Review paper

Human studies other than clinical trials: the role of a medical therapeutic experiment in the Polish legal system

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Abstract

In accordance with Polish law, doctors are entitled to conduct two types of medical experiments: research and therapeutic. The research experiment focuses on expanding medical knowledge, and it can be carried out in patients or healthy subjects. The participants in these experiments are not exposed to risk, or the risk is small and proportionate to the effects. By contrast, therapeutic experiments involve the use of new or only partially tested diagnostic, therapeutic, or prophylactic methods that can only be used if the existing methods are ineffective or provide insufficient efficacy. The aim of a therapeutic experiment is to improve the health of a patient, and it may offer the only chance to improve or maintain the patient's condition. A medical experiment must be approved by an independent bioethics committee. Herein, we provide an analysis of Polish legal documents and their relevance to medical experiments.

Introduction

The purpose of this article is to present the issues and regulations connected with medical experiments. The law applicable in Poland provides for the possibility of conducting medical experiments with the participation of persons subject to the fulfilment of requirements specified in certain statutes and ethical norms. This paper will explain the notion of a medical experiment and present the legal basis for its conduction. It will also discuss the place of a medical experiment in substantive criminal law, considering the criminal liability of a doctor in connection with conducting such an experiment.

The notion of a medical experiment

The word 'experiment' is derived from the Latin word *experimentum*, meaning a trial. An experiment is an attempt to implement an innovative idea or scientific theory, particularly when conducted for the first time. According to Tadeusz Kotarbiński, "an experiment is the intentional change of default conditions of an examined type of an incident, undertaken in order to discover its dependence or type of dependence, or independence of a given variable, or to demonstrate which factor the dependence concerns, or such but not another relationship or finally, absence thereof" [1].

A medical experiment triggers a phenomenon by interfering with a physiological process [2]. Medical experiments are aimed at eliciting a cure through innovative methods or by furthering the knowledge and understanding of medical science [3]. Such experiments are interventional studies and are regulated by the Act of 5th December 1996 on the professions of a doctor and dentist (AOPDD) [4]. A medical experiment conducted on people may take the form of a therapeutic experiment or a research study, both of which are defined below.

A specific form of medical experiment is a clinical trial, the subject of which is a medicinal product or a medical device. A medical experiment is a broader notion than a clinical trial; therefore, every clinical trial is a medical experiment but not every medical experiment is a clinical trial. Clinical trials of a medicinal product have been regulated by the Act of 6 September 2001 Pharmaceutical Law [5]. The aforementioned act defines a clinical trial as a clinical trial within the meaning of Article 2(2)(2) of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/

EC. According to that Regulation, "clinical trial" denotes a biomedical study that meets any of the following conditions: a) the assignment of the participant to a particular therapeutic strategy is predetermined and does not fall within the standard clinical practice of the Member State concerned; b) the decision to prescribe the investigational medicinal product is taken jointly with the decision to include the participant in the biomedical study; or c) as well as standard clinical practice, additional diagnostic or monitoring procedures are performed on the participants [6].

Clinical investigations of medicinal products are governed by the Act of 7 April 2022 on Medical Devices [7], which refers to the definition of a clinical investigation set out in Article 2(45) of Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002, and Regulation (EC) No. 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC [8]. Under this provision, a clinical investigation means a systematic investigation involving at least one participant, undertaken to assess the safety or performance of a device.

Pursuant to Article 31(1) of the Act on Medical Devices, the provisions of Article 29 of the Act of 5 December 1996 on the Professions of Physician and Dentist apply to clinical investigations.

Legal basis for medical experiment

Chapter 4 of the AOPDD uses the notion of a medical experiment and regulates the associated issues. A medical experiment involving humans may be a therapeutic experiment or a research experiment (Article 21[1]).

A therapeutic experiment is the introduction by a doctor of new or only partly tested diagnostic, therapeutic, or preventive methods to obtain direct benefit to the health of a person receiving treatment. It may be conducted if the currently available medical methods are ineffective or insufficiently effective (AOPDD Article 21[2]). The purpose of a therapeutic experiment is to provide treatment which, by definition, is experimental.

A research experiment is primarily aimed at expanding medical knowledge. It may be carried out both in patients and healthy subjects. Conducting a research experiment is admissible only if participation involves no risk, or if the risk is small and not disproportionate to the potential positive outcomes of such an experiment (AOPDD Article 21[3]).

A medical experiment also includes the conduct of examinations of biological material, including genetic material, collected from an individual for scientific purposes (AOPDD Article 21[4]).

A medical experiment may be conducted if the anticipated therapeutic or cognitive benefit is of vital importance and the expectation of the benefits, their usefulness, and the method of conducting the experiment are justified according to the state of knowledge at the time and are compliant with the principles of medical ethics (AOPDD Article 22). Prerequisites for admissibility of conducting a medical experiment are to fully inform the participants about the experiment, obtain consent from the participants, and obtain approval from an independent bioethical committee. A medical experiment is managed by a suitably qualified doctor (AOPDD Article 23).

A person who is to be the subject of an experiment is informed in advance about the purpose, methods, and conditions of the experiment; they are also informed of the expected therapeutic or cognitive benefits, as well as the risks, and are advised of their right to withdraw from the experiment at any stage (AOPDD Article 24[1,2,3]). If immediate discontinuation of the experiment could endanger the life or health of the participant, the doctor is obliged to inform the participant of this fact (AOPDD Article 24[4]). A medical experiment may be conducted only after obtaining the consent of its participant or of the person who may be directly affected by the consequences of the experiment (AOPDD Article 25[1]). Where it is impossible to provide written consent, consent given orally in the presence of two witnesses may be deemed equivalent. Such consent should be recorded in the medical documentation. Participation of a minor in a medical experiment – in civil law, a minor is a person who has not reached the age of 18 years, except for a female who, with the court's consent, enters into marriage after reaching the age of 16 years, which means she is no longer considered a minor – is admissible only with the written consent of their legal representative. In the case of a participant who is a minor under 13 years of age, the consent referred to in paragraph 1 shall be given by his or her legal representative. In the case of a participant who is a minor aged 13 years or older, the consent of both the minor and his or her legal representative is required. Where no agreement is reached between these persons, the matter shall be decided by the guardianship court (AOPDD Article 25[2,3]). The participation of a minor in a research experiment shall be permissible only where the anticipated benefits are of direct relevance to the minor's health and the risk is minimal and not disproportionate to the potential positive outcomes. A research experiment involving a minor shall not be permissible if the experiment, with comparable efficacy, can be conducted with a participant who has full legal capacity. Concerning a person subject to full interdiction (i.e. a person who has attained the age of 13 years and, due to mental disease, mental retardation, or other types of mental disturbance, in particular drunkenness or drug addiction, has no capacity to independently manage their conduct, which is adjudicated by the court after consideration of the best interests and welfare of the individual), consent for participa-

tion in a therapeutic experiment is given by their legal representative. If such a person is able to provide an informed opinion about participation, it is also necessary to obtain written consent (AOPDD Article 25[5]).

In the event of a person with full legal capacity being unable to provide an informed opinion about participation, consent to participate in the therapeutic experiment is provided by a guardianship court with jurisdiction over the registered office of the entity conducting the experiment (AOPDD Article 25[7]). In the event that the legal representative refuses to give consent for the patient to participate in a therapeutic experiment, an application may be filed with the guardianship court with jurisdiction over the registered office of the entity conducting the experiment, in order to obtain consent (AOPDD Article 25[9]).

Where the subject of the experiment is a minor, an incapacitated person, or a person possessing full legal capacity but unable to express an informed opinion regarding participation in the experiment, an application for consent to participate in the medical experiment may be submitted either by that person's legal representative or by the entity conducting the experiment to the guardianship court competent for the seat of the entity conducting the experiment (AOPDD Article 25[11]). Where the legal representative or the participant refuses to grant consent for participation in a research experiment, its conduct is prohibited (AOPDD Article 25[10]).

In the past, the Act on the Professions of Physician and Dentist provided that, in urgent cases involving an immediate threat to life, it was not necessary to obtain consent for participation in a medical experiment from 1) an intended participant from whom it is impossible to obtain written or oral consent, 2) a minor, 3) a person subject to full interdiction, 4) a person who has full capacity to act in the law but is not able to give an informed opinion about their participation in the experiment, or 5) a person whose legal representative refuses to provide consent for participation in the therapeutic experiment (previous Article 25[8] AOPDD). The content of that provision was not consistent with Article 39 of the Constitution of the Republic of Poland [9] and Article 27(2) of the Act of 6 June 1997 Criminal Code (CC) [10], which provide for the absolute necessity of obtaining informed consent from participants in a medical experiment. The mentioned article also does not correspond with Article 7 of the International Covenant on Civil and Political Rights of 16 December 1966 ratified by Poland, which stipulates that no one shall be subjected, without their freely expressed consent, to therapeutic or research experiments [11].

Urgent cases are those that arise suddenly, where the patient is unable to provide consent, and there is no time to apply for substitute consent, and the only possible treatment option is to conduct an experiment [12]. Due to the danger to life, immediate application of an experimental method is considered to be the only possible method of saving a person's life. There is no doubt that involving a person in the medical experiment without their informed consent by way of legal regulation should be subject to particularly strict rigors, which must be adhered to by any doctor managing the experiment [13].

The current Act on the Professions of Physician and Dentist permits the conduct of a therapeutic experiment without the required consent of the participant, but only upon the cumulative fulfilment of the following conditions: the participant is incapable of providing consent to participate in the experiment; an emergency situation exists, and due to the need for immediate action, obtaining consent for participation in the therapeutic experiment from the participant's legal representative or obtaining judicial authorisation is not possible within a sufficiently short time; an experiment of comparable efficacy cannot be conducted on persons who are not in an emergency situation; the participant has not previously objected to participation in such an experiment; the participant in a therapeutic experiment conducted under emergency conditions and – where applicable – his or her legal representative shall receive all relevant information regarding participation in the experiment at the earliest possible time; and an application for consent to participate in the therapeutic experiment, or for judicial authorisation to conduct the therapeutic experiment, has been submitted (AOPDD Article 25a).

The Act on the Professions of Physician and Dentist, in Article 23a(1), introduces restrictions on the participation of certain persons in a research experiment. It prohibits the conduct of a research experiment on the following: a conceived child; an incapacitated person; a soldier or any other person in a hierarchical relationship limiting the freedom to give voluntary consent; or a person deprived of liberty or subjected to detention.

In Article 27 of the Act of 5 December 1996 on the AOPDD, the legislature presents conditions for terminating a medical experiment (i.e. a therapeutic or a research experiment); the decision to discontinue an experiment rests with the doctor. It should be stressed that a person or another entity entitled to give consent to the experiment may withdraw their consent at any stage. If the individual or entity withdraws consent to participate in the experiment, the physician is obligated to discontinue the medical experiment (AOPDD Article 27[1]). Participants are informed of their right to withdraw their consent at any time [13]. The entity conducting the therapeutic experiment is obligated to terminate the experiment if, during its course, a health risk to the participant arises that exceeds the anticipated benefits for that participant (AOPDD Article 27[2]). The decision to stop the therapeutic experiment and the reasons why should be communicated to the patient [13]. A doctor

conducting a research experiment is also obliged to terminate it if an unexpected threat to the health or life of the participant occurs (AOPDD Article 27[3]). This means that the legal conditions for admissibility of the trial have been breached by the occurrence of a threat to the participant's health or life [13].

A medical experiment may be conducted only with the approval of an independent bioethical committee, which acts upon the application of the interested entity. The elements and conditions of such an application, together with its annexes, are specified in Article 29(22) and (23) of the Act on the Professions of Doctor and Dentist.

When evaluating the project, the bioethical committee considers the ethical criteria as well as the usefulness and feasibility of the project. Clinical trials are also included in the scope of evaluation of the bioethical committee. The bioethical committee therefore evaluates 1) the validity, feasibility, and protocol of the clinical trial, 2) an analysis of the anticipated benefits and risks, 3) the accuracy of the clinical trial protocol, 4) the choice of researcher and team members, 5) the quality of the researcher's brochure, 6) the quality of the centre, 7) the quality and completeness of the written information prepared for the clinical trial participants, 8) the procedure for obtaining informed consent, 9) the amount of damages or compensation provided in the event of a possible injury or death caused by participation in the clinical trial, 10) the amount of remuneration or compensation provided to persons conducting the clinical trial and participants, as well as any contract between the trial sponsor and the research centre, 11) the principles of participant recruitment, and 12) the civil liability insurance contract of the sponsor and the investigators [13].

The bioethical committee comprises persons with high moral authority and specialist qualifications. The committee issues its opinion on the experiment by way of a resolution adopted in a secret ballot [14, 15]. The committee's opinion does not constitute an administrative decision [14]. According to the Supreme Administrative Court, "a resolution of a bioethical committee on a project of a medical experiment is an administrative decision of a public administration body, adjudicating an administrative case initiated by a doctor as an entity who has a legal interest in issuing such a decision, thus may be appealed to the administrative court" [16]. A similar opinion about the legal nature of the bioethical decision was expressed by Bartłomiej Świątkowski, who found that that a bioethical committee is a public administration body, and its opinion is an administrative decision [17].

Bioethical committees are appointed by the district medical council, the president of a medical university or a university with a medical faculty, and the directors of specific institutes (AOPDD Article 29[4]). The panel of the bioethical committee is appointed by the president of a medical university or a university with a medical faculty, or the director of a research and development unit, and also includes a representative of a competent district medical council (AOPDD Article 29[7]). Bioethical committees operate a two-tier procedure, and the second instance is the Appellate Bioethical Committee. The minister responsible for health, after consultation with the Supreme Medical Council, appoints the Appellate Bioethical Committee, which considers appeals against resolutions of bioethical committees (AOPDD Article 29[6]). It shall also specify, by way of regulation, the detailed rules for the establishment and financing of bioethics committees, as well as the procedure for their operation (AOPDD Article 29[26]). An appeal against the resolution of a bioethical committee containing an opinion about the medical experiment may be filed by the entity intending to conduct a medical experiment, by the director of the medical entity, within the understanding of the provisions of the Act on medical activity, in which the experiment is to be conducted, or by the bioethical committee of the centre that is to participate in the multicentre medical experiment. The appeal should be filed through the bioethical committee that passed the resolution, with the Appellate Bioethical Committee in Warsaw [11].

In Article 28 of the AOPDD, the legislature obliges the author of a medical experiment to use the information acquired in connection with the medical experiment for scientific purposes. Such information may be used without the consent of the subject but in a manner that prevents the identification of the individual.

Medical experiment vs. substantive criminal law

Criminal law is a set of legal provisions prohibiting certain acts under penalty, which are defined as crimes by a statute. Substantive criminal law defines what acts (crimes) are punishable by what penalties under what conditions and outlines the preventive measures that may be applied under certain circumstances [18]. The legislative acts that regulate substantive criminal law are the CC Act of 6 June 1997 and specific statutes including criminal provisions (the so-called extra-codical criminal law) [8]. An example of a statute including extra-code criminal provisions is the AOPDD of 5 December 1996, which, in Article 58, includes the following:

– Section 2 imposes a penalty on a person who provides medical services without suitable qualifications, i.e. the diagnosis and treatment of diseases with a view to achieving financial benefit or misleading the patient regarding their qualifications;
– Section 4 penalises acts committed by any person who conducts a medical experiment without the legally required consent or without court authorisation;

– Section 5 penalises acts committed by any person who conducts a medical experiment in violation of the conditions referred to in Article 23a or Article 23b;
– Section 6 penalises acts committed by a member of a bioethics committee or an Appellate Bioethics Committee who, contrary to the obligation assumed, discloses or uses information obtained in connection with the performance of his or her duties.

Accordingly, a physician's conduct that intentionally violates the requirements and conditions governing a medical experiment is subject to criminal sanction. The content of Article 58 of the Act on the Professions of Physician and Dentist is clear and unambiguous; it does not require any special interpretation or statutory construction.

Article 1 of the CC provides general definitions of crime and conditions of criminal liability. Pursuant to Article 1 § 1 of the CC, criminal liability applies only to a person who commits an act prohibited under penalty by a statute in force at the time the offense is committed. An act prohibited by law, the social harmfulness of which is negligible, does not constitute a criminal offense (Article 1 § 2 of the CC). The perpetrator of a prohibited act does not commit an offence if no guilt can be attributed to them at that time (CC Article 1, section 3). An offence is an act committed by a person prohibited under penalty by a statute in force at that time, the social noxiousness of which is more than slight. A prohibited act is a conduct characterised in a criminal statute (CC Article 115, section 1). The detailed part of the CC defines types of offences and penalties. In connection with the performance of professional duties, a physician may, through their conduct, primarily fulfil the elements of a criminal offense under Article 160 section 2 of the CC (committed intentionally), under Article 160 sections 2 and 3 of the CC (committed unintentionally), being a person under duty of care over a person exposed to a danger of loss of life or serious detriment to health and under Article 192 of the CC. A doctor may also be the subject of an offence under Articles 150 (euthanasia), 152 (abortion with the consent of a woman), 157a (bodily injury to a conceived child), and 162 (the general legal obligation to provide help). Article 160 of the CC reads as follows: section 1. Anyone who exposes a person to an immediate danger of loss of life, a serious detriment to health, or a serious impairment of health is liable to imprisonment for up to 3 years; section 2. If the offender has a duty of care over the person exposed to danger, he or she is liable to imprisonment for between 3 months and 5 years; section 3. If the offender of an act specified in section 1 or 2 acts unintentionally, he or she is liable to a fine, the restriction of liberty or imprisonment for up to 1 year; section 4. An offender who voluntarily averted the threat of danger is not subject to a penalty for the offence specified in sections 1–3; and section 5. The prosecution of the offence specified in section 3 takes place at the motion of the aggrieved party.

An offence under Article 160 of the CC is exposing a person to the threat of danger. Intentionally exposing the life or health of a person to a direct danger may result from direct intent or a conditional intent. The offender must have been aware of the possibility of exposing the person to a direct danger of loss of life or serious detriment to health and must have had the intention to create such a state, or while anticipating the possibility of exposing the person to results specified in the statute, agreed to such exposure [19]. Unintentional exposure to danger may be attributed to the offender as a result of failing to exercise due care in a situation where exposure of the person to danger could have been foreseen [20].

The criminal liability of a doctor under Article 160 section 2 or section 3 of the CC was commented upon by the Supreme Court. In its judgement of 21 August 2012 File No. IV KK 42/12, the Supreme Court decided that a doctor shall bear criminal liability under the above articles when their conduct leads to direct danger of loss of life or serious detriment to the health of a person in their care [21]. However, the requirement of criminal liability of a doctor-guarantor under Article 160 sections 2 and 3 of the CC will only be fulfilled if it is established that the desired conduct, constituting the performance of his/her obligation, would have prevented real exposure of a person to direct danger of loss of life or serious detriment to health. Therefore, there is no doubt that the aforementioned effect is the exposure of a person to a direct danger of loss of life or serious detriment to health, and not only the state in which the life or health of a person is already in danger. A doctor is obliged to take all possible diagnostic and therapeutic actions, and it is not important whether the result of medical malpractice is the patient's death or serious detriment to health. In other words, a doctor is obliged to defend human life and health whenever they are threatened, and their responsibility is not prejudiced by the fact that, even if they acted adequately, it would not be possible to rule out a patient's death or serious detriment to health. A doctor as a guarantor of the life and health of a person is obliged to avert danger and not merely to prevent increasing it [22].

The liability of a doctor under Article 160 of the CC does not have to consist of diagnostic or medical malpractice. It may involve different acts or omissions that expose a person to a direct danger, loss of life, or serious detriment to health [23]. Article 192 of the CC includes the following: section 1. Anyone who performs a medical procedure without the consent of the patient is liable to a fine, the restriction of liberty, or imprisonment for up to 2 years; section 2. The prosecution takes place at the motion of the aggrieved party. The offence under Article 192 CC is called a 'medical

operation without consent'. The object of protection is the right of the patient to autonomy in subjecting oneself to a medical operation [24]. The offender may be anyone who performs a medical operation without the consent of the patient. However, the manner of realisation, including the special nature of a 'medical operation', indicates that its performance is possible within the framework of specific medical procedures. Therefore, anyone who operates within the scope of authorisation to perform certain medical services (e.g. a physician, a feldsher, a nurse, or a midwife) may be an offender [25]. A medical operation referred to in Article 192 section 1 of the CC is a broad notion, encompassing both diagnostic and therapeutic operations, as well as preventive treatments. Medical operations may be performed as part of medical services connected with the day-to-day practice of a doctor or as part of treatments having the nature of a medical experiment [26].

An essential element of a crime under Article 192 section 1 of the CC is the lack of consent of the patient to subject themselves to the medical operation. Approaches to obtaining the consent of the patient are regulated in the AOPDD. If there is no possibility of immediately obtaining consent from the patient, their legal representative, or a guardianship court, the doctor has the right (without obtaining such consent) to undertake the therapeutic activities necessary to avert the danger of loss of life, serious detriment to health or serious disturbance of health of the patient in the circumstances referred to in AOPDD Article 33, Article 34(3), (6), and (7) and Article 35. These provisions constitute legal protection for doctors against a possible allegation of committing an offence under CC Article 192 and allow sacrifice of the right of the patient to autonomy for the benefit of saving their life and health [26].

Chapter III of the CC provides for institutions excluding criminal liability, i.e. the so-called justifications. The notion of a justification includes circumstances defined by the law, which, due to the lack of social danger or uselessness of penalising, justify the decision of the legislature to adopt regulations cancelling the unlawfulness of the acts taken that otherwise would possess statutory features of a prohibited act [27]. The justification described in Article 27 of the CC is connected with four types of experiments (including a medical experiment) and deletes the unlawfulness of the act. Acting under the conditions of this justification makes the unlawful act of the person conducting the experiment lawful, which protects them from criminal liability [28]. Article 27 of the CC comprises the following: section 1. Anyone who intends to conduct a cognitive, medical, technical, or economic experiment does not commit an offence as long as the anticipated benefit is of vital cognitive, medical, or economic importance, and the expectation of the benefits, their usefulness, and the method of conducting the experiment are justified according to the state of knowledge at that time; section 2. Experimentation is inadmissible without the consent of the subject, duly informed about the anticipated benefits and possible adverse effects and their probability, as well as about the possibility of withdrawing from participation in the experiment at any stage; section 3. Principles and conditions for admissibility of the medical experiment are provided by the statute (AOPDD) [8]. Article 27 of the CC concerns scientific experiments, including medical experiments, as experiments that are aimed at treating a patient using innovative methods or at acquiring knowledge in medical sciences. Consent to participate in a medical experiment is specifically regulated in the CC. According to some, Article 27(1) and (2) of the CC does not apply at all to a medical experiment due to the content of paragraph 3, which refers to the AOPDD. Chapter IV specifies the principles and conditions for admissibility of a medical experiment. Such controversy results from defective wording in Article 27 of the CC. Due to the content of paragraph 3 of Article 27 of the CC, which is devoted only to a medical experiment, it is proposed to exclude a medical experiment from the catalogue of experiments mentioned in CC Article 27 [28]. Article 27 section 1 specifies conditions for the legality of all types of experiment jointly. However, Article 27 section 3 indicates that principles and conditions for admissibility of a medical experiment are specified in the statute, which regulates the issues related to the medical experiment, i.e. the AOPDD. Therefore, with regard to a medical experiment, the provisions contained in this Act should be given precedence [3].

It cannot be ruled out that during a medical experiment the doctor who conducts it may, by his or her actions, fulfil the criteria of the prohibited act referred to in Article 160(2) and (3) or Article 192 of the CC, which may furthermore result in the death of the patient (Article 155), involuntary serious harm to health (Article 156[1] and [2]), infringement of the function of a body organ or disorder of health (Article 157[1] and [3]), or such an infringement or disorder lasting no longer than 7 days (Article 157[2] and [3]). In such an event, the unlawfulness or criminality of the act is excluded by the justification described in Article 27 of the CC only if the prerequisites for accepting such justifications are met, as discussed below. When evaluating whether the actions of a doctor match the criteria of a prohibited act and constitute the justification provided for in Article 27 of the CC, the authority conducting the procedure must establish the purpose of the medical experiment, importance of the anticipated benefit, justifiableness of the experiment, and consent of the participants. A doctor should act to conduct a medical experiment, motivated by the anticipated benefit of the experiment and in expectation of the benefits. The purpose of the doctor-investiga-

tor should not only be to conduct the experiment but also to obtain the expected benefit [29, 30]. The subjective prerequisite for the justification of the experiment will not be fulfilled if the offender acted with a view to conducting the experiment but did not pursue medical benefits [28]. The doctor must be aware of the prerequisites of the justification. The prerequisite for the above justification is the vital medical importance of the expected benefit; the benefit must be of great significance. It should be stressed that evaluation of this prerequisite should not be limited to the short-term benefits, and the long-term effects should also be considered, because the benefits resulting from the experiment may be evident many years after completion. The prerequisite for conducting the medical experiment is for the anticipated medical or cognitive benefit to be of vital importance and the expectation of benefits, usefulness, and manner of conducting the experiment to be justified according to the state of knowledge at that time and compliant with the principles of medical ethics [28].

The participant in the medical, therapeutic, or research experiment is a person. The purpose of the therapeutic experiment is to achieve a direct benefit to the health of the person under treatment by introducing new or only partly tested diagnostic, therapeutic, or preventive methods. Such an experiment may be conducted only when existing medical methods are ineffective or insufficient. The purpose of the research experiment is to expand medical knowledge, and it can be conducted in patients or healthy subjects. The conduct of such an experiment is admissible if participation in the experiment involves no risk, or if the risk is minimal and not disproportionate to the potential positive outcomes. The evaluation of whether the expected benefit of the experiment is of vital medical importance requires professional knowledge. In the event of medical experiments, such evaluations are made by a bioethical committee that includes authorities in the given field of medicine.

It follows directly from Article 27 section 1 of the CC, i.e. that the expectation of benefits, usefulness of the experiment, and manner in which it is conducted must be justified according to the state of knowledge at that time [31]. Establishing whether the usefulness of the experiment is justified considering the current state of knowledge requires comparison of the expected benefits and the possible detrimental effects. Such a comparison should include both the probability of achieving the expected benefit and the occurrence of detrimental effects [29]. As a rule, one may state that an experiment will be useful only when both these factors support the expected benefit. Therefore, we will not deal with a legal experiment if there is a higher probability of detrimental effects than beneficial outcomes, or the value of the detriment exceeds the value of the expected benefit. It must also be assumed that the higher probability and value of benefits imply admissibility of a higher probability and value of detriments [28].

When comparing the value of the expected benefit and anticipated detriment, one should consider intangible values, such as quality of life or enabling further medical progress. The fact that the benefits and detriments resulting from the experiment may be experienced many years after its completion should also be considered [28, 31]. According to Article 27 section 1 of the CC, the method of conducting the experiment should be justified according to the state of knowledge at that time, i.e. it must fit within the principles based on knowledge resulting from experience and practice as well as theory. It follows directly from Article 27 section 2, which states that the experiment is inadmissible without the consent of the participants. This requirement corresponds to Article 39 of the Constitution of the Republic of Poland, which states that "no one may be subjected to scientific experiments, including medical experiments, without freely given consent" [7]. The consent of a person to participate in the medical experiment should be specific and provided in writing (or, if that is not possible, expressed verbally in the presence of two witnesses) prior to the experiment, in the form of a declaration of will free of vices of consent under the civil law (ostensibility, error, fraud, duress, exploitation). Verbal consent should be recorded in the medical documentation.

All participants must have complete knowledge of the experiment and its possible effects or consequences, provided in a comprehensible, clear manner by the investigator. Such information should be provided not only before or while obtaining consent, but also during the experiment, with a view to ensuring that the participant is aware of changing circumstances. The participant must be informed about the possibility of withdrawing from the experiment at any stage. Only consent preceded by the provision of complete knowledge about the experiment is effective and enables legal experimenting. Under the AOPDD, information relating to the medical experiment should include the purpose, methods, and conditions under which the experiment will be conducted, as well as the anticipated therapeutic or cognitive benefits, the risks, and the possibility of withdrawing from the experiment at any stage. In the event that immediate discontinuation of a medical experiment could cause danger to life or health, the doctor should fully inform the participant. The consent to an experiment is valid if it is provided by a person with full capacity to give it. Such capacity is determined by two elements, namely, sanity and legal age. A person of legal age is a person who has attained the age of 18 years or attained majority through entering into marriage [32, 33]. Legally valid consent is the consent given by a person who at the time of providing the consent is free from mental diseases, mental retardation, and other disturbances of mental activity. However,

it involves only factors that disturb the sphere of intellect (inability to recognise the meaning of the act) or will (inability to direct one's own conduct) [28]. The CC requires that consent is given by the person on which the experiment is to be conducted; therefore, it must be expressed in person and not through a representative. There are exceptions to this rule provided for in the AOPDD. The above statute in Article 25 provides for conducting a medical experiment on an insane person or person under the age of consent after obtaining the consent of their legal representative. In contrast to Article 27 of the CC, Article 25 regulates the admissibility of medical experiments 1) on persons who are not able to independently give their consent, i.e. minors, persons subject to full interdiction, and persons unable to recognise reality, despite having full capacity to make acts in the law, 2) in the situation when the legal representative refuses to give consent to participation of the patient in a medical experiment (in which case, there is an option to apply to the guardianship court to obtain such consent), and 3) without the necessity to obtain the consent of the participant or their legal representative or a guardianship court in urgent cases when the life of a person is endangered [28].

Conclusions

Medical experimentation is closely related to the need to find new and innovative treatments for patients and acquire greater medical knowledge [33]. Innovation in medicine is often linked with a threat to the life or health of a person and therefore requires its own place in the legal order.

Polish law permits medical experiments to be conducted subject to compliance with the provisions of the legal acts of statutory rank. Violation of prerequisites for lawfully conducting a medical experiment may result in the criminal liability of the doctor. The legislature recognised the need to consider a medical experiment as a circumstance excluding unlawfulness of a prohibited act connected with the medical experiment. Acting under the terms of the justification in accordance with CC Article 27 results in the prohibited act of a doctor becoming legal and not giving rise to criminal liability. Such a position by the legislature is understandable.

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Conflict of interest

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