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Off-label use of Misoprostol during childbirth, causing hypoxic ischemic encephalopathy. Legal and ethical consequences

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Abstract

A recent decision of the Court of Appeal of Cluj from Romania intrigued the medical community as it sentenced a gynecologist to pay 450.000 Euro in damages after an off-label use of Misoprostol during childbirth, causing hypoxic-ischemic encephalopathy. The physician was also condemned to two years in prison for abuse of authority and work negligence, and had his right to practice medicine suspended for five years. This case has potentially significant consequences for the medical practitioners in general, and for physicians from the field of Obstetrics-Gynecology in particular. In this report, we will analyse it from a legal and ethical point of view, considering current legal regulations and standards of medical ethics. We will perform a comparative legal analysis of the case based on the previous versus actual Romanian Criminal Code, followed by a basic ethical, principialist analysis.
Keywords: *foetus harming, criminal liability, childbirth ethical issues*

Introduction

A recent decision of the Court of Appeal of Cluj intrigued the medical community as it sentenced a gynecologist to pay 450.000 Euro in damages in a distinct malpractice case. From where will the physician pay this amount? Who will pay? These are just two of the questions any physician will ask. The amount in question was paid by the Local Council of Turda with money from the reserve fund of the Romanian Government, which were to serve for "judicial decisions"[(1)]. The physician was condemned for abuse of authority and work negligence and had his right to practice medicine suspended for five years. In this article, the authors will analyse the case from a legal and ethical point of view, considering current legal regulations and standards of medical ethics.

Case Report

In 2008, a pregnant woman (41 weeks) came to her gynecologist in a city from Cluj county from Romania. After the first consult, the physician proposed to the patient the labor induction. The procedure was initiated on the same day. The patient gave her verbal agreement for the medical procedure. Without asking the help of a neonatologist, the gynecologist administered her, vaginally, Misoprostol (Cytotec®). This medication, which can induce labor, is not found in the Romanian pharmacological register and is not authorise for distribution and use in Romania or the European Union. The patient gave birth to a child, who was diagnosed with hypoxic ischemic encephalopathy Sarnat II (i.e. neonatal convulsions). Afterward, the infant has been hospitalised several times, being the subject to medical investigations and treatment, with no notable progress. After four months, the infant was diagnosed with cerebral paralysis, motor retardation, epileptic seizures, perceptive-motor stimulation and permanent therapy with "Keppra", for recovery. During next admissions the patient was diagnosed mixed tetraparesis (i.e. both pyramidal and extrapyramidal), severe motor retardation, severe psychic retardation, convulsive neonatal syndrome, hypoxic-ischemic encephalopathy, and weight hypotrophy. The mother filed a criminal complaint against the physician. This case was tried at the Cluj Court of Appeal, which sentenced the physician for two years in prison for abuse of authority against the interests of persons, and to one year and six months, for work negligence. The case was tried by the Romanian Criminal Code from 1969. As the physician was sentenced at two concurrent offences, he received the hardest punishment, namely two years of prison. He also received an interdiction to practice his profession for five years. Him, together with the Municipal Hospital from Turda had to pay civil compensations for moral damages of 450.000 Euro.

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Discussion

Why was the gynecologist sentenced for the abuse of authority and work negligence and not for a crime against bodily integrity or harm?

From the case presentation, it appears unclear why the physician was accused of abuse of authority and not a crime against the health of a person. The social value to be protected by the Criminal Code should have been the life of an individual and not the way society works, as implied by the accusation of abuse of authority. However, according to the old Criminal Code, the foetus, injured during childbirth was not considered a subject of rights. The Criminal Code stated that the right to life of a person begins only after the end of labor, when the child is expelled and the ectopic life begins[1]. The medical error was done in 2008, before the adoption and the entering into force of the New Criminal Code from 2009[1] which has specific regulations that could have been applied to this case. In the context of the earlier Criminal Code, the passive subject of a crime against life or the integrity of the body or health could only be a person in the legal sense. A person is considering owner of rights only after the ending of the childbirth, which meant that between the birth triggering and its end, the foetus did not have criminal protection. This case does not fulfil the criteria for illegal abortion (art. 185) from the previous Criminal Code, as the course of pregnancy was never interrupted, the childbirth being triggered and completed. The foetus was not yet a person. Therefore, he could not be a passive subject of a crime against person. Moreover, the physician was accused of abuse of authority against the interests of persons (art. 246) and for committing a crime of negligence at work (art. 249, align. 1) from the Criminal Code from 1969[2].

What would be the judicial classification according to the New Criminal Code?

The new Criminal Code adopted in 2009[1], which started to be applied from February 1st, 2014, protects the foetus during the pregnancy and labor. The criminal protection of the right to life begins only after childbirth. The legislator has chosen to protect the fetus, as a distinct passive subject, by establishing the crime of injuring the fetus, in the art. 202 from the New Criminal Code[1]. Even if the intention of the legislator was to cover the legislative hiatus present in the old regulation, the solution could have been the anticipation of the moment in which the foetus became owner of civil rights. In most of European law systems, a person is considered alive from the beginning of the biologic process of birth, more precisely at the start of labor, irrespective if the process is started naturally or is triggered[3]. Our legal system opted for an intermediate solution. The legislator chose to criminalise the harm committed against the foetus between the beginning of the process of birth its end, timeframe that before was neither considered illegal abortion nor a crime against life or the integrity of the body or health.

If illegal abortion has a correspondent in the previous criminal legislation, the crime of injuring the foetus represents a novelty through which the legislator wanted the protection the life becoming[4]. The foetus enjoys judicial protection distinct from that of the mother, as it is a distinct subject of civil rights. According to the Criminal Code, there are three possible possibilities:

- The harm is committed during pregnancy and has as a subsequent result bodily injury of the woman or the death of the child (art. 201 align. (3));
- Harming the foetus during birth leading bodily harm preventing ectopic life (art.202 align. (1,2));
- The harm is committed during birth by the mother in a state of mental disorder (art. 202 align. (4)).

According to these dispositions of the New Criminal Code, the physician could have been charged for harming the foetus during birth, which then caused a bodily harm. The punishment could have been between one and five years of prison (art. 202 align. (2)). As it was committed without intent, the special limits of the punishment would have been reduced by half (art. 202 align. (5)).

Which were the elements the patient should have been informed, according to the Romanian legislation in force?

The patient "gave her verbal agreement for the pharmacological labor triggering", as stated in the description of facts from the motivation of the Decision of the Court[2]. It also indicated that the physician did not inform the patient about the fact that Cytotec® was not authorised in Romania nor that it was purchased illicitly. Also, labor triggering is an off-label use of the active substance, mainly used in gastric pathologies. The patient was not informed about the potential side effects of its administration, as mentioned in the leaflet and the scientific literature.

Romanian law requires an informed consent from the patient in written form (and only exceptionally otherwise). This is detailed in Law 95/2006 on the reform of the health system, art. 649, align.(1). align.(3) from the same article mentions that the physician has an obligation to inform the patient about the diagnostic, nature and purpose of the treatment, the risks and consequences of the proposed treatment, viable alternatives to treatment, and prognosis. The consent of the patient to the medical act does not extend on other medical interventions.

The code of medical deontology (2012) states, in art. 14, how should the patient be informed[5]. The physician must obtain a written, signed consent form only after properly informing the patient (or other person empowered to give consent) about the purpose, nature of the intervention, foreseeable consequences and risks.

The patient's right to information is detailed in Law 46/2003. According to it, every patient has the right to be informed about this health status, diagnosis, prognosis, proposed medical interventions, potential risks of each procedure, alternatives, and the possibility of failure of the treatment.

What are the principles of the medical ethics that the physician does not consider when deciding the administration of the substance concerned to her patient?

While practicing profession, the physician should act according to the principles of medical ethics, including au-

tonomy, beneficence, non-maleficence and justice. In our case, the first three ethical principles were not complied with by the specialist. Thus, the principle of autonomy mandates that any medical act has to be performed only if agreed upon by the patient[6,7]. The respect for patient autonomy has practical consequences within the physician-patient relationship like telling the truth, respecting the private life of the patient, protecting the confidentiality, and obtaining the informed consent[8]. According to the Council for International Organizations of Medical Sciences[9] there are four main elements that should be respected in order for a specific informed consent to be validated: (i) the patient received the needed information, adequate to his level of understanding, (ii) the physician checked that the information was understood, (iii) the patient is capable of making an informed decision (has decision capacity), and (iv) the agreement of the patient is free and voluntary[10]. Just signing the informed consent form is not enough for it to be valid. In fact, the "Informed Consent Guidelines" from the International Federation of Gynecology and Obstetrics are stipulating that "informed consent is not a signature but a process of communication and interaction" and that the "difficult and time-consuming" nature of obtaining informed consent does not "absolve physicians caring for women from pursuing... informed consent"[11]. The physician from our case did not, according to the court summary, told the whole truth to his patient and subsequently has not obtained a valid consent, as provided by the norms in force and the standards of the medical ethics.

The principle of beneficence implies that the physician has a professional obligation to act toward the medical well-being of the patient. In our case beneficence is mainly directed toward the medical benefit of the mother and the child, and only in exceptional circumstances, the physician should have put the wellbeing of one over the other. There is a certain progression of the duty of the physician to do good: a) *the obligation not to harm* (not to cause harm or suffering), b) *the duty to prevent the harm or suffering*, c) *the duty to suppress the harm or suffering*, and d) *the duty to do well and to promote the welfare*[12]. By administering a substance without a proven benefit in that circumstance (off-label use), and considering that inducing labor could have been obtained using drugs which were proven to be useful for it, the physician did not respect the duty to do well and to promote the welfare of the mother and the unborn child.

The principle of non-maleficence or non-harming involves the obligation of not causing, intentionally, a prejudice. In the literal sense, it means not to hurt/harm. The physician should avoid bringing harm both to his patient and her child to be born[13-15]. As the physician is a health care professional, being specialised in obstetrics and gynecology, he knew the risks associated with the administration of that substance. Moreover, in the verdict motivation[2] is shown that in a term pregnancy, that particular drug was not recommended because it could lead to frequent uterine contractions, of low intensity, with the incomplete relaxation of the myometrium and subsequently foetal sufferings. In the leaflet of Cytotec® is mentioned that its administered to pregnant women which could lead to abortion, or labor issues. Furthermore, there have been reported cases of uterine rupture after its administration to pregnant women to induce an abortion to pregnancies over eight weeks of labor.

Conclusions

We cannot know with accuracy what was the reason for which the physician did not respect the legal provisions of his profession and did not consider the potential negative consequences of his act. Informing the patient and achieving the informed consent are essential requirements of the physician-patient relationship. Even if the physician may consider that these professional obligations are slowing the medical act, this "slowing" is a positive one: the increased awareness about the risks of the intervention. Respecting the procedure of informed consent is essential for a correct understanding of the medical act nowadays. Moreover, a good medical practice cannot be performed without involving the patient in medical decisions that might have significant consequences on his/her life or wellbeing. ■

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