PRZEGLĄD PRAWA MEDYCZNEGO

Preventive removal of an organs based on the result of a genetic test. Selected legal aspects and the patient's right to decide on their treatment

Reference version

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Summary

In existing clinical practice, one of the standard therapeutic methods is the removal of an organ that is already affected. However, there is no established practice of removing healthy organs. Such action, if not medically justified, would, moreover, be illegal under law. The exceptions to this are ovariectomy (removal of ovaries) as a treatment for hormone-positive breast cancer and orchidectomy (removal of testicles) as a treatment for hormone-positive prostate cancer. In addition, as of 2019, prophylactic removal of the breast gland (mastectomy) has also begun to be reimbursed in Poland for women carrying BRCA1 / BRCA2 mutations. However, other procedures that can eliminate the potential incidence of cancer through prophylactic removal of the organ are not reimbursed, nor are they the subject of medical standards (guidelines). Thus, the question of the limits of acceptability of such procedures remains open.

Key words

Genetic testing, mutations, prophylactic organ removals, legality of the procedure, patient's rights

Introduction

Based on the results of genetic testing, we learn that a given organ may or may not become diseased. Genetic testing does not answer the question of whether someone will develop cancer, but only whether that person's risk of developing cancer is higher than average in the population, due to a detected genetic defect. The legal situation would be clear if genetic testing results gave a 100% probability of the occurrence or non-occurrence of cancer in a currently healthy organ. However, since this is not the case, doctors may have concerns that removing a healthy organ that could only potentially become diseased could result in civil or even criminal liability for the doctor, due to the content of Article 156 § 1 of the Criminal Code[1] , which states that a person who causes serious damage to health in the form of deprivation of the ability to procreate (excision, infibulation, or other permanent and significant mutilation of the sexual organ) or other serious disability, serious incurable or long-term illness, is subject to imprisonment for a term of 3 to 20 years.[2] On the other hand, the constant development of knowledge and its dissemination, for example, through databases available on the Internet, will influence the decisions of many people. Therefore, more and more people may decide to undergo genetic testing as a simple preventive measure, especially if cases of such diseases have already occurred in their family. Understandably, some people with a detected mutation who are still oncologically healthy but face the prospect of regular check-ups and living in fear of the onset of the disease may seek ways to avoid becoming ill by, for example, undergoing surgery to remove the organ at risk of disease. Just like in every other situation where clear guidelines have not yet been established, the question arises as to the limits of a doctor's responsibilities and the limits of a patient's right to decide on their own treatment.

Genetic test results and the risk of developing cancer, using breast cancer, ovarian cancer, and colorectal cancer as examples

Today, science can identify numerous mutations (e.g., BRCA1/2, CHEK2, NOD2, PALB2, p53) whose presence in carriers is associated with a higher incidence of cancer, faster disease progression, and poorer prognosis. Of course, not every mutation carries the same risk. For example, the BRCA1/2 mutation carries a 75% risk of developing breast cancer, while other mutations increase this risk by ‘only’ about 10%. This knowledge also influences the decisions

[1] Act of 6 June 1997 – Penal Code (Journal of Laws 2024, item 17).

[2] The amendment to § 1 and 3 of Article 156 entered into force on 1 October 2023 (Journal of Laws 2022, item 2600 and 2023, item 403); while the added point 3 in § 1 of Article 156 and the added Article 156a entered into force on 15 August 2023 (Journal of Laws 2023, item 289).

of the public payer (the National Health Fund – NFZ) regarding the reimbursement of certain treatments. We will return to this issue in the next section.

Scientists have developed a special catalog of somatic mutations, COSMIC, which is the most detailed and comprehensive source for studying the impact of somatic mutations on cancer development in humans.[3]

To illustrate the scale of the phenomenon, basic information on genetic inheritance and mutations in breast and ovarian cancer will be briefly discussed. In general, most cancers, including breast cancer (70-75%) and ovarian cancer (75-90%), arise as a result of the accumulation of somatic mutations, i.e., non-hereditary mutations that are acquired during an individual's lifetime and are not inherited because they are limited to the DNA of cancer cells. Another 15-20% of breast cancers are familial; they develop as a result of the combined action of constitutional genetic susceptibility and the harmful effects of environmental factors, resulting in the appearance of mutations associated with cancerous transformation. Finally, 5-10% of breast cancers and 10-25% of ovarian cancers are hereditary.[4] There are currently about 100,000 women in Poland who are carriers of pathogenic BRCA1/2 mutations, i.e., at significant or high risk of developing breast or ovarian cancer, exceeding 40-50%.[5]

Hereditary breast and ovarian cancer can manifest itself as one of three syndromes:

1. Hereditary breast cancer specific to a particular organ (Hereditary Breast Cancer-site specific (HBC-ss) – in this syndrome, breast cancer occurs in a given family, but not ovarian cancer;

2. Hereditary ovarian cancer (HOC) – in this syndrome, ovarian cancer occurs in a given family, but not breast cancer; and

3. Hereditary breast-ovarian cancer syndrome (HBOC) – in this syndrome, both breast and ovarian cancer occur in a given family.

In the Polish population, the incidence of founder mutations in breast cancer patients, regardless of their age, is approximately 3%; therefore, there is no justification for performing population-based genetic screening.[6] Genetic testing does not provide any information about the patient's

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[3] *COSMIC: The Catalogue Of Somatic Mutations In Cancer*, 'Nucleic Acids Research' 2019, vol. 47, issue D1

[4] A. Doraczyńska-Kowalik, G. Janus-Szymańska, R. Matkowski et al., *Podstawy medycyny personalizowanej w leczeniu raka piersi i raka jajnika*, 'Nowotwory' 2020, no. 5, pp. 255–272.

[5] https://biotechnologia.pl/farmacja/mz-refundacja-profilaktycznej-mastektomii,18510, [access: 09.07.2023].

[6] J. Lubinski, B. Gorski, T. Huzarski, T. Byrski, J. Gronwald, P. Serrano-Fernandez et al., *BRCA1-pozytywne nowotwory piersi u młodych kobiet z Polski*, 'Breast Cancer Research and Treatment' 2006, no. 1, pp. 71-76.

current state of health, but only determines their predisposition to the disease. They are performed on two groups of patients: sick and healthy individuals. The first group includes patients: (1) in whom genetic testing will influence the type of treatment, (2) with a suspected hereditary predisposition, which is justified primarily in individuals who developed cancer at a young age, especially if they have relatives who have already been diagnosed with cancer, and (3) all patients with medullary thyroid cancer, adrenal cancer, ovarian cancer, and patients with numerous (50 or more) polyps in the large intestine, regardless of the age at which they fell ill and their family history. In turn, healthy individuals are recommended to undergo genetic testing if a family member has been diagnosed with a mutation indicating a risk of developing cancer. Genetic counseling, which is reimbursed as part of outpatient specialist care, consists of two stages: (1) counseling and genetic testing, and (2) monitoring and diagnostic testing.[7] It is worth noting that the most important factor is the genetic testing method used, rather than how it is financed—whether from the patient's own funds or public funds. Genetic testing performed on people from the above-mentioned risk groups is reimbursed by the public payer (NFZ) and carried out within the network of genetic counseling centers, which require an e-referral issued by any doctor in the public healthcare sector.

Approximately 1% of breast cancer patients are also found to carry other mutations with a high degree of penetrance (TP53, PTEN, STK11, CDH1), and another 2% carry other mutations with a medium and low degree of penetrance (CHEK2, ATM, PALB2).[8] However, the most common causes of the above-mentioned syndromes are mutations in the BRCA1 and BRCA2 genes. It is assumed that in the Polish population, the risk of developing breast cancer for BRCA1 mutation carriers is 75%, and for ovarian cancer 47%, while for BRCA2 mutation carriers the risk is 31-56% and 11-27%, respectively. Prophylactic removal of the ovaries and fallopian tubes in these patients reduces the risk of ovarian cancer to approximately 5%. When we talk about a 47% risk of developing ovarian cancer in BRCA1 mutation carriers, it means that statistically, 4.7 out of 10 women with a confirmed BRCA1 mutation will develop ovarian cancer in their lifetime. With such a high risk, it is recommended that these women undergo bilateral removal of the ovaries and fallopian tubes after completing their reproductive plans.[9] As for breast cancer, considering that it is the most common cancer in women, with a steady

[7] Regulation of the Minister of Health of 21 July 2022 amending the regulation on guaranteed benefits in the field of outpatient specialist care (Journal of Laws 2022, item 1542).
[8] J. Jassem, B. Radecka, *Rak piersi* [in:] *Onkologia Kliniczna tom 2*, eds. M. Krzakowski, P. Potemski, P. Wysocki, Gdańsk 2023, p. 720.
[9] N.D. Kauff, J.M. Satagopan, M.E. Robson et al., *Risk-reducing salpingo-oophorectomy in woman with a BRCA1 and BRCA2mutation*, 'The New England Journal of Medicine' 2002, no. 21, pp.1609-1615.

upward trend, it is a significant social problem. In 2020, approximately 25,000 people (mainly women) were diagnosed with breast cancer in Poland, and nearly 9,000 patients died from the disease. According to the GLOBOCAN 2020 database, the five-year incidence of breast cancer in Poland in 2020 was nearly 97,000 people. The incidence of breast cancer among women increases with age.[10]

Women with hereditary breast cancer usually develop the disease 15-20 years earlier than women with sporadic cases, i.e., those without a genetic basis. They are more likely to develop multifocal or bilateral cancer, and the initial stage of the disease is usually more advanced. Other cancers (mainly colon, prostate, endometrial, and sarcomas) are also more common in these individuals or their relatives. Women who are carriers of the BRCA1 mutation cannot use hormone replacement therapy, as its use may increase their risk of breast cancer by more than 30%.[11] Due to the high risk of developing the disease in carriers of these mutations, the removal of healthy breasts or ovaries is recommended for all patients who are carriers of the BRCA1/BRCA2 mutation after the age of 40.[12] The age of 35 or the end of childbearing (birth of the planned number of children) has long been accepted in American literature.[13] This age limit is based on the fact that the risk of ovarian cancer, even in carriers of the BRCA1/2 mutation, increases after the age of 40.[14] In this literature, the age of 35 years or the end of reproduction (birth of the planned number of children) is considered. These recommendations are in line with the guidelines in force in Poland: "Due to the significant risk of ovarian cancer in carriers of the BRCA1 and BRCA2 gene mutations, bilateral removal of the adnexa is recommended after the completion of reproductive plans (adnexectomy procedures to reduce the risk are not included in the basket of guaranteed services in Poland). Given the evidence indicating that a significant proportion of ovarian cancers originate in the fallopian tubes, preventive removal of the fallopian tubes should also be considered for women at low risk of

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[10] *Analiza problemu decyzyjnego. Alpelisyb (PIQRAY®) w skojarzeniu z fulwestrantem w terapii miejscowo zaawansowanego lub rozsianego raka piersi HR+ HER2- z obecnością mutacji PIK3CA*, Kraków 2021, pp. 7, 12-16.

[11] R. Wiraszka, M. Siołek, B. Kozak-Klonowska, *Zespoły rodzinne i dziedziczne raków piersi, jajnika i jelita grubego – przegląd literatury i wstępna ocena ich występowania w regionie radomskim*, 'Radomski Rocznik Lekarski' 2003, vol. 8, pp. 65-69.

[12] J. Lubiński, *Dziedziczny rak piersi i jajnika* [in:] *Nowotwory Dziedziczne 2002*, 2003.

[13] *Hereditary risk of breast and ovarian cancer: Implications for medical care* [in:] *Identyfying and managing hereditary risk for breast and ovarian cancer*, American Medical Association 2001; TS. Frank, GC. Critchfield, *Identyfying and managing hereditary risk for breast and ovarian cance*r, 'Clinics in Perinatology' 2001, no. 2, pp. 395-406.

[14] K. Jaszczyńska-Nowinka, *Ocena stężeń SDF1 i ekspresji jego receptora CXCR4 u chorych na raka jajnika*, Poznań 2011, p. 10.

ovarian cancer undergoing surgery for non-oncological reasons, after they have fulfilled their reproductive goals and after menopause.[15]

Another organ at high risk of disease is the large intestine. We are referring specifically to patients with Lynch II syndrome (HNPCC – hereditary non-polyposis colorectal cancer). Lynch II syndrome accounts for 2-5% of all colon cancers, with the risk of developing the disease in mutation carriers being 52-82% compared to 5% in the general population. This syndrome is also responsible for the development of other cancers at a significantly higher rate than in unaffected individuals. The lifetime risk of developing ovarian cancer is 12% vs. 1%, and for endometrial cancer, 40-60% vs. 2.7%.[16] According to current data in the literature, colonoscopy with polypectomy reduces the risk of developing cancer in the HNPCC group from approximately 40% to approximately 15%.[17] However, this does not reduce the risk to zero, and in individuals who have hundreds of polyps found during colonoscopy, a colectomy, i.e., complete removal of the large intestine, should be performed. In Poland, the Agency for Health Technology Assessment and Tariff System (AOTMiT) issued guidelines in 2020 confirming the validity of performing colectomy in carriers of the APC gene mutation.

However, the 2020 guidelines of the European Society for Medical Oncology (ESMO) recommend the use of laparoscopic colectomy in cases of colon cancer due to fewer complications and better tolerance in the patient group. The German GGPO 2019 guidelines pay particular attention to the issue of familial polyposis, regardless of genetic analysis. Prophylactic colectomy is recommended depending on the diagnosis and the patient's decision. Patients with classic FAP[18] should undergo prophylactic proctocolectomy no earlier than the end of puberty. In cases of endoscopically uncontrollable polyposis, colectomy is indicated.[19]

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[15] A. Basta, M. Bidziński, A. Bieńkiewicz et al., *Zalecenia Polskiego Towarzystwa Onkologii Ginekologicznej dotyczące diagnostyki i leczenia raka jajnika*, 'Current Gynecologic Oncology' 2017, no. 1, p. 6.

[16] B. Mąka et al., *Rzadka postać zespołu Lyncha z trzema synchronicznymi, o podobnym zaawansowaniu, ogniskami gruczolakoraka okrężnicy*, 'Chirurgia Polska' 2013, no. 1, pp. 88-92.

[17] K. Gan, *Postępowanie po polipektomii polipów jelita grubego, żołądka i dwunastnicy*, 'Gastroenetrologia Praktyczna' 2013, no. 3, pp. 59-74.

[18] FAP – *familial adenomatous polyposis*.

[19] Agency for Health Technology Assessment and Tariff System, Healthcare Benefits Department, *Preventive colectomy in individuals with a genetic risk of developing colorectal cancer*, Warsaw 2020, p. 21.

Legal aspects

There is no doubt that with such a high risk of cancer, which is several dozen percent among people with a given mutation, preventive removal of the organ is, in the light of current medical knowledge, a permissible action and in the best interest of the patient.

More difficult to assess are situations where the percentage difference in risk is not so clear, and medical standards, i.e., guidelines and recommendations issued by a group of experts, have not yet been developed.[20] The issue raised is not marginal. Let us assume a situation where a patient with the CHEK2 mutation (which does not justify subcutaneous removal of the mammary gland under conditions guaranteed by public funds) reports to a healthcare facility with a declaration that she consents to such a procedure, but is refused for the above reason, and is refused to have the procedure performed for a fee due to the lack of guidelines. About a year later, however, she develops breast cancer. Against whom, if anyone, can she bring a claim for compensation in civil proceedings? Can the person who refused to operate on her be held criminally liable? Or, on the contrary, will performing the procedure cause legal problems for the doctor?

Pursuant to Article 27 of the Criminal Code, a person who acts for the purpose of conducting a medical experiment does not commit a crime if the expected benefit is of significant medical importance and the expectation of achieving it, the purposefulness, and the manner of conducting the experiment are justified in light of the current state of medical knowledge. It would therefore seem that the provisions on medical experiments should provide the basis for the legal performance of the procedures in question. In our opinion, however, the possibility of considering such a procedure to be a medical therapeutic experiment should be rejected, even after obtaining the consent of the Bioethics Committee and other conditions referred to in Article 21 et seq. of the Medical Treatment Act.[21] Firstly, in 2020, a disastrous amendment was made to Article 21 of the Medical Treatment Act, replacing the term describing the person who

[20] Medical standards (guidelines) should be distinguished from organizational standards issued in certain areas of medicine by the Minister of Health in the form of regulations. It cannot be ruled out that a doctor's conduct may violate both types of acts at the same time, but we are concerned with expert guidelines, which constitute recommendations for conduct in the light of current medical knowledge (EBM). The published European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis are based on the latest research and clinical evidence, clarifying and standardizing existing recommendations for diagnosis, screening, and surveillance in colorectal cancer prevention. The Polish Society of Gastroenterology has adapted the European Guidelines by publishing the guidelines of the Polish Society of Gastroenterology on colonoscopy surveillance after polypectomy, and supplementary recommendations, approved by the Main Board of the Polish Society of Gastroenterology (PTGE), concern aspects of surveillance not covered by the European guidelines or represent expert opinions on clinically important issues for which there is a lack of relevant scientific evidence.

[21] Act of 5 December 1996 on the Professions of Physician and Dentist (Journal of Laws 2023, item 1972).

is a subject of a medical treatment experiment for health benefit, 'the person being treated', with the words 'the sick person'.[22] A person undergoing preventive organ removal, even at the highest risk, is not yet a sick person. Although one may wonder whether a purposive interpretation could be used instead of a linguistic interpretation, the principle of the so-called rational legislator casts doubt on the validity of this solution, and the doctor would remain in legal uncertainty. Therefore, one should agree with P. Konieczniak's view that it is currently not permissible to conduct a medical experiment on a healthy person, even with regard to preventive methods.[23]

Secondly, the essence of an experiment is a variable and unknown outcome, whereas removing a healthy organ before cancerous changes occur gives a very high probability – approaching certainty[24] – that the risk of cancer has been eliminated. This makes it all the more important to rule out the classification of such procedures as medical research experiments.

We also reject the concept of applying the doctrine of necessity to preventive amputations. Although the literature presents views on the possibility of invoking a state of necessity, for example, in transsexual operations[25], the existence of a premise of direct threat to the protected interest (Article 26 § 1 of the Criminal Code) is doubtful due to the lack of urgency and certainty of the threat.

The issue, therefore, boils down to whether the actions of a doctor performing such a preventive procedure are unlawful.

The unlawfulness of the procedure results in civil and criminal liability. Pursuant to Article 23 of the Civil Code[26], health is a personal right. The perpetrator who violates a personal right is liable for both material and non-material damage (harm, pain, mental suffering). The latter is compensated by damages. Article 448 of the Civil Code stipulates that in the event of a violation of a personal right, the court may award the person whose personal right has been violated an appropriate sum of money as compensation for the harm suffered or, at their request, award an appropriate sum of money for a social purpose indicated by them, regardless of other measures

[22] Act of 16 July 2020 on the amendment of Act on Professions of Physician and Dentist and several other acts (Journals of Laws 2020, item 1291).
[23] P. Konieczniak, *Eksperyment medyczny – sytuacja prawna po nowelizacji ustawy lekarskiej,* 'Przegląd Prawa Medycznego' 2021, no. 1-2, pp. 80-81.
[24] According to various sources on mastectomy – 90-98% certainty.
[25] P. Daniluk, *Stan wyższej konieczności jako okoliczność wyłączająca bezprawność „chirurgicznej zmiany płci"*, 'Państwo i Prawo' 2008, no. 1, p. 99.
[26] Act of 23 April 1964 – Civil Code (Journal of Laws 2024, item 1061).

necessary to remedy the effects of the violation. If the doctor is a contract employee, he or she is jointly and severally liable for both types of damage with the healthcare entity under civil liability. If, however, he is an employee hired under an employment contract, he is liable only up to three times the salary he receives at the healthcare facility, unless he caused the damage intentionally. In criminal proceedings, the court may also award compensation or a fine, and if it does not do so, the injured party may pursue compensation through civil proceedings.

Under criminal law, the possible liability of a doctor for causing serious, moderate, or minor bodily harm, punishable under Articles 156 and 157 of the Criminal Code, respectively, should be considered. As a rule, a doctor's actions for therapeutic purposes are not treated as a crime involving bodily harm. However, it may be considered as such if the doctor fails to meet the conditions that legalize his or her conduct in specific situations.

The starting point should be considering whether the cases discussed in the article involve a therapeutic purpose. The definition of a 'therapeutic purpose' was formulated by P. Daniluk. According to him, it is a situation 'when a given action is objectively directed at a disease in the biological-medical sense and aims at its prevention, diagnosis, therapy, or rehabilitation of the person affected by its effects'.[27] With a 'positive' genetic test result, we can speak of a direct threat of disease, and surgical intervention will obviously be aimed at preventing the onset of the disease, even if the risk is remote.[28] An example that comes to mind is preventive vaccinations, whose therapeutic purpose is beyond doubt, even when the risk of contracting a given disease is low.

There is an ongoing debate in criminal law doctrine regarding the legal nature of medical procedures – some authors advocate the concept of primary legality of such procedures, while others advocate the concept of secondary legality.[29] The concept of primary legality of medical treatment assumes that a doctor's actions aimed at saving life and health are lawful from the outset and cannot be treated as an attack on the life or health of the patient. Such actions are therefore immediately lawful and free from criminal illegality. However, they may lose their legal character if the doctor fails to comply with certain rules or requirements. In such a situation, what is referred to as secondary illegality occurs, which may lead to the doctor's

[27] P. Daniluk, *O pojęciach „zabieg leczniczy" i „pacjent" w rozumieniu art. 192 § 1 k.k.*, 'Prawo i Medycyna' 2011, no. 4, p. 66.
[28] M. Boratyńska, *Wolny wybór. Gwarancje i granice prawa pacjenta do samodecydowania,* Warszawa 2012*,* p. 213.
[29] Overview of arguments relating to both positions: A. Liszewska, *Kilka uwag na temat charakteru czynności leczniczych,* 'Acta Universitatis Lodziensis Folia Iuridica' 1995, no. 63, pp. 103-114.

criminal liability. In turn, the concept of secondary legality of medical procedures is based on the classic assumption of counter-type (justification). According to this approach, a doctor performing a procedure violates the integrity of the patient, which means that his action initially fulfills the characteristics of a prohibited act, as defined in criminal law. In other words, his action is initially unlawful. However, if the procedure is performed in accordance with specific conditions, such as the purpose and method of action, then this initial unlawfulness is excluded and the act becomes legal. In this sense, the doctor performing the operation technically meets the criteria for a crime against health or life, but a subsequent analysis of compliance with the conditions for a counter-type may mean that the act is not considered illegal.

We will leave aside the assessment of the accuracy of both approaches, and for further consideration, we will adopt the second view as potentially 'less safe' for the physician.

The conditions for the legality, i.e., the absence of unlawfulness, of a medical procedure are, as a rule, the therapeutic purpose, the informed consent of the patient or their legal guardian, the compliance of the action taken with current knowledge based on EBM and professional diligence, and the predominance of the expected benefits to the patient over the anticipated negative effects, i.e., the avoidance of iatrogenic actions, in accordance with the principle of *primum non nocere.*[30] Performing a medical procedure without the patient's consent (or even extending its scope)[31] is a separate offense listed in Article 192 of the Criminal Code. Of course, for the procedure to be legal, it must be performed by a person with formally confirmed qualifications.[32]

It should be noted here that criminal law doctrine presents an accurate view of the broad meaning of the term 'medical treatment'[33], which should be understood not only as treatments with a direct therapeutic purpose, and thus the purposive interpretation prevails over the literal one. The opposite position, based on a linguistic interpretation that the aim of medical treatment must be curing[34], is not acceptable, as it does not take into account the WHO's holistic definition

[30] The issue of exceptions to the prohibition on doctors acting without the patient's consent or going beyond EBM is beyond the scope of this article. However, it is worth noting the apt observation by M. Boratyńska and P. Konieczniak that compliance with EBM does not always have to be in concreto consistent with the principle of patient benefit after taking into account the balance of gains and losses. (M. Boratyńska, P. Konieczniak [in:] *System Prawa Medycznego. Tom II. Część 1. Regulacja prawna czynności medycznych,* eds. M. Boratyńska, P. Konieczniak, E. Zielińska, Warszawa 2019, p. 75).

[31] See, for example judgement of the Supreme Court of 28.11.2007, ref. V KK 81/07, OSNKW 2008, No. 2, item 14.

[32] Valid license to practice, sometimes a specific specialization.

[33] A. Zoll, *art. 192* [in:] *Kodeks karny. Część szczególna. Komentarz, t. II: Komentarz do art. 117–277 k.k.*, ed. A. Zoll, Kraków 2006.

[34] R. Rejmaniak, *Problemy interpretacyjne wybranych pojęć zawartych w art. 192 k.k.,* 'Czasopismo Prawa

of health. According to said definition, health is a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity.[35]

With regard to the patient's right to obtain information and give consent, this issue is regulated by the Act on Patient Rights and the Patient Ombudsman, which states that the patient has the right to accessible information about their health condition, and the right to give consent to specific health services or refuse such consent, after obtaining the relevant information.[36] This means that the doctor should provide the patient with information in a manner adapted to their ability to understand, i.e., in a language that is understandable to the individual patient. It should also be emphasized that the patient's consent to a medical procedure must be given before the procedure is performed, which means that medical information should be provided well in advance to give the patient sufficient time to consider, ask additional questions, and even consult with other specialists or at other centers. The legality of a preventive organ removal operation is conditional on the consent of the patient, who has been duly informed not only about the threat posed by the mutation, but also about the risks associated with the procedure itself, and on how the patient will function after the organ removal. It is necessary to present alternative methods of treatment (in this case, prevention), with a reliable indication of their effectiveness. If the doctor knows that more accurate or comprehensive genetic tests are available, even if they are not reimbursed, they should also provide the patient with the relevant information.

Only such information will allow the patient to transform it into real knowledge and awareness, which will form the basis for properly given, informed consent to the proposed medical procedures. Any paternalistic pressure should be excluded, such as referring to potential motherhood or other emotions, unreliable comparisons of different methods, exaggerating risks, or, conversely, downplaying them.

Austria provides an example of a good legal solution. Due to individual differences in risk perception and diversity of life plans, particularly with regard to the potential desire to have children, Austrian genetic law prohibits the provision of advice aimed at encouraging or discouraging preventive surgical procedures. Preventive procedures such as preventive mastectomy (PBM), preventive salpingo-oophorectomy (PSO), or preventive hysterectomy

Karnego i Nauk Penalnych' 2012, no. 4, p.70.

[35] 'Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity', https://www.who.int/about/governance/constitution.

[36] Act of 6 November 2008 on Patients' Rights and Patients' Rights Ombudsman (Journal of Laws 2024, item 581), Article 9(2).

(CPM), may only be offered to women at risk after they have been thoroughly informed about the age- and mutation-dependent risk of disease and about the impact of PSO on fertility and hormone levels. According to § 69 of the Austrian Genetic Engineering Act (Gentechnikgesetz), genetic counseling must include 'a comprehensive discussion of all relevant results of genetic testing and the potential medical, social, and psychological consequences.' Genetic counseling must therefore not aim to persuade the patient to choose one of the possible further courses of action, which means that, for example, an unambiguous recommendation to perform PBSO is not acceptable under Austrian law.[37]

It is also worth noting Article 5 of the European Convention on Bioethics[38], according to which any intervention in the field of health is possible 'only after the free and informed consent of the person concerned has been obtained.' The Convention also requires that the person undergoing medical intervention be given sufficient information about the purpose and nature of the intervention, as well as its consequences and risks.

Assuming that the patient consents to the procedure in question, the most important issue is to assess whether the procedure would be consistent with EBM. Pursuant to Article 6(1) of the Act on Medical Activity, the patient has the right to health services that meet the current requirements of medical knowledge. It should be noted here that the fact that a given procedure is not included in formalized medical standards does not mean that it is not consistent with current medical knowledge, which may be available, for example, in the form of publications in recognized foreign scientific journals. Furthermore, the literature indicates that since EBM is based on epidemiology and statistics, a conscientious physician should be able to independently assess risk factors and not rely excessively on clinical practice guidelines.[39] Furthermore, a violation of one of the specific guidelines does not always have to be tantamount to an error resulting in disciplinary or criminal liability.[40]

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[37] C. Singer, M. Tea, G. Pristauz et al*., Clinical Practice Guideline for the prevention and early detection of breast and ovarian cancer in women from HBOC (hereditary breast and ovarian cancer) families*, 'Wiener klinische Wochenschrift' 2015, no. 127, pp. 981–986.

[38] The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine concluded on 4 April 1997 in Oviedo, Article 5; Although Poland has signed the convention, it has not yet ratified it, so formally the convention is not part of the Polish legal system, but Article 26 of the 1969 Vienna Convention on the Law of Treaties (known as the 'mother of all conventions') introduces the principle of pacta sunt servanda, i.e. the performance of a treaty in good faith, which obliges states to act in the spirit of such a convention already in the period between the signing of the convention and its ratification.

[39] W. Borkowski, *Medycyna oparta na dowodach (ebm) w systemie opieki zdrowotnej i leczeniu indywidualnego pacjenta, część III. Nauczanie epidemiologii i statystyk,* 'Przegląd Epidemiologiczny' 2009, no. 63, pp. 422-423.

[40] See the justification of the judgement of the Supreme Court of 21.10.2021, ref. I KK 65/21.

In our opinion, the preventive removal of a healthy organ somewhat deviates from the traditional distinction between 'EBM-compliant method' and 'medical experiment'.[41] If EBM is understood as a 'proven, tried and tested' method, then in relation to the preventive removal of healthy organs, the assumed effect of almost complete elimination of the risk of developing a given type of cancer will always occur. At most, the surgical technique itself can be verified. Therefore, since current medical knowledge indicates that a given mutation increases the risk of disease, and preventive removal of the organ 'cures' this risk to a high degree, this should support the recognition of such procedures as EBM-compliant. Whether or not the procedure is included in the catalogue of guaranteed services is irrelevant for assessing whether it is consistent with current knowledge. As mentioned above, due to the difference in the risk of developing breast cancer depending on the type of mutation, only BRCA1/2 mutation carriers are eligible for reimbursement for preventive mastectomy (breast removal). The decision to finance subcutaneous mastectomy (removal of the mammary gland) in BRCA1/2 mutation carriers from public funds was made after the Agency for Health Technology Assessment (AOTM) issued recommendation No. 72/2018 of July 30, 2018.[42] The document states that: According to the guidelines of the Polish Society of Clinical Oncology, the following groups are at very high risk of developing breast/ovarian cancer (more than 10 times higher risk compared to the general population): people with a confirmed BRCA1/2 gene mutation or a family history of the disease, i.e., ≥3 cases among first- or second-degree relatives (including the proband) or a family history of the disease, i.e., first-degree relatives diagnosed with metachronous or synchronous breast and ovarian cancer. According to the guidelines of the Polish Society of Clinical Oncology, the high-risk group for breast/ovarian cancer (4-10 times higher risk of developing the disease compared to the general population) includes: individuals without confirmed BRCA1 mutation or a family history: 2 cases in first- or second-degree relatives before the age of 50 or 3 cases at any age (including the proband). The relevant regulation of the Minister of Health came into force on January 11, 2019.[43] Therefore, no decision was made to recommend reimbursement of the procedure for people with a low risk

[41] Supporters of such a dichotomous division are M. Boratyńska i P. Konieczniak [in:] *System Prawa Medycznego. Tom II. Część 1. Regulacja prawna czynności medycznych,* eds. M. Boratyńska, P. Konieczniak, E. Zielińska, Warszawa 2019, p. 73-75.

[42] Agency for Health Technology Assessment and Tariff System Department of Health Technology Assessment, *Prophylactic mastectomy in women at very high and high risk of breast cancer Report on the assessment of healthcare services*, Warsaw 2018.

[43] Regulation of the Minister of Health of 9 January 2019 amending the regulation on guaranteed hospital treatment services (Journal of Laws 2019, item 77).

of breast cancer, despite the presence of mutations that increase the overall risk of cancer in these individuals.

However, the lack of reimbursement cannot be equated with a prohibition on performing such procedures in private healthcare settings. Reimbursement, although obviously based on medical knowledge, including the epidemiology of a given disease and prognosis, is a decision made within the framework of the state's socio-economic (or, as some prefer to say, economic) health policy. Many non-reimbursed health services at every stage, i.e., prevention, diagnosis, treatment, or palliative care, raise no doubts as to their legality.

Therefore, in order to determine whether a given non-reimbursable preventive organ removal procedure falls within the scope of EBM, it will be necessary to examine whether the procedure is described in recognized professional literature (domestic or foreign) as recommended, safe, and beneficial, and whether it is performed fairly widely in at least some other countries. However, recognizing that not every doctor has the opportunity to keep up to date with foreign-language literature, to avoid ambiguity, it would be advisable to issue guidelines prepared by appropriate expert teams composed of geneticists and clinicians.

Before that happens, however, it should be noted that greater importance is now being attached to the mental well-being of patients, as evidenced, among other things, by the departure from the traditional division in the latest ICD-11 disease classification into somatic and mental spheres, which is understood very broadly. According to the WHO definition, mental health also includes an individual's well-being and productivity: ‘Mental health is a state of well-being in which an individual realizes his or her abilities, can cope with the normal stresses of life, can work productively, and is able to make a contribution to his or her community’.[44] Therefore, referring to a holistic approach to health, especially in light of the above definition of mental health, in some cases, the patient's fear of cancer alone may constitute a valid indication for preventive organ removal surgery. However, the patient's fears would have to take the form of significant anxiety disorders or other mental disorders. By ‘significant,’ we mean a degree of severity of the disorders that negatively affects the person's daily functioning. Moreover, it seems that the procedure should be performed after a prior attempt to treat these disorders. It should be noted that the patient's right to treatment primarily covers the negative aspect, i.e., they have the right to refuse treatment entirely or to choose among existing methods. However,

[44] S. Galderisi, A. Heinz, M. Kastrup, J. Beezhold, N. Sartorius, *Propozycja nowej definicji zdrowia psychicznego,* ‘Psychiatria Polska’ 2017, no. 3, p. 407.

the patient cannot demand a specific treatment where there are no substantive grounds (medical indications) for doing so.[45]

It should be added that in some countries, healthy organs and limbs may be removed in cases of apotemnophilia[46] and psychiatric treatment has been unsuccessful. This practice is controversial, but it demonstrates the increasing importance that modern medicine attaches to understanding health as an integral combination of somatic, mental, and sexual components. Therefore, severe mental disorders can sometimes even constitute an indication for the removal of a healthy organ.

However, assuming that the average patient does not suffer from such severe anxiety disorders, with regard to preventive organ amputation procedures, an additional premise should be identified that serves as a counter-argument to the alleged unlawfulness of the doctor's actions, namely, the result of a genetic test indicating an increased risk of cancer. One may wonder whether this requirement is not already included in the feature of compliance with EBM, since the test result determines the existence of at least relative medical indications according to current medical knowledge. However, we highlight this element to emphasize that such radical procedures should be justified by a significantly increased risk of disease development.[47]

It is also worth mentioning that, according to M. Boratyńska, compliance with the principles of social coexistence should also be a prerequisite for legal justification of non-therapeutic procedures.[48] However, as we have already pointed out, the preventive removal of organs has a therapeutic purpose and is therefore a therapeutic procedure, so this feature will result from the very nature of this type of operation.

In summary, if the procedure is within the scope of EBM and the patient consents to it, and if the expected benefits outweigh the typical negative effects, there should be no grounds for criminal or civil liability on the part of the physician for performing it (provided, of course, that no error is committed during the procedure or in the course of postoperative care). As noted in

[45] Doctors sometimes encounter this kind of pressure from patients and even their families. However, doctors must be able to refuse, as it is precisely taking certain actions, rather than refraining from them, that may constitute medical malpractice.

[46] A mental disorder characterized by aversion to one's own body part, most often a limb or part of a limb, often accompanied by the expectation of amputation. For the sake of clarity, it should be noted that it is currently listed in the ICD-11 international classification of diseases under the name ‘Body integrity dysphoria’ (6C21).

[47] We do not rule out the possibility of performing such procedures on patients with extremely severe anxiety, but in such cases, mental disorders will be an independent medical indication.

[48] M. Boratyńska, *Wolny wybór…,* p. 211.

the literature, it is currently undisputed in legal doctrine that all medical procedures[49] that are not exclusively therapeutic in nature are counter-types[50], and therefore the perpetrator does not commit a crime in the given circumstances. Pursuant to Article 2(1) of the Medical Practice Act, the practice of medicine includes the provision of health services consisting, inter alia, of the prevention of diseases. Also, the terms ‘medical activities’ or ‘medical procedures’ appearing in regulations or in legal doctrine, although they do not have a legal definition, are not limited to strictly therapeutic activities and are broadly understood as "any medical procedure taking the form of a therapeutic (medical) or non-therapeutic medical procedure undertaken in relation to a patient at the stage of prevention, diagnosis, therapy, and rehabilitation, which, due to the medical technique used, involves a violation of the patient's bodily integrity by damaging their bodily tissue or physically invading their body without damaging that tissue".[51]

The procedures discussed in this article are not the only cases in which the removal of a healthy organ is not a crime. Examples include the removal of bone marrow or an organ for transplantation from a living donor, the removal of an accessory rib or part thereof when it causes anatomical complications, or (as was common in the past) the removal of the appendix during abdominal surgery.

Moving on to the opposite issue, i.e., the right to compensation (damages) for failure to perform the procedure in the event of a ‘positive’ genetic test result, we enter the realm of patient autonomy. M. Boratyńska and P. Konieczniak frame this dilemma in the form of a question: ‘Does patient autonomy extend so far that they are allowed to effectively insist on minor or even serious bodily harm, and in the event of refusal, seek compensation or initiate criminal proceedings as a result?’.[52] In conclusion, the authors state that where the interests of the individual do not conflict with any specific principle of social coexistence, they should be taken into account, even if this entails serious bodily harm, provided that there are at least relative medical indications. However, they note that respect for the patient's autonomy leads to a more flexible interpretation of surgical indications.

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[49] A medical procedure is a narrower concept than a therapeutic procedure and a therapeutic activity.

[50] A. Złotek, *Charakter prawny zabiegu leczniczego – zarys problemu*, ‘Czasopismo Prawa Karnego i Nauk Penalnych’ 2010, no. 2, p. 53.

[51] M. Filar, *Lekarskie prawo karne*, Kraków 2000, pp. 247-248.

[52] M. Boratyńska, P. Konieczniak, *Autonomia pacjenta a wskazania medyczne,* ‘Studia Iuridica’ 2008, no. XLIX, pp. 9-10.

This conclusion would, therefore, argue in favor of the right to compensation for a patient who has been denied preventive organ removal surgery. In practice, however, constructing a successful legal claim may encounter significant obstacles. Returning to the issue of reimbursement for the medical procedures in question, the lack of reimbursement means that the patient cannot claim compensation if they are refused a procedure financed from public funds. In a situation where Poland does not reimburse a given medical procedure, but it is permitted in another European Union (EU) member state or in countries belonging to the European Free Trade Association (EFTA), individuals insured under the universal health insurance system are, in theory, entitled to healthcare in other EU or EFTA countries. However, this does not mean that all medical procedures are covered, only those that are medically necessary. These benefits are provided only on the basis of an EHIC (European Health Insurance Card) issued by the National Health Fund (NFZ). In addition, healthcare benefits are provided in accordance with the rules applicable in the country of stay, and in most European countries, Polish patients pay extra for benefits from their own funds. This is treated as the patient's own contribution to the cost of the service and is not refundable.[53] Such procedures include life-saving procedures, but do not include preventive removal of a potentially diseased organ. Polish law also allows for the possibility of submitting an E112/S2 application for treatment in another EU/EFTA member state under the coordination regulations, but this only applies to situations where the wait for guaranteed medical services is too long.[54] The keyword here, 'guaranteed' medical service, also excludes this administrative procedure. Therefore, if we do not classify the treatments in question as necessary – that is, as having absolute medical indications (which is a subjective concept)[55] – no reimbursement is due. If a lawsuit is to be brought, it should be against the State Treasury or the National Health Fund for incorrectly determining the basket of reimbursed services, rather than against a specific healthcare provider, let alone a doctor. It would also be difficult to argue that a patient would be entitled to compensation from a private facility operating on a commercial basis. This is because the healthcare services provided there are based on a contract. Furthermore, pursuant to Article 38 in conjunction with Article 30 of the Medical Law, a doctor has the right to refuse treatment unless the delay could result in the risk of loss of life, serious bodily injury, or serious health disorder, and the factual circumstances qualifying for preventive organ removal are not clearly

[53] Article 25(3) of Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems.
[54] Act of 27 August 2004 on healthcare services financed from public funds (Journal of Laws 2022, item 2561).
[55] M. Boratyńska, P. Konieczniak, *Autonomia…,* pp. 14-16.

assessed as urgent. The patient may also be at a disadvantage in terms of evidence if the doctor justifies the refusal on the grounds of insufficient experience, even if this is not true.[56] Finally, such a differentiation in subjective liability would raise fundamental doubts as to its compatibility with the constitutional principle of equality if a wealthy patient who could afford private surgery were entitled to compensation, while a poorer patient in the same health situation would be deprived of such a claim.

However, this topic would require in-depth discussion and perhaps even legislative intervention. In any case, changes in the mindset of the medical and legal communities would certainly be helpful in effectively pursuing such claims, which in turn requires educational measures, especially those supported by psychological and psychiatric knowledge. A strong argument is provided by studies showing that, in retrospect, most women do not regret their decision to undergo preventive mastectomy.[57] It therefore seems that patients and oncologists should advocate for the inclusion of preventive organ amputations in the list of reimbursed services to a greater extent.

Conclusions

We see no grounds for considering that a physician may face criminal or civil liability for performing a preventive organ removal procedure in cases where genetic testing reveals a significantly increased risk of cancer compared to the rest of the population, provided that the procedure is performed in accordance with the conditions described above. However, it must always be the free choice of a patient who has been duly informed and has not been subjected to any pressure. In certain cases, the introduction of a mandatory psychiatric or psycho-oncological consultation prior to the procedure may be considered. De lege ferenda, the Austrian solution discussed above seems to be a good model to follow.

Geneticists and clinicians should reach a consensus on the conditions for authorizing the removal of potentially diseased organs, i.e., developing a list of genetic syndromes and surgical procedures, as well as age limits for performing such procedures. After analysis and recommendation by the Agency for Health Technology Assessment, this list should be

[56] This would, however, entail the obligation to effectively refer the patient to another center.

[57] Agencja Oceny Technologii Medycznych i Taryfikacji Wydział Oceny Technologii Medycznych, *Profilaktyczna mastektomia u kobiety z grupy bardzo wysokiego i wysokiego ryzyka zachorowania na nowotwór piersi Raport w sprawie oceny świadczenia opieki zdrowotnej* (Agency for Health Technology Assessment and Tariff System Department of Health Technology Assessment, *Prophylactic mastectomy in women at very high and high risk of breast cancer Report on the assessment of healthcare provision*), Warszawa 2018, pp. 77-78, 86-87 and 92.

submitted to the Minister of Health for a decision on the scope of reimbursement. The preventive removal of a potentially diseased organ is significantly cheaper for the public health system than the subsequent treatment of cancer, even though the person carrying the mutation remains a carrier and must continue to receive intensive medical care.

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