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Zgoda pacjenta na wykorzystanie materiału genetycznego w Polsce i na świecie

Streszczenie

Obecnie wypracowane, opublikowane i stosowane modele świadomej zgody w przypadku wykorzystania, obróbki lub użycia materiału genetycznego wydają się niewystarczające i mogą prowadzić do nadinterpretacji lub złej interpretacji zasad formalnych użycia składowanego materiału genetycznego. W praktyce medycznej dąży się do uzyskiwania zgody pacjenta na wszelkie zabiegi, nie tylko terapeutyczne, lecz także na inne, np. mające charakter diagnostyczny. Zabiegi te, często pozbawione bezpośredniego celu leczniczego, łączą się nierzadko z dużym ryzykiem dla zdrowia pacjenta, który powinien o tym wiedzieć. Najczęściej stosowaną formą zgody jest tzw. zgoda świadoma, przy której kładzie się nacisk przede wszystkim na zrozumienie przez pacjenta tego co musi podpisać na określonym formularzu. Świadoma zgoda jest podstawowym elementem w kwestii subiektywnego zezwolenia na poddanie się jakiemukolwiek działaniu ingerującemu w sferę cielesno-psychiczną człowieka. Aktualnie obowiązujące przepisy zawarte w wielu niezsynchronizowanych ze sobą aktach prawnych w sposób wybiórczy traktują koncepcję świadomej zgody w przypadku pracy na materiale genetycznym (wykorzystanie, użycie, obróbka) i jego terminalnego (okresowego) wykorzystania. Kwestia biobankowania materiału genetycznego (zarówno na świecie jak i w Polsce) nie ma jeszcze jednego wiodącego i lansowanego rozwiązania, a występujące normy określające typ i rodzaj zgody są raczej częściami różnych aktów formalnych, niż jakimś jednym standaryzowanym modelem. Potrzebna jest nowa ujednolicona wykładnia prawa będącą podstawą dla pojęcia zgody jako oświadczenia woli w przypadku wykorzystania materiału genetycznego.

W pracy przedstawiono prawno-formalne ujęcie kwestii pojęcia i zakresu zgody, jako oświadczenia woli w przypadku wykorzystania materiału genetycznego. Dokonano analizy obecnie występujących w Polsce i na świecie rozwiązań prawnych ujęć kwestii pojęcia i zakresu zgody, jako oświadczenia woli w przypadku wykorzystania materiału genetycznego. Omówiono faktyczne i hipotetyczne kwestie sporne i interpretacyjne. Przedstawiono autorskie rozwiązanie uściślające kwestie świadomej zgody, które może być wykorzystane w praktyce.

Słowa kluczowe: oświadczenie woli, materiał genetyczny, zgoda pacjenta, polityka zdrowotna.

Patient consent to the use of genetic material in Poland and worldwide

Abstract

Currently developed and functioning models of so-called informed consent seem to be insufficient in case of the application, handling, or use of the genetic material, and may lead to over-interpretation or misinterpretation of the formal rules for using the stored genetic material. In medical practice, the aim is to obtain patient's consent to any interventions not only therapeutic, but also other, having a diagnostic character. These interventions often lacking direct medicinal goal, are often associated with a high risk to the health of the patient, who should be informed about that. The most common form of consent is called informed consent, in which the emphasis is primarily put on the patient's understanding of what needs to be signed on a specific form. The informed consent is a fundamental element of the subjective permission to submit to any intervention that interferes in bodily-mental realm of man. Currently valid provisions contained in a number of non-synchronized with each other regulatory acts selectively treat the concept of informed consent in the case of working with genetic material (the use, processing) and its terminal (temporary) use. The issue of storing genetic material in biobanks (both worldwide and in Poland) does not have a leading and promoting solution, and the present standards specifying the type and nature of consent are rather formal parts of different formal acts than a single standardized model. There is a need to have a new uniform interpretation of the law, which could be the basis for the concept of consent as a declaration of intent for the use of genetic material.

The report presents a formal-legal approach to the issue of the concept and scope of consent as a declaration of intent, in the case of genetic material use. The currently existing in Poland and in the world legal solutions of the interpretations of the concept and scope of consent, as a declaration of intent for the use of genetic material, have been analyzed. The actual and hypothetical disputable and interpretation issues have been discussed. The paper presents original solution clarifying the issues of informed consent, which can be used in practice.

Keywords: declaration of intent, genetic material, patient's consent, health policy.

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INTRODUCTION

The The legislation in effect (national, EU, worldwide), did not work out a fully rational concept of principles governing the issue of storage of genetic material (agreement with its elements), due to the novel character of this problem, and the solutions in operation are imprecise considering their scope, and insufficient from the aspect of use in the case of collection and use of genetic material. The solution presented below, which specifies the issues of informed consent, may be used in practice, both with respect to executing regulations to current legality, and may constitute an independent legislative solution.

Formal-legal definitions of consent

Current regulations in effect contained in many mutually non-synchronized legal acts, in a selective way approach the concept of informed consent in the case of work with genetic material (application, use, processing), and its terminal (or temporary) use.

The basic legal Act which could rationally standardize these problems is the Committee on Bioethics of the Council of Europe, called the Oviedo Convention. This Convention was signed by Poland in 1999; however it has not yet been ratified [1]. The Convention imposes on individual countries the duty to specify limits and conditions of development of bioethics, and may also relate to the tasks in the area of genetics (on the basis of analogy and not directly). The concept of informed consent introduced by the Committee on Bioethics is insufficient in the case of work with genetic material, this work understood as its storage, use and subsequent processing, with its later terminal use. The Matter, which the Convention concerns in the section of the terminal use of genetic material, is not unequivocally specified, and the existing records may be interpreted on the basis of analogy, and not directly. Article 5 of the Committee on Bioethics of the Council of Europe states that an intervention in the health field may only be carried out after the person concerned has given free and informed consent [1]. Prior to intervention, this person shall beforehand be given appropriate information as to the purpose and nature of the intervention, as well as on its consequences and risks. This article stipulates the free and informed consent of anyone whom the medical intervention concerns. It seems obvious that the postulate of freedom is a starting point for informed consent and the elements contained therein. Article 16 of the Convention states that this consent should be given expressly, specifically and documented [1]. From the context of this recording, it may be presumed that it should be unequivocal, formulated and expressed in written form. Nevertheless, it comes to mind that these conditions could be specified directly, and not in the context which, in the case of storage of genetic material, is of great interpretative importance. According to Article 19 of the Convention, pertaining to the issues of expressing consent for the removal of organs or tissue from a living person for transplantation purposes, the consent must be given expressly and specifically, either in written form or before an official body [1]. This clause is more precise, specifies the circumstances and formalizes the dimension of the consent.

The Madrid Declaration of the World Health Organization of 1987 is the subsequent legal Act (here, of lesser rank and importance), which in Article 3 states that the procedure in the matter of medical intervention must be very precisely discussed with the patient, and the consent of the patient or his/her caregivers/legal representatives must be informed, voluntary and in written form [2]. In this Act, the postulate of informed consent and its written expression is more specific and clear.

However, Article 12 of the Resolution of the Parliamentary Assembly of the Council of Europe of 17 April 1989, states that while conducting genetic research, the condition must be fulfilled of obtaining patient consent concerning information about the study results [1]. The legal regulation thus quoted pays attention to the issue of providing information (so-called full), which is important for the potential patient consent (or lack of such consent) for genetic research.

Article 16 of the Act of 6 November 2008, in the matter of patient rights and the Patient Rights Ombudsman, states that the patient has a right to express consent (or refuse such consent) for the provision of specified health services [3]. The quotation from the Act pertains to only one basic patient right, i.e. the right of a patient to express consent, or refuse such consent in the matter of the provision of health services.

The subsequent Article 32 of the Act of 5 December 1996, in the matter of the Occupation of a Physician and Dentist, states that a physician may perform an examination or provide other health services, with the reservations and exceptions prescribed by the statutory law, after the expression of consent by a patient [4]. This article, in a concise way, again states the basic patient right, the right to express consent for an examination or medical procedure. Article 34 states that a physician may perform a surgical procedure or apply a treatment or diagnostic method associated with an increased risk for the patient, after obtaining a written patient consent [4]. According to this article, the precondition of a written consent is reserved for methods related with risk higher than normal, generally outstripping the type of formal (written) consent, which currently seems to be the standard procedure in medicine.

Article 19 of the Act 1 Clause 3 of the Act of 30 August 1991, in the matter of Health Care Facilities, states that a patient has the right to express consent for the provision of specified medical services or to refuse this consent, after obtaining adequate information [5]. Again there occurs the element of informed consent; however, without the determination of its conditions or specific details. The concept of so-called informed consent, which will be discussed in a later section of this article, also occurs in the Regulation by the Minister of Health in the matter of Detailed Requirements of Good Clinical Practice [6]. Thus, an informed consent to participate in the examination is the process during which the potential participant voluntarily expresses the wish to participate in the specified examination, after being informed about all aspects of the examination, which are important while making the decision about participation. The consent is given in a written form, in the so-called 'Form of Informed Consent' [6]. Further on, according to this Act, as an expression of informed consent is considered a declaration of intent to participate in a clinical examination expressed in a written

form, dated and signed, voluntarily submitted by a person capable of providing such a declaration, and in the case of a patient incapable of submitting such a declaration – by a legal representative; the declaration also contains a mention that it was provided after obtaining adequate information concerning the essence, importance, effects and risk associated with the clinical examination, and also after being informed about the due right to withdraw from the clinical examination at any time [6]. In this document, the element of volunteering, full information, and way of formalization of expression of consent in written form, is relatively clearly accented.

The Civil Code as the basic Act concerning the specification of voluntary actions and legal relations between the participant of social life, states in Article 60 that with the reservations and exceptions provided by law, the intention of the person performing the legal Act may be expressed by each behaviour of such a person, which reveals his/her intent, is a sufficient way, including also the disclosure of this intent in an electronic form (declaration of intent) [7]. In the presented article, attention is paid to the subjective possibility to express intent which, in the case of building civil-law relationships, is a basic requirement. Article 78, in turn, pertains to the maintenance of a written form of a legal action, for which it is sufficient to provide a personal signature on the document covering the contents of the declaration of intent, i.e. provision of signature [7].

Form and type of consent

At present, the form of implied consent, e.g. by nodding, is increasingly more rare, which rightly evokes controversy with respect to the actual manifestation of will, for instance in the case of understanding the information communicated. The form of consent is a formal expression of one's own free will, i.e. in practice, it resolves itself into the signing of an appropriate document in an adequate form [8]. At present, there is a tendency towards the so-called informed consent, which will be discussed further on, with the emphasis placed primarily on the understanding by a patient of what is submitted for signing. A current tendency is also the mechanism of obtaining patient consent to all procedures, not only therapeutic, but also other procedures, e.g. of a diagnostic character. These procedures, frequently deprived of a direct diagnostic goal, are often associated with a high health risk for the patient, who should be made aware of this [9]. For example, especial controversy and doubt may be evoked by the blood test for the presence of HIV, as well as the problem of informing these patients and obtaining their consent for performing the test [10]. For example, in the USA, in such a case the Confidentiality Act of Illinois requires the written informed consent of a patient. The patient must be informed in advance that the test for the presence of the HIV virus is voluntary, and consent may be withdrawn any time, the patient must know the goals and recommendations for performing the test, maintenance of anonymity, and limitations in disclosing the results of the test [11]. In Poland, the team for the AIDS at the Chief Medical Council, in 1992 adopted the following approach – a physician performing diagnostic actions to diagnose the disease has no obligation to obtain patient consent concerning the scope of examinations performed, including the test for HIV infection; however, a physician is obliged to inform patients, at their express wish, about the aim of performing the examinations (including those for HIV infection) [11].

At present, the types of consent are as follows:

- own consent – the intent expressed by a patient concerning instructions concerning medical procedures or interventions, which is applied if there are no special circumstances which would make it impossible, e.g. the state of sanity.
- surrogate consent – is applied when a patient cannot decide about own treatment, e.g. due to insanity. The requiring of information and consent is expressed by someone else. Surrogate consent is expressed by the statutory representative in the case of an underage person (under 16), and in the case of a person incapable of expressing consent (a legally incapacitated person), or a guardianship court, if the given person does not posses a statutory representative or cannot come to an understanding.
- parallel consent – in certain situations a consent by both a patient and caregiver (actual or formal) is needed. Parallel consent is applied when a patient is underage, but is aged over 16, and also when a patient is legally incapacitated, but is capable of expressing himself/herself, with recognition, in the matter of the health service provided.

Informed consent as a basic element in the matter of subjective permission to be subjected to any intervention interfering with the human physical-psychological sphere

The constant development of medicine, accompanied by an increasing invasiveness and variety of interventions within human body, requires the development of appropriate regulations specifying the principles of interference of physicians with the body and psyche of a patient, and enabling the patient's full autonomy. A gradual transition in physicians' behaviours and actions has been observed from paternalistic approach towards partnership, aimed at mutual decision-making with respect to the diagnostic and treatment methods by both parties participating in this process [12]. The mechanism discussed is most clearly observed with relation to the undertaking of medical interventions, after obtaining patient consent [13].

The concept 'informed consent' first appeared in the legal terminology in 1957 in the case of Salgo vs. Leland Stanford Junior University Board of Trustees [14]. However, it was introduced much later into the legal regulations applied in everyday medical practice, and became the foundation of patient autonomy, and simultaneously, patient's subjective consent to the risk appearing in association with medical interventions planned, both therapeutic and diagnostic. An informed patient consent to the planned diagnostic or therapeutic procedure is not only the basic precondition of physicians' acting in accordance with the law, but also an important criterion of ethical evaluation of their intentions and actions. The necessity to obtain the informed consent is emphasized in many legal systems in various countries in many verdicts concerning this matter. For example, in the USA, the standard for case law became the verdict of 1914 in the case of Schloendorff vs. Society of New York Hospital, Cardozo wrote in the Court's opinion: 'Every human being

of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained' [14]. The French Court of Appeal in the verdict of 1988 reminded that without free and informed patient's consent a physician cannot undertake any medical intervention if there is no obvious necessity or direct risk for the patient [11].

One of the definitions of 'informed consent' (developed in the USA and adopted by some European countries) states that a patient has the right to consciously participate in all decisions including him/her in the process of health care, after achieving a clear, brief explanation of all aspects of the medical interventions proposed, with the consideration of rational alternatives of medical procedures, assessment of the risk of death, serious complications related with each alternative method of medical intervention, determination of probable convalescence problems and possibilities to achieve a successful outcome [8]. A patient has the right to know the details of the diagnosis and results of examinations at any time when he/she expresses such a need, and has an access to own medical records and results of examinations. A competent patient cannot be subjected to any medical procedures or examinations without his/her earlier expressed an informed consent. Consent obtained in this way plays a dual role, i.e. specifies and explains to what a patient may agree, and fully legally authorizes a physician to a specified action. In the concept of informed consent it is noteworthy that for procedures related with the risk of death or severe disability, all aspects pertaining to the problem should be explained in a written form requiring the signature of a patient or a legal representative entitled to make decisions in the name of the patient when he/she is incapable of making such a decision [15]. Informed consent means satisfying the condition of passing appropriate information by a physician in a way accessible to a patient, understanding of the information acquired and evaluation of the consequences of the decisions made, which may (or may not) be foreseen by the physician [12]. While obtaining an informed consent a physician must know that it is inseparably connected with the maintenance of a patient's autonomy, understood as as a subjective and free volitional decision made with the upholding of the three following elements:

1. patient's intentional actions (a patient expresses consent in the proposed form);
2. understanding of information obtained from physician (patient has been fully familiarized with the explanations, scope of problems and contentious questions related with the intervention);
3. lack of external factors affecting the decision made (patient's decision concerning the intervention is fully rational, well thought-out and adequate to the occurring situation) [16].

Summing up, in the matters of widely understood medical intervention a so-called consent must be obtained from the patient or person concerned, i.e. a declaration of intent enabling acting in a concrete, specified direction (examinations, interventions, as well as the specification of issues concerning certain dispositions related with biomedicine – the possibility to donate organs or genetic material, etc.). This consent must be informed, i.e. satisfy the precondition of informing, explaining, and understanding the information or details communicated, also expressed in written form, i.e. in the form of a specified form (or forms) and signed by the subject concerned (patient, legal representative).

Collection and storage of genetic material with possibility of its later use

The above-mentioned concepts of consent concerning the donation, storage and later (timely) use of the genetic material collected seem to be insufficient. This probably results from the fact that efforts to solve the problem of storage of genetic material in institutions, called Biobanks, are still being actively carried out in the search for good rational solutions [17]. Currently, Biobanks worldwide experience a dynamic development – which has been rapidly accelerated, especially after the sequencing of the human genome in 2000. These are both private and State institutions which collect biological material for clinical purposes (in association with transplantations, transfusions, genetic diagnostics), for research purposes (e.g. studies on neuro-degenerative disorders, monozygotic twins or isolated populations), as well as for the needs of police investigations [17]. In the activity of this type of institution, legislative solutions which are adequate from the formal aspect must play the key role, including the solution of the problem of donation, storage and later (timely) use of the collected material [17]. Considering the novelty of the scope of the problems undertaken (the status from before the development of the Act in the matter of Biobanks), this institution may be defined, while searching for the definition by analogy, e.g. Polish Transplantation Act revised in 2009 defines biobanks as organizational units carrying out activity related with the collection, processing, sterilization, storage and distribution of tissues and cells. Studies on the storage of genetic material are characterized by low risk for the donor, lack of clearly specified goal at the moment of collecting samples (data), and specificity of studies, e.g. multiple use of the same samples, lack of clearly defined benefits from this type of activity [17].

The issue of biobanking of genetic material (both worldwide and in Poland), to date lacks one leading and promoted solution, and the existing standards specifying the type of consent are rather parts of various formal Acts than one standardized model. The greatest controversy and doubt is evoked by the scope of consent for scientific research which will be conducted in the future (and frequently the specific goal, scope, place of study, and the researchers being presently unknown) [17].

Existing solutions concerning the problem of consent to donate and use genetic material

The proposed formal solutions presented below are not complete total solutions, but rather try to solve the problems of consent by analogy, taking certain definitions from already existing or developed legal Acts or guidelines.

The UNESCO and WHO bioethics committees propose 'consent in blanco' for research which may be undertaken in the future [17]. This consent is characterized by a very wide

scope of declaration of consent in the case of use of genetic material. The subsequent solution is so-called presumed consent (former) with the possibility of its denouncement and potential determination, or if and after what time the information concerning DNA donor will be withdrawn from a database. A single consent would be more convenient for the researcher, nevertheless, the value and validity of the consent expressed for something unknown is questioned, even more so, as indicated by the studies, a large population group is in favour of obtaining a repeated consent while using the samples in subsequent studies.

The CIOMS (Council for International Organizations of Medical Sciences) is of the opinion that if the studies are associated with minimum risk, and the obtaining of consent would make this study impossible to conduct, the ethics committee may revoke the requirement to obtain consent (or its certain elements) and transfer decisions in the matter of the use of the samples to bioethics committees. Caufield et al. suggested an authorization model, that would make it possible to define what usage of the samples the donors do not accept, or what situations demand asking them for a subsequent consent (e.g. clinical examinations of importance to them, or commercial use of the results) [17]. In turn, the First Genetic Trust, an American biotechnological concern, worked out a procedure of dynamic consent by sending to the donor via electronic mail information in the matter of the use of his/her samples prior to the subsequent study. However, such an approach has its limitations – it may exclude the samples of donors who have no access to this type of service, or do not possess skills of using electronic mail (e.g. the elderly) [17]. The European Society of Human Genetics proposed the differentiation of the rules of informed consent according to whether the collection has existed before or it is being created – in the latter case, consent is always required, while the existing biobanks may be divided into those possessing in their collection samples coded without the possibility of identification of the donor, and samples for which the identification of the donor is possible. With respect to the first type, samples may be used without repeated consent (after acceptance by a bioethics committee), whereas, when the obtaining of repeated consent is possible, the researchers should apply for such a consent [17].

Controversies and areas of postulated solutions

In this sub-section, problematic issues concerning the act of consent in the case of donation and transfer of genetic material will only be mentioned. Their solution requires the specification of many factors occurring in various legal systematics; nevertheless, the elements mentioned seem to be a priority in a correct and rational model of informed consent in the area of biobanking of genetic material. Firstly, by the determining and enabling an expression of the declaration of intent, controversies should be specified concerning the property title of the genetic material stored. A basic question arises 'whose is the genetic material collected?' There may be several solutions, for example, it may be the property of an individual who donates it, together with all formal principles which accrue to the property entitlement (issues of legacy, alienation, cession, etc.). An additional problem is posed: during what period of time is this right to accrue, or should it be related with the life span of the donor, or shorter, or established as a specific time, e.g. 100 years. Another possible solution is the consideration in the declaration of informed consent the possibility to transfer property entitlement to a specified subject; however, in such a situation there again appears the question what subject it should be (or may be), whether this may be, e.g. the offspring (beneficiaries) of the genetic material donated. Should it be exclusively an institution collecting genetic material (biobank), or statutorily established entity (such as a Blood Bank), or should it be the State Treasury? Each of these solutions entails a number of doubts, interpretations and material difficulties; nevertheless, the scope and goal of this article does not concern the analysis of this subtle scope of problems.

The subsequent issue which at present is controversial, is the determination of the donating subject, i.e. specification who can donate genetic material. With respect to an individual with full capacity to perform acts in law, it seems that there is no doubt concerning this issue; however, matters of opinion occur in the case of legally incapacitated individuals, those under-age and children. The problem concerns power of attorney in the form of a notarial deed, representation (guardian) and judicial consent for this type of activity. Namely, can formal decisions of other parties (appointment of caregiver, authorization, guardianship) be so far reaching and so widely interpreted, because this is not a case of direct threat to life or medical intervention aimed at improving the state of health. An extremely subtle matter is the question of whether in the case of children and those incapacitated there may exist the possibility of a decision made by someone else (court, guardian), concerning the collection and donation of genetic material. This matter is certainly very problematic and requires wide discussion. The subsequent problem worth specifying is the determination of formal principles pertaining to the matter, i.e. donated genetic material. There arises the question concerning the content of the right to the material, i.e. determination of the legal share in the genetic material collected, i.e. if the declaration of consent covers all the genetic material, or only its components; and finally, if it concerns only one of its components (e.g. necessary for a study).

The subsequent issue evoking similar problems is the time (a terminal element of the proposed form of consent) of storage and specification of formal participation in the rights to genetic material. This situation is similar to the specification of the right to property and time when it accrues; however, in the part of the declaration of intent in the matter of the storage of genetic material it may be clearly specified what period of time genetic material may be stored in a biobank. With respect to this, principles must be specified which determine what will happen after the specified time, i.e under what conditions this material can be destroyed, or continue to be stored.

The above-mentioned aspects are only an attempt to present the complicated scope of problems concerning the storage of genetic material, which evokes many formal questions.

CONCLUSION

There is no doubt that the legal form of consent, i.e. written consent (signing of an appropriate document after comprehension and agreement) is the only permissible route towards the determination of principles of donation, storage and use of genetic material in institutions called biobanks. However, the above-mentioned problems appear pertaining to the matter of property, time of storage, and rights to genetic material. The authors postulate two possible ways to solve this issue. The first is the currently existing concept of informed consent to donate genetic material, expanded by the above-mentioned elements, i.e. this would be formally specified consent to donate genetic material, expanded by the terminal element (time). In a formal document (act, declaration of intent), the elements concerning rights to property would be clearly defined, and consequently, time and conditions of storage (terminal element), as well as the rights (or lack thereof) to this genetic material during the period of storage. The second possible solution is the introduction of contract systematics and the creation of a pattern of a specific declaration between the participating parties (the collecting subject, which is the biobank, and the donor), where the above-mentioned elements would also have to be included (matters of property and duration of storage). This declaration, due to basic principles governing the legal regime, could be specified each time for the needs of an individual donation, its detailed important components being determined and defined.

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