

Diligence of prenatal tests and their consequences for the health of the future child

Reference version

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Author(s)	Maria Boratyńska
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Summary

Performing prenatal tests and intrauterine treatment are closely related, because the lack of the former excludes the latter. It is also indirectly related to the termination of pregnancy by a planned caesarean section, when the fetus shows defects that require such a decision. In Poland, prenatal surgeries are not a common practice, however, they are successfully performed in specialised centres and with guaranteed reimbursement. This makes them more and more commonly considered by patients. The success of the procedure in most diseases does not lead to the reversal of the defect, only to the inhibition of its development, which is still considered as a success. Children are born in a better condition and have a chance to survive or to live a better life than compared to if they were untreated. Operations of this kind are technically difficult and dangerous for a woman's health. As for the fetus, there is a risk of failure. As with every surgery, there are medical indications for them: fetal, positive factors on the mother's side and more or less strong contraindications. If the treatment has a formal status of an experiment, this should be reflected in the inclusion and exclusion criteria formulated in the protocol of the experiment, which is a document submitted to the bioethics committee giving its opinion on the project. The qualification for treatment should be based on the said criteria. The information provided prior to the withdrawal of consent should order the issues of the expected effectiveness of the treatment, the prognosis of the improvement of the child's health condition, but most of all – the health burden for the woman. Surgery does not constitute a therapeutic activity for a woman, and it is only verified by fully voluntary consent once the adequate information is provided. The surgery is an act of sacrifice on the part of the woman, so it cannot be required nor enforced, just like a caesarean section from the fetal indications. Any chance of success, however, is cancelled out by not detecting the defect during the proper period of pregnancy. Therefore, doctors performing prenatal examinations have a great moral responsibility for the further course of events. Imprudently performed diagnostics leads to false positive results and makes it impossible to take any remedial measures. With the current state of knowledge and sensitivity of the diagnostic equipment, such care may be required and evaluated according to objective criteria that can be arranged in a checklist. Subjective perceptiveness retains its importance, but certain deficiencies are in themselves evidence of culpable professional incompetence or deliberate concealment of information. The analysis of the cited compensation, disciplinary and prosecutorial cases leads to the conclusion that in many cases USG examinations, which are crucial for determination of the condition of the fetus, were carried out superficially and without the doctor's interest in a reliable result. Patients who were

kept in the illusion that their children would be born healthy did not seek prenatal medical help. The children were born with more damage than they would have been treated at the right time. Some of them died right after the birth. These women, who were completely unaware of the situation, wrongly blame the obstetricians. The judiciary recognises the harm resulting from the mother's lack of information and a violation of the right to an informed decision, but refuses to accept an adequate causal link between the negligence of information and the prenatal uninformed impediment to the deterioration of the health of the born child and rejects the claim for compensation for the damage caused.

Key words

prenatal tests, intrauterine surgery, fetal treatment, due diligence, right to information, patient's autonomy, prenatal damage, nonpreventional damage, misinformation harm, criteria of medical perceptive care

Introduction

Prenatal diagnostics is used for the early detection of health defects during the fetal period. Its development leads to advances in the science of such defects and contributes to the development of new treatment methods. Thanks to it, it is possible to identify and diagnose genetic diseases and congenital defects in the fetus even in the early stages of pregnancy.¹ This is undoubtedly for the benefit of the future child:² it serves to obtain knowledge about possible eligibility for treatment.³ Treatment is difficult and carries a high risk of failure, but advances in knowledge, gained through the performance and continuous improvement of prenatal diagnostics, enable the effective rescue of an increasing number of children who, in the past, had no chance of survival.

Legal and bioethical considerations have so far focused on the consequences of a lack of information about prenatal testing, refusal to issue referrals for such testing, failures to inform about the results, and their impact on decisions about continuing the pregnancy. Medical studies emphasise the cognitive value of these tests and the therapeutic possibilities they open up. Court rulings also raise the disturbing issue of prenatal testing performed, seemingly in good faith, but affected by error.⁴ The lack of adequate information about the health of the fetus results in unjustified optimism on the part of the expectant mother and the inability to make decisions about the treatment of the fetus, and entails the loss of an opportunity to improve the health of the child after birth. The article addresses this issue, in particular: the issue of a woman's freedom of choice regarding treatment, including the assessment of refusal to consent to in utero treatment; the legal nature of in utero treatment in light of the risk to the health of the future mother; the criteria for fault in the assessment of imaging tests; the group of persons suspected of culpable medical errors; the causal link in the case of loss of treatment opportunities and the significance of the experimental factor. An analysis of the cited compensation, disciplinary and prosecutorial investigations leads to the conclusion that in many cases the ultrasound examinations, which were crucial for determining the condition of the fetus, were performed superficially and without the doctor's interest in a reliable result. Such an approach is detrimental to the health of the fetus and seems unreasonable, unless it is considered to be

¹ These include haemophilia, Duchenne muscular dystrophy, phenylketonuria, cystic fibrosis, Down syndrome, Turner syndrome, Edwards syndrome, Patau syndrome, open neural tube defects, heart defects and defects of the urinary system. (E. Wojtowicz, U. Rychlik, A. Marszałek, J. Palka, *Diagnostyka prenatalna – terażniejszość i przyszłość*, Diagnostyka Laboratoryjna, 2014, 50(1), p. 71).

² R. Dębski, *Diagnostyka płodu*, Ogólnopolski Przegląd Medyczny 2007, no. 7, p. 32.

³ See *Położnictwo i ginekologia*, t. 1, ed. G. Bręborowicz, Warszawa 2010, pp. 472 et seq.

⁴ See the frequently cited judgment of the Supreme Court of 06.05.2010, II CSK 580/09, OSP 2/2011.

dictated by the doctor's own convenience in avoiding participation in later decisions about continuing or terminating the pregnancy.

I. Purpose and functions of prenatal diagnostics

An increasing number of conditions qualify for treatment during the fetal period, which increases the chances of birth with fewer health complications. Among the conditions that can be treated are diaphragmatic hernia,⁵ spina bifida, haemolytic disease caused by serological conflict⁶ and certain heart or kidney defects. Early diagnosis also allows for targeted management of the pregnancy, including planning the delivery and immediately transferring the newborn to a specialist who is prepared for the medical history and who will professionally care for the baby and implement treatment without delay. This prevents situations in which the baby's condition deteriorates unexpectedly at home, when the appropriate treatment could have been started immediately after delivery.⁷ Some of the defects diagnosed through prenatal testing, including certain genetic defects, require a decision to be made regarding the delivery by planned caesarean section.⁸

The most information about the condition of the fetus can be obtained through ultrasound,⁹ which is a non-invasive examination and should be routinely performed three times during an uncomplicated pregnancy,¹⁰ and more frequently in high-risk pregnancies. The timing

⁵ In very advanced cases of this condition, 90% of children die immediately after birth. The use of prenatal therapy (fetal tracheal occlusion) contributes to approximately a twofold increase in their chances of survival (normally 10–20%, so thanks to the efforts of doctors, this can increase to 20–40%; see *Wytyczne Grupy Roboczej Europejskiego Towarzystwa Kardiologicznego (ESC) do spraw postępowania w chorobach sercowo-naczyniowych u kobiet w ciąży*, „Kardiologia Polska” 2011, no. 69 (supl. 7), pp. 341–400).

⁶ Advanced forms of serological conflict lead to significant anaemia, oedema and intrauterine death in the foetus. Transfusions in the womb are a life-saving method. After this therapy, the vast majority of children survive: the risk of fetal heart rhythm disorders, uterine contractions and premature birth or even intrauterine fetal death is approximately 5%. Failure to use intrauterine treatment in advanced cases of fetal anaemia caused by serological conflict inevitably leads to intrauterine fetal death. See (*Stanowisko Polskiego Towarzystwa Ginekologicznego w sprawie debaty publicznej dotyczącej postulowanych zmian w zakresie prawnej dopuszczalności wykonywania zabiegu przerywania ciąży*, „Ginekologia i Perinatologia Praktyczna” 2016, vol. 1, no. 3, p. 97).

⁷ These are clinically silent defects. A newborn with a severe heart defect is most often a large, full-term boy, born on time, with a maximum score (10) on the Apgar scale, often without a heart murmur. His condition begins to deteriorate in the first days of life, and the symptoms often mimic generalised infections. In cases of newborns with duct-dependent systemic circulation, their condition deteriorates later, sometimes after discharge home. J. Dangel, *Diagnostyka prenatalna – mity i rzeczywistość*, „Nauka” 2007, no. 3, p. 41).

⁸ J. Dangel, *Diagnostyka prenatalna...*, p. 45 and cited therein: B. Goc, Z. Walencka, A. Wloch et al., *Trisomy 18 in neonates: prenatal diagnosis, clinical features, therapeutic dilemmas and outcome*, J. Appl. Genet. 2006, no. 47(2), pp. 165–170.

⁹ J. Dangel, *Diagnostyka prenatalna...*, p. 32.

¹⁰ *Ibidem*.

of these examinations is determined primarily by medical criteria and the stage of pregnancy that allows for the detection of specific defects. In addition to imaging tests, laboratory tests, including genetic tests, are also used. At present, most diagnosed genetic defects cannot be treated, and gene therapy is still in the experimental stage,¹¹ but knowledge is gradually advancing. In addition, the detection of a genetic defect enables the implementation of diagnostics for associated defects, including heart and urinary tract defects.

The interests of the future child are reflected in prenatal testing to detect possible defects and consider their treatment immediately after birth or in utero. It is in the best interest of the child to be born in the best possible state of health and, consequently, to diagnose those defects that can be treated early enough or at least improve the condition by limiting adverse health effects. It is in the best interest of future parents to ensure that their child is born as healthy as possible. Such an analysis of interests may have further consequences from the point of view of tort liability.

The right to prenatal testing (provided for in two acts: on family planning¹² and on support for pregnant women and families 'For Life'¹³) fulfils various informational functions that are derived from other patient rights. Its implementation offers the following possibilities: under Article 446¹ of the Civil Code for prenatal damage, if the examination was carried out carelessly and the lack of proper diagnosis prevented treatment from being undertaken.

1. It enables the detection and diagnosis of fetal defects, including diseases that can be treated. This makes it possible to propose and plan methods of therapy in utero, as well as immediately after birth, sometimes even before dangerous symptoms occur. **This function stems directly from medical knowledge and should be considered primary and most important.**

2. Provides information about health status. The right to information is an inherent right of every patient, allowing them to obtain knowledge about their own body, although it is most often perceived as a prerequisite for respecting decision-making autonomy. The inseparable connection between the fetus and the body of the woman carrying it means that the health of

¹¹ E. Syweński et al., *Plód jako pacjent – rys historyczny*, „Perinatologia, Neonatologia i Ginekologia” 2008, no. 4, p. 316.

¹² Act of 07.01.1993 on family planning, the protection of the human fetus and the grounds for the admissibility of abortion (Journal of Laws 1993, no. 17, item 78, as amended), article 2 para. 2a.

¹³ Act of 04.11.2016 (consolidated text: Journal of Laws 2019, item 473), article 6 point 1.

the fetus is directly or indirectly related to the health of the future mother. The natural concern for the future child during pregnancy is also reflected in an interest in its health.

3. It prepares them for the birth of a sick child, allows them to come to terms with the idea and reduces trauma. Although this is tragic knowledge, it is of fundamental importance to those trying to conceive.¹⁴ Decisions made with this awareness in mind give them the mental strength to cope with the difficulties of caring for a sick or disabled child. This function is linked, among other things, to the Act on Support for Pregnant Women and Their Families.

4. In the event of serious fetal defects, it allows a woman to make an informed decision about whether to continue or terminate the pregnancy. This right of choice stems from the judiciary's recognition of the personal right to family planning¹⁵ and is confirmed in the laws on family planning and support for pregnant women and their families.

5. An unfavourable result may provide a factual basis for a lawful termination of pregnancy.¹⁶

At this point, it is worth emphasising that the reduction of prenatal testing to a basis for termination of pregnancy, as found in law doctrine, is a mistake in its assumption, because this diagnosis serves primarily the welfare of the future child, and the right to terminate a pregnancy on the basis of these tests is only a side effect, not the purpose of the tests themselves.¹⁷

In *RR v. Poland* case, the ECHR noted that “prenatal genetic testing serves various purposes and should not be equated with encouraging pregnant women to seek abortion. First, it can primarily dispel the suspicion that the fetus is affected by a certain type of defect. Secondly, a pregnant woman may also decide to continue with the pregnancy and give birth to the child. Thirdly, in some cases (...) prenatal diagnosis of a condition may enable prenatal treatment to be undertaken. Fourthly, even in the case of a negative diagnosis, it gives the

¹⁴ J. Różyńska, *Etyka i diagnostyka przedurodzeniowa* [in:] *Bioetyka*, eds. W. Chańska, J. Różyńska, Warszawa 2013, p. 347.

¹⁵ The Supreme Court adopted this position in its judgments of 21.11.2003, V CK 16/03 (OSNC 2004, no. 6, item 104), of 12.06.2008, III CSK 16/08 (OSNC 2009, no. 3, item 48), in the resolution of 13.10.2005, IV CK 161/05 (OSP 2006, no. 6, item 71). See also judgment of the Supreme Court of 06.05.2010, II CSK 580/09, OSP 2011 no. 2.

¹⁶ M. Boratyńska, *Badania prenatalne i przedimplantacyjne* [in:] *System prawa medycznego*, ed. E. Zielińska, vol. 2, part 2, *Regulacja prawna czynności medycznych*, eds. M. Boratyńska, P. Konieczniak, Wolters Kluwer 2019, pp. 239–240.

¹⁷ M. Szeroczyńska, *Zgoda na leczenie operacyjne płodu* [in:] *Prawo wobec problemów społecznych. Księga jubileuszowa Profesor Eleonory Zielińskiej*, eds. B. Namysłowska-Gabrysiak, K. Syroka-Marczewska, A. Walczak-Żochowska, Warszawa 2016, p. 816.

woman and her family time to prepare for the birth of a child affected by the condition in terms of counselling and coping with the stress caused by such a diagnosis”¹⁸.

The purpose of the examination is to obtain information, and how this information is used by authorised persons is entirely up to them. The lack of information makes it impossible to legally terminate a pregnancy, but it also makes it impossible to undertake treatment.

II. Decision-making autonomy of the expectant mother. Assessment of health risks and treatment options

Medical protection of the fetus or child¹⁹ always comes at the expense of the woman’s health, with the possible exception of oral vitamin administration. Out of concern for their future child, patients generally do not refuse to take medication, but they may be discouraged from doing so by the side effects. Examples include hospital support for high-risk pregnancies, where women receive high doses of drugs that can lead to permanent damage to their health. Performing procedures on the fetus in utero, in turn, requires serious damage to the woman’s body. In order to reduce the health risks, the fetoscopic method is used for some procedures²⁰. However, depending on the type of procedure, it may be necessary to perform a laparotomy and incise the uterus.²¹ It goes without saying that for the woman, these procedures have no therapeutic purpose²² and increase the subsequent risk of childbirth. Voluntary sacrifice is socially accepted and justified here by the therapeutic goal in relation to the fetus, but refusal serves to preserve one’s own health and for this reason should also be respected. A woman’s risk to her health and life for the good of the unborn child is purely altruistic,²³ as is donation

¹⁸ Thesis no. 71.

¹⁹ This refers to the surgical delivery of a baby due to a threat to the child’s life. At the stage of delivery or before its commencement in a full-term pregnancy, we can no longer refer to the fetus, but rather to a child capable of independent life.

²⁰ A fetoscope is a long, thin needle equipped with a video track and surgical instruments. The device is inserted into the uterus through a small (approx. 3 mm) incision in the pregnant woman’s abdomen. This reduces the degree of intervention and thus the risk of fetal and maternal death. (J. Jońca, *Nienarodzeni pacjenci*, „Wiedza i Życie”, March 2019, p. 19).

²¹ *Zabiegi wewnątrzmaciczne*, Interview with Marzena Dębska, MD, PhD, specialist in obstetrics and gynaecology, ultrasonography and prenatal diagnostics, from the Bielański Hospital in Warsaw, <http://ginekologiawpolsce.pl/zabiegi-wewnatrzmaciczne> [13.02.2020].

²² Similarly – M. Szeroczyńska, *Zgoda na leczenie...*, p. 823.

²³ K. Szewczyk, *Bioetyka*, vol. 1, *Medycyna na granicach życia*, Warszawa 2009, p. 277.

for transplantation.²⁴ Therefore, it should be classified in the same way from an ethical point of view: as an act of sacrifice, not an obligation.²⁵

It is worth noting that medical procedures on fetuses, although a remarkable achievement of modern medicine, still carry a high risk of failure. The assessment of the chances of success is largely statistical in nature, and in specific cases, the procedure may entail much more serious complications than originally thought, both for the fetus and for the self-sacrificing future mother.²⁶ Given the uncertainty of the prognosis, it is all the more important to make the patient aware of this before she makes a decision, to confront her expectations with the medical realities²⁷ and to leave her complete freedom of choice.

Opening the abdomen of the expectant mother may be justified by the therapeutic purpose of acting in the best interests of the fetus, but only if it is legalised by the voluntary and informed consent of the patient, who thus evaluates her personal rights:²⁸ fulfilled parenthood, enjoying an undisturbed family life (which is impeded by the illness of the fetus and the subsequent disability of the child) and the health of the future child – at the cost of bodily harm and risk to life. For the purposes of analysis, the fetus can be described here as a *sui generis* patient, i.e. as a good that is inextricably linked to the woman's body until a certain point in time and developing there, protected to the extent specified by law and requiring medical support to the extent that it does not interfere with the woman's legal rights, including her physical integrity and inviolability. The woman's informed consent, given in an act of sacrifice of her own legal rights, is of key importance for the admissibility of medical intervention. This applies equally to every procedure regardless of its degree of complexity: difficult fetal

²⁴ M. Szeroczyńska, *Zgoda na leczenie...*, p. 823; K. Szewczyk, *Czy płód jest pacjentem? Medyczne modele relacji kobieta brzemienna – dziecko nienarodzone*, *Diametros* 2012, no. 32, p. 114.

²⁵ see M. Szeroczyńska, *Zgoda na leczenie...*, where a methodical debate was conducted with views granting third parties (the future father, the court, the guardian) decision-making powers aimed at overcoming the woman's negative will.

²⁶ See K. Szewczyk, *Bioetyka...*, vol. 1, p. 276.

²⁷ See K. Dąbrowska, J. Gadzinowski, *Czy operacje wewnątrzmaciczne są uzasadnione? – perspektywa neonatologa*, part II, *Przepuklina oponowo-rdzeniowa, uropatia zaporowa, wysięk opłucnowy*, „Ginekologia Polska” 2011, no. 82, p. 463. For example: results of a randomised clinical trial for meningocele MOMS (*Management of Myelomeningocele Study*), published in *New England Journal of Medicine* (NEJM 2011, 364: 993-1004) are following. Researchers from three American centres compared the frequency of implanting a shunt system into the child's head, psychomotor development and neurological functions in children with spina bifida operated on in utero and after birth. It was found, among other things, that implantation of a shunt system was necessary at the age of 12 months in 40% of children operated on during fetal life and in 82% of those operated on after birth. At 30 months of age, psychomotor development was significantly better in the group of children operated on in utero, and some of them were walking independently. (M. Koton-Czarnecka, *Operacje w łonie matki*, „Puls Medycyny”, online issue, <https://pulsmedycyny.pl/operacje-w-lonie-matki-884378>, 21.02.2020).

²⁸ See M. Boratyńska, *Opieka okołoporodowa, Cesarskie cięcie i zabiegi na płodzie in utero...* [in:] *System prawa medycznego*, ed. E. Zielińska, vol. 2, part 2, Wolters Kluwer 2019, pp. 480–483.

operations, such as caesarean sections, which, although routine and well-practised, always carry the risk of death.

However, this consent should be given with full awareness of both the possibilities of saving the health or life of the future child and, in particular, the health risks to the mother. Without detracting from the wonderful achievements of medical knowledge in this field and the skills involved in the surgical technique, operations of this kind carry serious health risks. Photographs of smiling patients with large bellies and even broader smiles from the doctors accompanying them²⁹ only prove that the pregnancy was maintained after the procedure and that the patient is in good condition. However, it is not known how the birth will proceed, in what state of health the woman will leave the maternity ward, and to what extent the procedure will improve the condition of the newborn child. A correct and appropriately early diagnosis provides the information necessary to draw up a specific balance of the benefits and burdens associated with treating the fetus in utero, and, on the other hand, the risks to the mother's own body. For example: intrauterine surgery to close a meningomyelocele can significantly reduce the degree of future disability in the child, but they carry a considerable risk of anaesthetic complications, intrauterine infection, placental abruption and premature birth. Performed on an open uterus, they are highly invasive.³⁰ For her own health, the patient should be given detailed information about the surgical technique and the risk of fatal complications. Similar operations performed after the birth of the child are much easier and do not burden the mother's body, but at the cost of greater disability in the child.³¹

A pregnant woman cannot be regarded as legally obliged to undergo treatment in the interests of her unborn child. Under criminal law, the mother is treated as the guarantor of the protection of the legal rights of the child only from the moment of its birth³² – with reference to Article 95 § 1 of the Family and Guardianship Code. However, even if the guarantor's

²⁹ See J. Jońca, *Nienarodzeni pacjenci*, p. 21.

³⁰ The procedure is performed between the 22nd and 27th week of pregnancy, because the uterus is less reactive at this stage, which in turn reduces the risk of premature birth. Doctors cut open the abdominal wall and remove the uterus, draining the amniotic fluid into special containers. It is necessary to maintain the appropriate moisture and temperature of the removed uterus. Cutting open the uterus exposes the fetal hernia, and then the spinal cleft can be closed, in the same way as in children after birth. The final stage is the suturing of the uterus, preceded by the replenishment of amniotic fluid, and the suturing of the abdominal wall. Throughout the procedure, the condition of the fetus is monitored by ultrasound. (M. Koton-Czarnecka, *Operacje w łonie matki...*)

³¹ Surgical closure of the hernia before birth reduces the risk of hydrocephalus. It also makes subsequent physical rehabilitation of the lower limbs more effective, and the child has a better chance of walking independently and developing intellectually normally. (M. Koton-Czarnecka, *Operacje w łonie matki...*)

³² J. Majewski, *O korzyściach i szkodach dotychczasowych dociekań nad problematyką źródeł obowiązku gwaranta*, „Kwartalnik Prawa Publicznego” 2004, no. 4, p. 125.

obligations were to extend to the prenatal period, they would not include undergoing medical treatment: Article 162 § 2 of the Criminal Code excludes criminal liability for failing to assist a person in danger if, in order to provide such assistance, assistance would require undergoing a medical procedure.³³ A criminal law analysis therefore leads to the conclusion that a pregnant woman is all the more free to decide not to undergo a medical procedure intended for the good of the fetus, regardless of the reasons, even if they are irrational. Furthermore, by opposing interference with her body, a woman exercises her rights as a patient, guaranteed by the Polish Constitution and statutes. Therefore, regardless of the motivation and consequences, it cannot be argued that such behaviour is unlawful.³⁴

This argument is cited in response³⁵ to the proposal that the self-determination of a pregnant woman in the name of protecting the health interests of the unborn child be limited by means of a broad interpretation of the circumstances and conditions determining material incompetence, and thus to consider a woman in this condition incapable of expressing informed consent.³⁶ The latter line of reasoning aims to deprive a certain group of people of their autonomy based on a physiological condition which, from a medical point of view, does not affect their intellectual competence.³⁷

Overriding a woman's refusal to consent to treatment of the fetus could not be justified by a state of necessity,³⁸ because Article 26 of the Criminal Code decriminalises an act (in this case, treatment without consent) only when the sacrificed good is of lesser value or does not represent a value that is clearly higher than the good being saved. The valuation of the legal interests of the woman and the unborn child requires that the woman be credited with both bodily integrity, i.e. bodily harm (usually to a significant degree), and freedom (decision-making autonomy), as well as harm in the form of trampling on her dignity and causing suffering. According to the common position of the doctrine, the patient's right to self-

³³ A. Zoll, *Prawo lekarza do odmowy udzielenia świadczeń zdrowotnych i jego granice*, „Prawo i Medycyna” 2003, no. 1(13), p. 23.

³⁴ E. Plebanek, *Autonomia ciężarnej pacjentki wobec czynności medycznych. Prawnokarna ocena sprzeciwu ciężarnej pacjentki wobec czynności medycznej ratującej życie i zdrowie pacjentki lub dziecka nienarodzonego (cz. I)*, „Prawo i Medycyna” 2015, no. 2(59), p. 45.

³⁵ E. Plebanek, *Autonomia ciężarnej...*, pp. 46–47; M. Szeroczyńska, *Zgoda na leczenie...*, pp. 819 et seq.

³⁶ J. Haberko, *Cywilnoprawna ochrona dziecka poczętego*, Warszawa 2010, pp. 397 et seq.

³⁷ M. Boratyńska, *Problem przymusu zabiegowego w ciąży* [in:] *System prawa medycznego*, vol. 2, *Regulacja prawna czynności medycznych*, part 2, Wolters Kluwer 2019, p. 492.

³⁸ Its application in medical law is otherwise considered systemically unacceptable due to the function of medical law provisions guaranteeing respect for patient autonomy and their *lex specialis* nature in relation to criminal law regulations. (See summary by M. Boratyńska, *Zasady prawa medycznego, Pozasystemowe klauzule genaralne* [in:] *System prawa medycznego*, vol. 2, part 1, pp. 205 et seq. and the literature cited therein).

determination has its source in human dignity and is considered to be higher in the hierarchy of constitutionally protected goods than health and life.³⁹ However, even if one were to disagree with this view, in order to protect the life of the unborn child, it would be necessary to sacrifice not one but several of the woman's legal rights, including her own life, which would be put at risk. The issue of a decision allowing the violation of a woman's bodily integrity in order to save the fetus or the unborn child directly affects her right to self-determination and cannot be reduced to the level of health risk alone.⁴⁰

Its possible implementation would require the use of coercion, i.e. the violation of a person's body combined with serious bodily harm, justified by the protection of another person's life. This does not meet the legal and ethical criterion of the undeniably higher value of the sacrificed good, especially since in the case of intrauterine surgery – as with caesarean section – the fatal outcome must be seriously taken into account. In the worst-case scenario, the requirement to sacrifice would therefore amount to an exchange: life for life.⁴¹ Over the past year, at least one case of death of a pregnant woman during surgery to correct a fetal defect has been reported.⁴²

This balance is independent of the recognition of the unborn as a separate legal entity from the woman, which lacks sufficient normative support and is characterised by a particular worldview.⁴³

These comments may seem exaggerated, but the issues raised are interrelated and their legal conditions are similar. Fetal surgery, even if it seems like an exotic idea to some, is a decision made by the patient on an equal footing with others – including termination of pregnancy by caesarean section. Admittedly, no one is pressuring women to undergo in utero treatment, but there are definitely attempts to force caesarean sections. Meanwhile, both types of procedures are serious abdominal surgeries, carrying the risk of death. There is no real choice

³⁹ A. Zoll, *Zaniechanie leczenia – aspekty prawne*, „Prawo i Medycyna” 2000, no. 1(5), p. 35; A. Zoll, *Granice legalności zabiegu leczniczego*, „Prawo i Medycyna” 1999, no. 1(1), p. 29; E. Zielińska, *Powinność lekarza w przypadku braku zgody na leczenie oraz wobec pacjenta w stanie terminalnym*, „Prawo i Medycyna” 2000, no. 1(5), p. 73; P. Kardas, *Zgoda pacjenta na zabieg leczniczy a problem odpowiedzialności karnej lekarza za niewypełnienie obowiązku zapobiegania skutkowi*, „Przegląd Sądowy” 2005, no. 10, p. 55; E. Plebanek, *Autonomia ciężarnej...*, pp. 34–35; M. Szeroczyńska, *Zgoda na leczenie...*, p. 821.

⁴⁰ See M. Świdarska, *Zgoda pacjenta na zabieg medyczny*, Toruń 2007, pp. 227–228; M. Szeroczyńska, *Zgoda na leczenie...*, p. 821.

⁴¹ M. Boratyńska, *Problem przymusu zabiegowego w ciąży*, p. 493.

⁴² Verbal information obtained from a pathologist who heads a forensic medicine facility in a large city.

⁴³ See overview of opinions: M. Szeroczyńska, *Zgoda na leczenie operacyjne płodu*, pp. 813–819; J. Różyńska [in:] *System prawa medycznego*, Wolters Kluwer, vol. 2, part 2, pp. 267–272, 275–280, and sources cited therein.

without the knowledge needed to make a decision, and this knowledge can only be provided by reliably conducted tests. If they are deliberately performed ‘untidily’⁴⁴ – they thus cut off access to knowledge: this can also be a form of medical paternalism, this time in the diagnostic dimension.

III. Undetected congenital defects and consequences for compensation. Criteria for diagnostic diligence

Poland is among the world leaders in terms of the number of prenatal heart surgeries performed on fetuses. These procedures have been performed for five years, and their number will soon reach one hundred, bringing us closer to the world’s largest centre, located in Boston, which has been performing them for fifteen years. The surgical technique is at a similar level in Poland, and even more operations are performed annually than at the hospital in Boston.⁴⁵ Only a few centres in the world perform intrauterine closure of spinal meningocele, including the clinic in Bytom since 2005. Prenatal surgery is also performed for diaphragmatic hernia and twin-to-twin transfusion syndrome.⁴⁶ This is primarily due to prenatal diagnostics, without which in utero therapy would be impossible. However, it is crucial that doctors detect fetal defects early enough.⁴⁷

The primary focus is on simple ultrasound findings that may be indicators of severe anomalies, and routine ultrasound examinations. These include, in particular, nuchal translucency screening.⁴⁸ The higher the nuchal translucency value, the greater the risk of severe fetal disease.

⁴⁴ This is how Joanna Szymkiewicz-Dangel, already quoted above, describes it, noting that she often treats patients with fetal defects that are too advanced for prenatal surgery to have a realistic chance of success.

⁴⁵ At present, this information may be out of date, as since April 2020, one of the leading centers at the Bielański Hospital in Warsaw has stopped performing these procedures. The reasons for this lie with the hospital management. The Children’s Heart Foundation has alerted the Patient Ombudsman, among others, to this matter. (Based on K. Sulowski, *Ataki prolajferów i śmierć dziecka*, „Gazeta Wyborcza” 5–6.09.2020, „Gazeta Stołeczna”, p. 1).

⁴⁶ The aim of the procedure is to separate the blood circulation of fetuses in a monochorionic twin pregnancy, i.e., with a shared placenta (see J. Jońca, *Nienarodzeni pacjenci*, p. 19).

⁴⁷ *Zabiegi wewnątrzmaciczne*, Interview with Marzena Dębska, MD, PhD, specialist in obstetrics and gynaecology, ultrasonography, and prenatal diagnostics, from the Bielański Hospital in Warsaw, <http://ginekologiawpolsce.pl/zabiegi-wewnatrzmaciczne> [13.02.2020].

⁴⁸ This is the name given to a small fluid-filled sac in the neck region of the fetus, the enlargement of which may indicate chromosomal abnormalities, heart defects, or other organ defects. Based on J. Dangel, *Zasady podejmowania decyzji na podstawie diagnozy prenatalnej ze szczególnym uwzględnieniem postępowania*

In the case of heart defects, it is very important for the neonatologist to thoroughly familiarize themselves with the type of defect diagnosed, and for the prenatal cardiologist to precisely plan the place of delivery and the perinatal management depending on the diagnosed pathology.⁴⁹

The clinical significance of prenatal ultrasound diagnostics is not always fully appreciated. However, according to renowned specialist Joanna Szymkiewicz-Dangel, “The era of merely suspecting fetal defects is over. The type of pathology and the condition of the fetus can be diagnosed very precisely”.⁵⁰ This means that the health of the future child lies in the hands of the ultrasound specialist, who will perform the examination at the right time, detect any fetal defects, and inform the future mother about further diagnostic and treatment options. Failure to detect a defect early enough deprives every one of these opportunities. The birth of a child with congenital defects directs the grief of the distraught parents towards the doctors who performed the prenatal diagnosis. Failure to perform it, blocking access to it, or providing false information leads to emotional harm to parents, increased health damage to misdiagnosed children, and in cases of unexpected perinatal death, to unjustified accusations against the doctors delivering the baby and caring for the newborn. The diligence of the sonographer is therefore of decisive importance, **and for this reason, the physician performing the examination bears a great moral responsibility.**

However, ultrasound diligence measures are somewhat difficult to grasp. An ultrasound machine is a computer that converts sound data. An ultrasound machine is a computer that converts sound data into an image and records it. The human factor involves placing the probe in the right place and at the right angle, which is why the results of two examiners (e.g., measurement of endometrial thickness) may differ significantly without fault. In any case, an incorrect reading does not necessarily in itself indicate negligence, as the correct method of operation cannot always be algorithmized. Negligence may be evidenced, for example, by failure to perform certain actions at the right time, deliberate use of faulty and therefore unreliable equipment, or failure to notice clearly visible anomalies. In addition to the objective element, diligence (or its legal equivalent – caution) includes an internal factor, so to speak, a psychological one. Accordingly, a finding of negligence (carelessness) may be based on

okołoporodowego w przypadkach prenatalnego rozpoznania nieuleczalnej choroby płodu, „Standardy Medyczne. Pediatria” 2011, vol. 8, p. 61.

⁴⁹ Ibidem, p. 67.

⁵⁰ Ibidem, p. 66.

deficiencies in the subjective sphere of action: concentration of attention, decision-making strategies, as well as processes preceding the decision – inferences, formulation of diagnoses and predictions.⁵¹ In specific types of medical activities, one of these factors—subjective or objective—may prevail or even be the only one present.⁵²

This applies in particular to practices based on perceptual or manual skills.⁵³ The rules of caution applied there are rather isolated and do not form a well-defined pattern of proper conduct.⁵⁴ Imaging examination is subject to certain objective rules – e.g. that the radiologist should scan the entire surface of the image – but the key element of the activity, i.e. visual interpretation itself, is not subject to such rules. This is because it is a process leading to the detection of diagnostically relevant signs. However, their logical interpretation is, of course, subject to rules and in some situations can be expressed in the form of an algorithm.⁵⁵

Perceptiveness and dexterity can be trained, but this involves repeating actions rather than memorising and understanding knowledge. Therefore, neither in medicine nor in any other field of human practice are there any ‘rules of perceptiveness’ or ‘rules of dexterity’.⁵⁶ If pathological features are overlooked in an image (or, conversely, non-existent ones are noticed), the question arises *ex post* whether this happened despite exercising caution or as a result of failing to do so – and this cannot be assessed by reference to rules, because there are none.

In this group of cases, legal assessments can only be made by referring to the category of internal caution and using the personal standards of a ‘model cautious person’.⁵⁷ In medicine, this would be a ‘prudent and careful’ doctor.⁵⁸ We must therefore seek an answer to the question of whether a model ultrasound doctor, when faced with an identical image, would accurately identify the objects that are key to making a diagnosis, or whether, on the contrary, ‘would have

⁵¹ P. Konieczniak, *Zasady (reguły) ostrożności* [in:] *System prawa medycznego*, vol. 3, eds. T. Dukiet-Nagórska, A. Liszewska, Wolters Kluwer (in print).

⁵² Ibidem.

⁵³ M. Boratyńska, P. Konieczniak, *Prawa pacjenta*, Warszawa 2001, pp. 159–160, 182–186.

⁵⁴ P. Konieczniak, *Zasady (reguły) ostrożności...* See also M. Boratyńska, *Biegłość manualna jako czynnik należytej staranności lekarskiej. O wkluciu centralnym, torakotomii i położniku, który nie używał kleszczy*, „Przegląd Prawa Medycznego” 2019, no. 1.

⁵⁵ Ibidem.

⁵⁶ Ibidem.

⁵⁷ Ibidem.

⁵⁸ This does not refer to a uniform model of a ‘good doctor in general’, but rather a good doctor in a given type of relationship, i.e. in a specific situational context, taking into account the type of professional activities performed, the type and level of specialisation, and similar factors. (B. Lewaszkiewicz-Petrykowska, *Wina lekarza i zakładu opieki zdrowotnej jako przesłanka odpowiedzialności cywilnej za szkody wyrządzone w leczeniu*, „Prawo i Medycyna” 1999, no. 1, p. 128).

the right' to overlook them because the image was difficult to interpret. Such standard can be considered as a model, but it can be suspected that in practice it is simply a mental concept of the ideal doctor that the evaluator would like to see.⁵⁹

With these reservations, the following examples can be evaluated.

1. The first one dates back to 2005 (date of the event).⁶⁰ In the documentation from the ultrasound examination at 22 weeks of pregnancy, the doctor noted the biparietal diameter of the fetal skull, the length of the femur and the abdominal circumference, which he considered normal. Based on these data, he calculated the gestational age to be 22 weeks and 5 days and estimated the fetal weight at 630 g. In addition, he examined the heart, internal organs, head, limbs, spine and chest bones, but did not record the results. On the same day, using equipment provided by the radiology laboratory, a second image of the fetus was taken, on which an expert later appointed in the compensation case noticed changes in the spine and flattening of the skull bones. These were not noticed by any of the doctors conducting the examination on either piece of equipment. The second image was not evaluated by a doctor at all and was given to the patient after it was taken. The doctor only noticed the fetal abnormalities during the next examination, in the 32nd week of pregnancy, and referred the patient to a hospital with a higher level of referral. In the court's opinion, there is no doubt that on the critical day (i.e. in the 22nd week), the doctor, while performing the examination, failed to comply with the statutory requirements of due medical diligence and the patient's right to receive health services corresponding to the requirements of medical knowledge. The examination was performed in a manner inconsistent with accepted standards in that the doctor failed to notice defects that were visible, thereby committing an error in assessing the condition of the fetus. This error is culpable and constitutes at least negligence. The violation of the patient's rights was a consequence of a lack of diligence in performing the ultrasound and failure to check the images from the examination. The described defects turned out to be symptoms of spina bifida (spinal cleft). The girl was born with hydrocephalus, an open meningocele of the thoracolumbar spine, paralysis and deformity of the lower limbs (clubfoot) and enlargement of the cerebral ventricles and kidney defects. Shortly after birth, she underwent several surgeries, but no significant improvement in her health was achieved. Currently, she is unable to even turn over on her own.

⁵⁹ P. Konieczniak, *Zasady (reguły) ostrożności...*

⁶⁰ Judgment of the Court of Appeal in Krakow of 12.05.2015, I ACa 204/15, Portal of Judgments of Common Courts [14.02.2020].

Initially, the patient sought compensation from the hospital for the harm suffered by herself and her daughter. The basis for the claims was the assertion that as a result of negligence and faulty diagnosis and prognosis consisting in failure to diagnose the conditions during the fetal period, she was deprived of the opportunity to take remedial measures, i.e. to implement appropriate treatment, in particular to undergo surgery on the fetus before birth. The procedures performed after birth were performed too late and did not restore her health. The claim was dismissed in its entirety by the Regional Court in Kielce (case no. I C 1951/06). In a second lawsuit, the patient sought compensation for herself and this time she won the case, citing failure to inform her about the fetal defects, which prevented her from considering a decision to terminate the pregnancy. The amount awarded was PLN 250,000. The justification comes from the second, published judgment.

Based on the submitted ultrasound examination results, the expert found swelling in the fetus's spine area. In the second image, she noticed flattening of the skull bones and widening of the lateral ventricles of the brain. At the same time, she concluded that the defects she described should have been noticed by a doctor with some professional experience. She testified that **'if she were in the doctor's place,'** she would order an additional control ultrasound examination with blood flow, which would confirm or rule out the existence of defects. She would inform the patient that she suspects abnormalities in the development of the fetus, but only after a prior control examination; or possibly refer her to a centre that specialises exclusively in diagnosing fetal defects. She also pointed out that it was wrong not to perform a nuchal translucency scan, which she believes is as basic as fetal measurements and weight estimation.⁶¹

The case was ultimately reduced to the issue of termination of pregnancy, although the patient's original intention was to obtain compensation for being unable to make a decision about surgical treatment of the fetus. As is known from medical sources, such treatment was already available in Poland at that time. Subsequently, the child was born with a very serious disability, and her basic needs are much more expensive to meet than those of a healthy child. The findings show that the fetal examination was performed using one device, while the other was used to take a picture probably only to be kept as a souvenir (which is common practice), because it was not analysed or described. However, the expert noticed pathological changes in both images. The doctor performing the examination only viewed the image on the first device

⁶¹ As one might guess, this was a comment concerning the overall care of the patient, as the examination is performed in the first trimester of pregnancy.

and did not notice anything alarming. When questioned at the hearing as a witness, he admitted that although he had taken a photograph of the fetus with a camera provided by the radiology laboratory, he had not looked at it. However, when it was shown to him during his testimony, he noticed “some space around the spine”. The reason for taking a second photograph remains a mystery; in any case, this is not routine practice. The circumstances do not indicate whether this was a control measure, but if so, the negligence is obvious. The expert also pointed out the failure to perform a screening test for nuchal translucency, which, as can be assumed, could have led to further in-depth diagnostics.

The diagnostic error was caused by the sum of these omissions, and the court found the doctor guilty of ‘at least’ negligence. It did not take into account the defendant hospital’s plea of limitation, recognising that in the circumstances (the mother’s preoccupation with caring for her disabled child, her strenuous attempts to treat her, fundraising for surgery abroad, travelling with her daughter to the USA and her first unsuccessful attempt to obtain compensation) this would be contrary to the principles of social coexistence.

2. The second case, much later – from 2012, also concerns spina bifida, hydrocephalus and fetal limb deformities.⁶² The defect was not diagnosed until the 37th week of pregnancy, when the patient was examined by a doctor other than her attending physician. Throughout her pregnancy, the woman was informed that the fetus was developing normally, which further exacerbated her shock at the discovery of serious malformations at a stage when it was already impossible to take any remedial action. The claim sought compensation for the harm suffered by the mother and son, as well as a pension for the boy. The court awarded compensation only to the mother, justifying this on the grounds of her dramatic experiences, moral suffering and psychological shock following the unexpected discovery of the defect **and the inability to make a decision about intrauterine surgery**. It dismissed the child’s claims in their entirety, citing the lack of an adequate causal link between the boy’s current condition and the diagnostic errors.

As a starting point, the Court accepted culpable negligence in prenatal diagnosis. It relied on the expert opinion that a doctor with the relevant medical knowledge, equipped with appropriate quality equipment and strictly complying with the applicable standards for

⁶² Judgment of the Court of Appeal in Białystok of 19.02.2018, I ACa 379/16, Portal of Judgments of Common Courts.

conducting prenatal examinations, could have detected the hernia in the second trimester of pregnancy. The ultrasound examination at 20 weeks was not performed in accordance with the standards, as it did not include the required assessment of the anatomical structures of the fetus.⁶³ The expert stated that the examination report contained incomplete information,⁶⁴ in particular a lack of data on the placenta and amniotic fluid. **Due to these deficiencies, he assessed the examination report as inadequate.**

The opinion further states that failure to recognise certain anatomical abnormalities in the fetus may be caused by: difficult technical conditions of the examination (excessive thickness of the pregnant woman's subcutaneous tissue, unfavourable fetal position, reduced amniotic fluid volume), poor quality of equipment, lack of skill and experience of the person performing the examination, lack of diligence and accuracy on the part of the examiner, the nature of the anatomical abnormalities and the timing of the examination. In this case, it was established that the equipment used was of adequate quality, but the images were blurred.

The expert concluded that he could not unequivocally determine whether the failure to diagnose the meningomyelocele was solely the result of the doctor's negligence or whether other factors contributed to the oversight. However, in a supplementary opinion, he noted that if it is impossible to perform a complete examination due to, among other things, the unfavourable position of the fetus, it is recommended to note this fact and indicate the possibility of further action (repeating the examination). The lack of a note may be an indication that the structures assessed are considered to be normal.

From all this, the Court concluded that the doctor's negligence did indeed occur. In the circumstances of the case, it found no grounds to assume that there was a technical difficulty caused by the position of the fetus, since this fact was not noted and no further examination was recommended. This difficulty could only have been significant in that it would have increased

⁶³ The expert stated that the purpose of ultrasound examinations in the 18th–22nd and 28th–32nd weeks of pregnancy is to perform a detailed assessment of the fetal organs for congenital defects (assessment of fetal anatomy). He then listed in detail, referring to the recommendations, what an ultrasound examination should include during this period of pregnancy: estimated fetal weight and gestational age, assessment of fetal structures and organs: i.e. assessment of the skull, central nervous system of the fetus – in at least three planes, face, neck, heart, abdominal cavity, fetal spine – at least in the sagittal and transverse planes, fetal limbs, assessment of the placenta, examination of the cervix, adnexa, assessment of amniotic fluid, examination of the fetal sex. In the section on documenting the ultrasound examination results, it is recommended to perform a detailed assessment and description of the correctness of individual anatomical structures

⁶⁴ Concerning the assessment of only certain fetal biometric features: (biparietal diameter of the head), AC (abdominal circumference of the baby) and HC (head circumference of the baby).

the scale of the negligence, because then the examination could not be relied upon and would have to be repeated, and the doctor did not order this.

The lack of diligence and accuracy on the part of the doctor is also evidenced, in the opinion of the Court, by the lack of an examination report. [In fact, it is an incomplete report, not a lack thereof – MB]. Hence the Court’s conclusion that if the examination had been carried out correctly, the doctor would have made a report taking into account all the structures of the fetus that were subject to assessment. Only then would it be possible to argue that the malformations, including the space between five vertebrae of the spine, were not visible at all in this particular case. The conduct of the doctor managing the pregnancy deviated from the established standard and gave the Court grounds to conclude that “she should have and could have done more and better”, namely, to perform and describe the ultrasound examination in accordance with standards. These omissions were causally related to the violation of the claimant’s rights as a patient: to obtain information about fetal malformations and to decide on intrauterine treatment, for which compensation is due.

The claims for compensation, a pension and determination of future liability filed on behalf of the child were based on the assumption that the damage to his person was caused by the doctor’s negligence and failure to detect a developmental defect in a timely manner, which worsened during the period of fetal life and, as a consequence, the failure to perform surgery during the prenatal period. If the defect had been detected in a timely manner and the procedure had been performed, the effects of the congenital defect would not have occurred or would have been significantly less severe. However, in the opinion of the Court, the claims were not admissible because the correctness of this thesis was not sufficiently confirmed by the evidence in the case. The Court shared the opinion of the institute – a team of experts in K. It follows from this that the standard practice at that time (i.e. in 2013) throughout the world in the case of such a malformation was to perform surgery only after the child was born, and that prenatal surgeries are offered in only a few centres in Europe and have the status of a medical experiment rather than a health service [? – MB]. In Poland, 71 such operations were performed (between 2005 and April 2015). Fetal surgery for myelomeningocele reduces the incidence of hydrocephalus by 30% and improves the child’s motor function, but does not offer any chance of complete recovery. It can only prevent the second stage of the defect, i.e. secondary damage to the spinal cord due to the adverse effects of amniotic fluid and the exposed spinal cord rubbing against the wall of the uterus. Fetal surgery is still at the clinical trial stage and it is not known whether it will become a standard treatment. In the case of this patient, there were also

relative contraindications to surgery: a previous caesarean section and diabetes, which increase the risk of complications. There were also relative contraindications in the fetus: foot deformity and poor mobility of the lower limbs, which indicate a poorer treatment outcome.⁶⁵

All indications and contraindications, as well as the risks associated with the operation, can only be determined after a thorough targeted diagnosis, which has not been performed. Prenatal surgery could, with a probability that is difficult to determine, reduce the risk of hydrocephalus and the need for a shunt, and possibly reduce the degree of neurological disorders. However, it is difficult to assess to what extent the child's development would be different. The experts assessed the probability of the patient being eligible for the procedure at 50%. They expressed the same degree of probability regarding the outcome in the form of an improvement in the child's condition, but also regarding his death. They also gave no guarantee that the procedure would remove the effects of the defect. They pointed out that, given the state of knowledge at the time, prenatal surgery was a medical experiment and not a typical medical procedure. Such a prenatal experiment is characterised by high risk and unpredictable outcomes.

In addition, a private opinion was submitted in the case by Prof. A.O. (who heads the only team in Poland performing this type of surgery), which indicates that the fact that the claimant had undergone a caesarean section is generally disqualifying due to the risk of complications.

From the expert opinions, the Court concluded that the likelihood of significantly alleviating the effects of the malformation as a result of prenatal treatment was low (mathematically calculated – less than 25%). It found no grounds to accept that the boy's current condition was in a normal, typical causal relationship with the failure to perform the operation. In the Court's opinion, this condition is also not an adequate, normal consequence of the behaviour of the doctor who managed the pregnancy.

The court awarded PLN 100,000 to the mother, as requested in the claim, emphasising that compensation was due regardless of what the patient's final decision on continuing the pregnancy would have been.

The Court's conclusion requires several additional comments. There were certainly good grounds to consider the doctor's conduct negligent in relation to both the patient and the

⁶⁵ However, the foot deformity was already present at birth, and it is not known whether it occurred at the appropriate time for possible prenatal treatment.

fetus (and later the minor child), and this was the Court's finding. As for the damage, however, it found only a violation of the claimant's personal rights, which also constituted a violation of the patient's rights, but did not find an adequate link between the incorrect diagnosis (failure to diagnose a developmental defect) and the final damage to the child. It found that the proposed surgical treatment would have been experimental in nature,⁶⁶ and therefore its outcome would have been uncertain. This issue should not have influenced the reasoning at all, as the results of routine treatment are also uncertain.⁶⁷ Since operations of this kind had been performed dozens of times before,⁶⁸ it was possible to make predictions about the chances of successful treatment in this case as well.

Since no fetal malformations were diagnosed, qualifying the pregnant woman for surgery is obviously only a hypothetical issue. However, it is difficult to understand why the Court framed it in terms of probability (50%).⁶⁹ The proper subject of assessment should be whether the clinical condition of the pregnant woman constituted an indication for surgical treatment (in which case treatment should have been offered to her) or not (in which case the issue of treatment would be irrelevant).⁷⁰ This has nothing to do with probability theory.⁷¹ If there were indications for treatment, the next step in the reasoning would be to establish or reject a causal link⁷² between the failure to perform the operation and the damage to the child's health (increasing as a result of the spontaneous development of the defect) and the damage to the parents (in the form of increased costs of maintaining a disabled child). In such cases, a hypothetical connection is established – whether the treatment, if undertaken at all, would likely

⁶⁶ The experimental nature of this type of treatment can be considered debatable, as it was a method already well established in medical practice and used repeatedly in the past. The mere fact that the centre where these operations were performed had previously sought the opinion of a bioethics committee does not automatically give them the status of an experiment.

⁶⁷ The Court's reasoning is based on a false dichotomy, according to which experimental activities, unlike routine activities, have unpredictable consequences. However, a margin of uncertainty also exists in the case of routine activities and may be equally wide. (See P. Konieczniak, *Eksperyment naukowy i techniczny a porządek prawny*, Warszawa 2013, *passim*).

⁶⁸ On a global scale, the number of similar operations was certainly even higher at that time, and in countries with more advanced medicine, no one would have called them experimental in 2011.

⁶⁹ The obvious explanation seems to be an unthinking reliance on experts.

⁷⁰ When reviewing the application, bioethics committees require the submission of a so-called experiment protocol, which contains the criteria for the inclusion and exclusion of participants. On the basis of this document, it should have been considered whether the claimant, being pregnant, met these criteria.

⁷¹ Statistics and probability theory apply to populations (groups) of patients, and their application to individual (specific) cases is justified as long as nothing is known about such a case.

⁷² Strictly speaking, it is not a matter of causality, because in this case the essence of the matter was not an action, i.e. iatrogenic damage to health, but an omission, i.e. failure to prevent the deterioration of health.

have prevented the damage (it does not have to be a guaranteed prevention ‘beyond doubt’)⁷³. In the case in question, the Court concluded that there was no such relationship, because the hypothetical operation would not have led to a ‘significant alleviation of the effects of the malformation’ (this is supposedly supported by the too low ‘mathematically calculated probability’ of such success).

If the conclusion were different, the extent of the damage would still need to be determined. In the case of a tort of omission, this is difficult because it concerns damage caused by natural causes. The liable party is obliged to repair it only to the extent that they should have been able to prevent it. In order to determine the specific extent of this, it would be necessary to compare the effectiveness of intrauterine surgery in fetuses with neural tube defects with a similar untreated ‘control group’⁷⁴. However, since the effectiveness of treatment may vary, it would be necessary to ultimately compare the condition of the specific injured party with the dominant (in statistical terms) participants in successful operations – i.e. with the ‘typical condition of a patient after a successful operation’ and not with any exceptional successes. The end result would be compensation not for all the effects of disability, but only for those that could have been prevented by the obligated party (or the person for whom they are responsible). **The harm to the child is a worse state of health than if the fetal surgery had been successful, while the harm to the parents is the increased costs of caring for a child with a more severe disability than if the treatment had been successful.** This is extremely difficult to estimate, but it can be done by comparing it with the costs incurred for children whose treatment was successful.

The medical problem consists in the inability to prevent the deterioration of health. In the child, immediately after birth, it was a consequence of a congenital open neural tube defect (myelomeningocele – MMC), which worsened during the fetal period, took the form of a meningomyelocele and caused further neurological damage. Medicine offers a way to stop the development of the defect through highly invasive intrauterine surgery. Establishing a causal link between diagnostic negligence and its harmful consequences for the child requires the

⁷³ Mutatis mutandis, the reasoning used to assess the validity of claims for wrongful birth and wrongful life applies here. See J. Różyńska, *Związek przyczynowy w sprawach z tytułu wrongful life*, „Prawo i Medycyna” 2014, no. 1, pp. 39 et seq. In particular, it analysed each increase in the probability of a given phenomenon occurring (here: undergoing prenatal surgery and improving health) in the presence of a causative factor (here: information about the diagnosis).

⁷⁴ Such studies were conducted abroad and published in 2011: see footnote 24.

identification of an unbroken chain of intermediate events. In the case of omission, it is necessary to determine by deduction whether the effect of the impact has transferred from one link to the next. Omission is not in fact causal in nature, as it involves a lack of interference in the natural course of events. The mental operation consists in creating a construct of an alternative reality in which the required action has been taken. The doctor was required to make a careful diagnosis. Assuming that this was done, the patient would have received the appropriate information. With this information, she would have sought medical help and been referred for a consultation at the hospital in Bytom. There, she would have undergone assessment for the procedure. According to the expert (who also heads the team there), a previous caesarean section would have disqualified her 'by 50%', i.e. it did not in itself constitute a criterion for exclusion.⁷⁵ After learning the details of the planned procedures (removal of the uterus, possible complications, etc.), the patient would either be terrified and withdraw or, on the contrary, be confirmed in her intention – but this alternative occurs in connection with every consent to treatment. Therefore, if she was likely to be eligible for surgery and gave her consent, the surgery would have been performed. The dominant results suggest that in the case of a successful operation (not every operation may be successful, so this does not prove anything, unless the statistics for this diagnosis were significantly poor), the child's health would be better (less hydrocephalus and neurological damage, perhaps the ability to move independently preserved), and the costs of maintaining them would be correspondingly lower. This would also eliminate the harm caused by a health disorder exacerbated by diagnostic negligence.

The patient declared that she was willing to take the risk. This chain of connections can only be broken by the hypothetical existence of a criterion excluding her from participation in the experiment, contained in the experiment protocol. In its absence, the issue boils down to the fact that the child was born in worse health than if the prenatal surgery had been successful. Failure to perform the procedure resulted in the loss of a real chance to halt the progression of the defect. Part of the doctrine treats such phenomena in terms of loss of chance of cure when the patient lost it as a result of, among other things, diagnostic error or failure to fulfil the duty to inform.⁷⁶ The damage associated with the loss of chance may be treated as damage that may

⁷⁵ As one might expect, this would depend on the assessment of the scar, similar to qualifying for a natural birth.

⁷⁶ Similar to M. Nesterowicz, *Zadośćuczynienie pieniężne za doznaną krzywdę w „procesach lekarskich”*, „Państwo i Prawo” 2005, no. 3, p. 10.

be subject to compensation.⁷⁷ In the discussion on the adequacy of this type of causal link, an important role should be played not so much by the prevailing attitude of future mothers in society towards the diagnosis of specific defects in the fetus, but rather by the proven attitude of the specific patient.

3. The third, most recent case is known from the investigation stage. The child died shortly after birth, and the mother demanded punishment for those who failed to diagnose a congenital heart defect at a stage that would have allowed the child to survive. She herself requested an autopsy. The medical documentation of the incident was reviewed by a team of experts from the forensic medicine department at the request of the public prosecutor.⁷⁸

The birth took place in 2014. The pregnancy was full-term and, according to the doctors, proceeded without complications. Due to her age (39), the patient received a referral from her attending physician for prenatal ultrasound examinations at an academic centre in a larger city. She attended these examinations twice, in the first trimester and in the 20th week. Both results were read by doctors as normal. Later in her pregnancy, the patient had four more ultrasound scans at her local clinic. She gave birth by caesarean section due to obstetric indications – breech presentation. The boy scored 10 on the Apgar scale. His health deteriorated the very next day, but it took longer to determine the causes because the symptoms were non-specific. It was not until the third day of the child's life that a specialist consultation with a paediatric cardiologist took place. The cardiologist found the child to be in very poor general condition⁷⁹ and, alarmed by a loud systolic murmur over the heart, performed an echocardiogram (i.e. a specialist ultrasound scan).⁸⁰ The examination revealed a congenital defect in the form of severe aortic valve stenosis and severely reduced left ventricular contractility, bicuspid aortic valve and left ventricular fibroelastosis.

The boy was taken by ambulance to a specialist hospital in a large city, where he stayed for a week, and then travelled by helicopter to another large city for heart surgery. He was

⁷⁷ P. Grzebyk, *Rekompensata utraty szansy* [in:] *Odpowiedzialność odszkodowawcza*, ed. J. Jastrzębski, Warszawa 2007, p. 35 et seq.

⁷⁸ The reference number of the prosecutor's files has not been provided. The opinion was made available to the author as a courtesy and on condition of anonymity.

⁷⁹ He was pale, with below-normal peripheral oxygen saturation, circulatory and respiratory failure; he also had acidosis that could not be corrected. The enlarged liver reached the iliac crest.

⁸⁰ It has already been mentioned that heart defects in newborns are often *clinically silent*, and only other, non-specific symptoms lead to the correct diagnosis.

approved for the surgery, but it was postponed due to serious contraindications: haemorrhages in the brain. Three weeks after birth, the child died without undergoing the surgery. The autopsy revealed a congenital heart defect called HLHS – evolutionary hypoplasia of the left side of the heart, hypoplasia of the ascending aorta and the aortic and mitral valves.

During the prosecutor's questioning of witnesses, the paediatric cardiologist who detected the defect during an echocardiogram explained that the defect is very serious and the chances of survival are often slim. Tests carried out on women during pregnancy for this purpose often **take a very long time to detect defects** or to make sure that everything is fine. As for treatment, it is also attempted during fetal life. When it is known that a child will be born with such a defect, a paediatric cardiologist is called in advance and waits on standby, because a cardiological consultation is needed immediately, as is cardiological protection. Time is of the essence here, because children with heart defects of this type should undergo specialist treatment as soon as possible, and be born in appropriately equipped centres with a higher level of referral.

When questioned by the prosecutor, the doctor who performed the ultrasound scan at 20 weeks of pregnancy stated that the equipment he uses is high quality, and that the examination also aims to detect fetal heart defects and **lasts approximately 10–30 minutes**. He firmly maintained that he had not found any abnormalities and that if he had seen a heart defect in the ultrasound image, he would have recorded it in the documentation.

The experts raised objections to the results of this examination, in which the chest, heart and arterial trunks were assessed as 'normal'. In their opinion, the defect may not have been visible or recognisable in routine ultrasound examinations, i.e. without the function of assessing blood flow through the valve. Aortic stenosis at this stage of fetal development may be difficult to see, but a Doppler examination (flow examination) always shows abnormal flow through the valve, which should have been noted during the examination. **(For unknown reasons, the examination report did not include a flow assessment.)**

The changes observed around the 20th week of pregnancy are relatively minor, but without surgical valve enlargement, they lead to progressive hypoplasia of the left side of the heart in a relatively short time. Timely diagnosis of the defect should result in referral to a prenatal cardiology centre. Sufficiently early diagnosis and prenatal aortic valve widening surgery changes the natural course of the defect's development, but it is risky and does not always save the fetus's life. Such procedures are performed between the 21st and 30th week of

pregnancy. Intrauterine therapy does not fully guarantee success and carries certain risks for the fetus, but it is currently the optimal treatment for this type of heart defect, improving the prognosis not only for the survival of the newborn, but also for the quality of its later life.

The management of the patient's pregnancy was also assessed as correct. The experts even emphasised the high level of professionalism and conscientiousness of the local doctors, especially the referral to a higher-level centre for tests when the facility did not have equipment with comparable diagnostic capabilities. The obstetric and neonatal procedures, including diagnostic and therapeutic activities, were also assessed as appropriate and justified by the clinical condition of the mother and newborn. Before being transferred to a specialised cardiology facility, the child required stabilisation of vital signs in intensive care. The postponement of the surgical procedure was appropriate and was necessitated by the very high risk of further intracranial haemorrhage: the planned operation would have required extracorporeal circulation, with the need to use drugs to reduce blood clotting.

The only negligence was therefore the incorrect interpretation of the ultrasound scan at 20 weeks of pregnancy by a doctor who had high-class and adequate quality diagnostic equipment (*Voluson E6*) at his disposal.

IV. Penal and disciplinary consequences

The outcome of the investigation is unknown, but experts clearly pointed to negligence on the part of the doctor who performed the mid-term ultrasound scan. The documentation cited in the opinion shows that all doctors who treated the patient during her pregnancy and delivery, as well as the child until he was transferred to intensive care, were summoned to the prosecutor's office – a total of six people. Each of them could be given the status of a suspect in criminal proceedings because of the ultrasound technician who performed the examination incorrectly.

Children with HLHS should be born in a carefully planned manner and operated on immediately after birth, which requires prior diagnosis. Prenatal surgery is even better, as in the case of MMC, because it prevents deterioration. When fetal death occurs before birth, deliberate failure to perform prenatal diagnostics may be classified as 'causing the death of an unborn child' (Article 157a §1 of the Criminal Code) if the circumstances indicate that this is why rescue came too late. From the types of unintentional offences against life and health, a basis

for conviction can be derived in the event of failure to prevent danger arising during the fetal period, before the human being was born. The specificity of the act (omission) directed against the health of first the fetus and then the newborn child consists in the unintentional or intentional prevention of treatment at the right time. The offence consists in ignoring, and even more so in concealing, the symptoms of a developing disease. If the congenital defect:

- 1) worsens with the development of pregnancy (MMC) or fetus (HLHS);
- 2) requires surgical intervention immediately after birth or earlier – in utero;
- 3) in particular, it is necessary to plan for delivery under special conditions, especially termination of pregnancy by planned caesarean section – disregarding or concealing early symptoms is tantamount to at least culpable exposure to health problems or even death.

The mid-pregnancy ultrasound scan at 20–22 weeks is, as we can see, of paramount importance, as it allows for the early detection of any fetal abnormalities. This information can be used in three ways: to plan treatment before or after birth, to terminate the pregnancy or, in the case of a fatal disease, to use the services of a perinatal hospice.⁸¹ It is widely known that diagnostic errors are made with the aim of preventing the termination of such pregnancies. **Concealing knowledge from the expectant mother leads to dramatic consequences for the child as well, so associating unfavourable information solely with grounds for terminating the pregnancy is a paternalistic abuse.**

4. The experts immediately found the correct cause of death and accurately identified the negligence, but this is not always the case, as evidenced by two criminal and disciplinary cases from 2014 and 2015, described by Agnieszka Bielska-Brodziak and Tadeusz Urban in an article with the telling title ‘How much does a word weigh?’⁸². In healthy patients with normal pregnancies, perinatal intrauterine fetal death occurred. In both cases, autopsies of the newborns revealed premature closure of the foramen ovale in the heart. In a newborn who has started breathing, this is normal, but in a fetus, it is a serious pathology. According to scientific reports, intrauterine closure of the foramen ovale results in fetal death or perinatal death.⁸³ The reports

⁸¹ See the Madzia Słabiak case: *Dyskusja: O racjonalne decyzje w opiece neonatalnej* 15.09 -, <http://www.ptb.org.pl>, https://perinatalne.pl/pliki/Artykul/1025_lethaldefectsinfetusesandneonatespalliativecareasalternativetoegenicabortionpdfdangelneonatalna3.pdf [22.02.2020].

⁸² A. Bielska-Brodziak, T. Urban, *Ile waży słowo? O kosztach złego doboru biegłych sądowych i sposobach ich minimalizowania*, „Przegląd Prawa Medycznego” 2019, no. 1.

⁸³ A. Bielska-Brodziak, T. Urban, *Ile waży słowo?*, op. cit., p. 35.

of both autopsies also found congestion and enlargement of the medulla of the adrenal glands, which is responsible for the production of catecholamines, mainly adrenaline, secreted in response to stress. **This indicates chronic stress to which the fetus was subjected.**⁸⁴

The public prosecutor's office charged the doctors who performed the deliveries with 'unintentionally causing the death of an unborn child'. The proceedings were discontinued only thanks to the thoroughness of successive experts who gave their opinions on the cases. In the first case, it was a private opinion prepared by the head of a university department dealing with the diagnosis of fetal birth defects, submitted in self-defence by the accused. In the second case, it was prepared by a team appointed by the Regional Professional Liability Ombudsman (disciplinary proceedings were conducted in parallel with criminal proceedings), which included, among others, a paediatric cardiologist specialising in prenatal diagnosis of the cardiovascular system. Teams of experts from forensic medicine institutions appointed by the prosecutor (in the first case, there were even two; only the third supported the private opinion) issued opinions unfavourable to the obstetricians. Both narrowly avoided serious trouble.

What is important from the point of view of the analyses conducted here is why in neither of the two cases was the lethal fetal defect diagnosed earlier. If this had been done, the patients would have known what to expect, they would have had no reason to suspect improper care during childbirth, and the obstetricians would not have been put in the position of **having to prove their innocence**.

5. The last case in question, also disciplinary, was heard by the District Medical Court in Warsaw.⁸⁵ At the same time, an investigation was conducted by the public prosecutor's office. The gynecologist was punished with a reprimand for a culpable diagnostic error consisting in failing to diagnose, during an ultrasound examination (in 2006) very serious congenital defects in the fetus (massive hydrocephalus, suspected severe heart defect, complete bilateral cleft lip and palate, clubfoot, with suspected structural defects of the nervous tissue). Only at the end of the pregnancy (around the 36th week) was a single examination effectively performed on a different machine in the same hospital, but one floor higher, and the patient was then referred for additional tests. Diagnostic cordocentesis (collection and analysis of blood from the fetal umbilical cord) revealed serious genetic defects.

⁸⁴ Ibidem.

⁸⁵ Judgment of 09.04.2009, ref. 69/08. See M. Boratyńska, *Wolny wybór. Gwarancje i granice prawa pacjenta do samodecydowania*, Warszawa 2012, pp. 250–251, M. Boratyńska, P. Konieczniak, *Standardy wykonywania zawodu lekarza* [in:] *System prawa medycznego*, vol. 2, part 1, Wolters Kluwer, p. 314.

The defendant treated the patient as part of his private practice. The pregnancy was managed correctly in all respects. The doctor performed ultrasound examinations at the hospital because he did not have his own equipment. He used a thirteen-year-old device that was so worn out that the anatomical structures of the fetus were not visible on it at all. According to the expert's opinion, defects of this kind are noticeable in an ultrasound scan at around 20–22 weeks of pregnancy and should be diagnosed. The doctor performing the ultrasound scan is not obliged to determine the exact type of defect, but should raise such a suspicion and refer the patient to a centre with a higher level of referral. The failure to diagnose the defects objectively prevented the patient from making a decision about continuing or terminating the pregnancy. The defendant did not inform her of the diagnosis because he did not know about it himself, but this did not prevent him from assuring the patient that 'everything was fine'. (The baby girl died after seven months despite two heart operations and the insertion of valves due to hydrocephalus. According to the expert, the combination of defects gave her no chance of survival.) In his explanations, the doctor himself confirmed that the ultrasound machine could not be trusted because it was outdated, he himself did not trust it and neither did other doctors, but nevertheless, everyone in the hospital uses it. The offence therefore consisted not in the mere use of equipment with poor technical capabilities, but in a culpable diagnostic error: overinterpretation of the ultrasound image obtained and inconsistency in reasoning; the doctor was generally aware of the poor quality of the device, yet in this case he treated the result as reliable. According to the Court, "regardless of the date of manufacture and brand of the device, either the anatomical structures of the fetus are visible or they are not, and in the latter case, no opinions based on such an examination may be issued". The patient did not receive any descriptions of the examinations, only the images themselves – that is, it was as if she had not been given the results at all. The court found the defendant guilty of failing to exercise due diligence, but in my opinion, telling the patient that everything was fine, even though the imaging examination did not allow the anatomical structures of the fetus to be seen at all, is evidence of gross negligence, if not sabotage of prenatal diagnostics.

Conclusion

Prenatal operations are viewed in a prospective assessment as an uncommon solution, and in the rulings of common courts, they have not yet been taken into account in the causal chain leading to the prevention of harm to the child. However, there is a gap in reasoning here,

and there is a chance that the judiciary will recognise it over time. A line has been drawn, however, to treat them as a matter for real decisions by future mothers. This conclusion can also be drawn from reports in the medical press: the number of procedures is constantly increasing because patients are demanding them and, at the same time, funding is guaranteed.⁸⁶ In one of its judgments, the Court of Appeal⁸⁷ referred approvingly to the opinion of experts that the timely diagnosis of a fetal spinal hernia is appropriate for making the following decisions: 1) continuation of the pregnancy, termination by caesarean section and surgery on the newborn within the first 48 hours of life, 2) termination of pregnancy in accordance with the law in force in Poland, 3) prenatal surgery between the 21st and 26th week of pregnancy.

Physicians are generally fully aware of the gravity of their diagnoses and strongly encourage patients to confirm or rule them out through specialist testing. In this area, however, there is sometimes a surprising lack of concern. In four of the cases discussed, prenatal tests appear to have been performed only for show, without any interest in reliable results. In the other two cases, there is no data on whether they were performed at all. It is easy to ‘overlook’ a defect in order to avoid the burden of informing the patient. The social harmfulness of such behaviour lies in the manipulation of information: in concealing the truth for one’s own convenience and peace of mind. This conclusion is obvious, since the alarming symptom is either clearly visible or the image is so blurred that the test should be repeated. The Medical Court rightly pointed out that it is not a matter of accurately determining the type of defect oneself. In order to exercise due diligence, it is sufficient to raise a reasonable suspicion and refer the patient to a centre with the facilities to verify it.

A worrying result (e.g. increased nuchal translucency or ‘some space near the spine’) requires referral for more advanced diagnostics, including genetic amniocentesis as soon as possible, because waiting for the results of cell culture from amniotic fluid takes about two weeks. Spina bifida is an open neural tube defect, evidenced by the presence of fetal nerve cells in the fluid. Genetic defects are often accompanied by organ dysfunction, which requires further

⁸⁶ See the Health Policy Programme of the Minister of Health: *Program kompleksowej terapii wewnątrzmacicznej w profilaktyce następstw i powikłań wad rozwojowych i chorób dziecka nienarodzonego – jako element poprawy stanu zdrowia dzieci nienarodzonych i noworodków na lata 2018–2020*, <https://www.gov.pl/web/zdrowie/program-kompleksowej-diagnostyki-i-terapii-wewnatrzmacicznej-w-profilaktyce-nastepstw-i-powiklanwad-rozwojowych-i-chorob-plodu-jako-element-poprawy-stanu-zdrowia-plodow-i-noworodkow-nalata-2014-2017> [21.02.2020].

⁸⁷ Judgment of the Court of Appeal in Białystok of 19.02.2018, I ACa 379/16.

targeted diagnostics and, on this basis, planning for delivery and treatment before or after it. In many cases, ‘sloppy’ testing directly harms the health of the newborn child.

The patient has a choice regarding further decisions. However, in the absence of relevant information, she has no options for action. In the last weeks of pregnancy, she will at most learn about the need for a caesarean section. She is therefore paralysed in her decision-making due to a lack of key data.

Diagnostic negligence can be difficult to assess in terms of culpability, but its consequences are far-reaching. If the opinion of an experienced doctor is correct, that ultrasound technology is now so advanced that, with due diligence, certain anomalies can be detected without much difficulty,⁸⁸ then failing to notice them can be treated as a culpable diagnostic error. Certain shortcomings are in themselves evidence of professional incompetence or deliberate concealment of information. Their commission should lead to liability regardless of any connection with damage to legal rights – and thus at least to disciplinary punishment by a medical tribunal.

However, diligence will be assessed according to indirect criteria: whether the examination was performed at the right time; whether the image was analysed; whether the description is complete; whether the result was given to the patient; whether technical difficulties were noted and, as a result, a repeat examination was ordered or the patient was referred elsewhere; whether the examination was accompanied by appropriate information (included in the information sheet) about the need for further diagnosis or possible courses of action; whether appropriate referrals were issued; what is the quality of the images produced and what can be clearly seen in them; what was the technical condition of the equipment and whether its class corresponded to the type of examination. In other words, a checklist needs to be drawn up.

An unreliable prenatal diagnostician may do harm not only to the patient and her child, but also to themselves and his colleagues involved in perinatal care.

⁸⁸ The exchange of experiences and good practices is facilitated by richly illustrated professional publications, e.g. in the quarterly „Ultrasonografia” – see http://www.usg.com.pl/ptu/dat/attach/35_ultrasonografia46small.pdf.

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