team is a psychologist who could provide support to the pregnant woman and other family members. All decisions and the strategy of conducted tests, fetal therapy, childbirth and infant care should be carefully documented. Collected data should be forwarded to parents in order to facilitate future therapy and rehabilitation of the child. The necessity of creating an interdisciplinary team is visible in the course of percutaneous umbilical cord blood sampling which is a method that allows for combining diagnostic and therapeutic elements.

## Palliative care

IPD allows for a precise verification of the suspicion of a lethal defect of the fetus and the only adequate form of helping a child with fatal disease is palliative care. In 2005,the first center in Europe integrating noninvasive prenatal diagnosis with perinatal palliative care – Agatowa Ultrasound Clinic in Warsaw has been set up [24]. In fact, Poland has the best network of home hospices in Europe, which in 2010 offered palliative care for 94% of the countries inhabitants [25].

According to the personalistic principle of solidarity, prenatal diagnosis revealing a defect inevitably leading to the child's premature death is a moral imperative for an empathetic accompaniment of the unborn child, his mother and other family members. Palliative care should cover the period from the tragic diagnosis through the natural death of the small patient (whether it occurs before or after birth) to the end of the parent's mourning. Such care is always focused on protection of the child's dignity, improving the quality of life, defense against futile therapy and iatrogenic diseases. It means the patient's symptomatic treatment, as well as psychological, social and spiritual support for the whole family. To guarantee parents a viable alternative to selective abortion, PE calls for caring for the continuous development of palliative care and its integration with IPD.

The first stage of care in the face of diagnosed lethal defect of the fetus should be perinatal palliative care, which encompasses psychological support provided for parents who are internally preparing for an inevitable death of their child. Perinatal hospice, "the hospice in the womb" is not a specific place, but rather the surrounding of people who are trying to help the sick child and its relatives. These people should include obstetricians, nurses, psychotherapists, clergy and social workers [26]. In Poland, there is a need for the development and approval of a perinatal hospice program, which would enable creating education systems for people willing to provide this type of palliative care. In addition, this program should regulate the functioning of such hospices in different diagnostic centers. In developing this document we should profit from the experience of the Agatowa Ultrasound Clinic, perinatal hospices in the United States, which continue the work of A. Kuebelbeck [27,28] and the proposition of the so called "educational therapy" implemented in the Day Hospital di Ostetricia e Ginecologia a Roma under the chairmanship of G. Noia [29].

If a child with a lethal defect survives the perinatal period, the tasks of the "hospice in the womb" should be continued by the hospices providing palliative pediatric care. Taking into account that Poland lacks perinatal hospices, this vulnerability should be temporarily replaced by home hospices for children. T. Dangel proposes the following schema: "After establishing lethal prenatal diagnosis, a consultation with a specialist from the field of pediatric palliative care is advisable. It is also beneficial for the parents to meet other parents who have children with a similar condition and who are now patients of the home hospice. In case parents decide on palliative care, a caesarian section and resuscitation of the newborn should be avoided. For this purpose, a prior appropriate entry in the medical records is necessary. If the child survives the prenatal period, it may be listed under the home hospice care" [24].With regard to the existing network of pediatric hospices, there is a demand for their continued development to enable access to all residents of the country. According to the report "Pediatric palliative home care in Poland 2010" it must be noted that "there exists a need to create home hospices for children in Zielona Góra, Gorzów Wielkopolski, west side of the Dolnośląskie voivodeship and a second one on Warszawa and the already existing home hospices for children in Bydgoszcz, Gdańsk and Toruń should increase their precincts" [25].

## CONCLUSION

In the view of PE, conditions necessary for dignified conduct of IPD include a correctly understood "therapeutic aim" and rational medical indications. Genuine care for the life and health of the conceived child and his mother demand from those responsible for the medical infrastructure guarantees of access to invasive research and the integration of prenatal diagnosis, therapy and palliative care. Physicians, diagnosticians and other healthcare workers are summoned to keep maximum precautions during the prenatal tests, being empathetic and helpful in building emotional bonds within the family. Only these measures will be evidence of the progress of true humanization of medicine.

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