**Siedlecki Zygmunt, Gutkowska Agnieszka, Śniegocki Maciej. Surgical treatment of brain tumors without informed consent - medical, organizational and legal aspect. Journal of Education, Health and Sport. 2020;10(10):72-81. eISSN 2391-8306. DOI http://dx.doi.org/10.12775/JEHS.2020.10.10.007**
**https://apcz.umk.pl/czasopisma/index.php/JEHS/article/view/JEHS.2020.10.10.007**
**https://zenodo.org/record/4104511**

**The journal has had 5 points in Ministry of Science and Higher Education parametric evaluation. § 8. 2) and § 12. 1. 2) 22.02.2019.**


**Received: 21.09.2020. Revised: 29.09.2020. Accepted: 18.10.2020.**

# Surgical treatment of brain tumors without informed consent - medical, organizational and legal aspect

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**Abstract**

Brain tumors are often manifested by mental disorders. Changes in personality, behavior and logical functions are often the dominant pathological symptoms in patients with brain tumors. There are also cases where brain tumors occur in patients with psychotic disorders or mental retardation and in these particular cases, they aggravate the already advanced mental disability. As a result, patients with brain tumors are often intellectually disabled and it is not possible to perform informed consent to treatment. In clinical practice, those patients who require neurosurgical treatment must give their informed consent, and when it is not possible, the judicial consent must be adjudicated. In urgent cases, medical decision on surgery is necessary in algorithm of life saving surgery, due to size of tumor and brain edema. We present the current state of knowledge and the facts about neurosurgical prcedures performed in patients with brain tumors without obtaining informed consent. We analyze the medical, legal and organizational status, pay attention to the nuances and the need for outstanding clinical experience in such a delicate matter. Clinical experience and legal awareness is essential for a qualifying neurosurgeon.

**Key words: brain tumors, mental disorders, judicial consent**

## Introduction

Brain tumors account for 2% of malignant cancers in Poland. A similar incidence is for

Europe, and other continents of world [1]. Brain tumors account for 3% of cancer deaths in both sexes. The most brain neoplasms occur in age of 50-64, more often in males than in females [1]. Brain tumors treatment is multidisciplinary, in modern neurooncology. It is necessary to involve a surgeon, radiotherapist and chemotherapist. Most often the first stage of comprehensive management is a neurosurgical procedure. Neurosurgical treatment often constitutes total tumor resection but also in particular cases, cytoreduction, or just biopsy [1,2]. Sometimes total surgical removal is the only stage of treatment and no adjuvant therapy is necessary [2,3]. However, according to the law, regardless of type of particular neurosurgical procedure, it always requires informed consent of treated patient, just like any medical procedure [4]. Responsibility to give informed consent to treatment and any medical procedures for the patient is regulated by legal acts: the Act on the Medical Profession in the Republic of Poland, the Medical Code of Ethics and, the European Bioethical Convention of the European Union [4]. Before undergoing a surgical procedure, the patient must be informed in detail about the essence of the operation, benefits and possible complications [4,5]. The patient must understand and be aware of disease, and must know what would happen if the surgical procedure would be abandoned. The patient also needs to be aware of any possible alternative treatments, if any [5]. By signing the consent, the patient accepts that physician will incise his skin and tissues. Patient also takes the risk of common postoperative complications. In the case of incapacitated patients, i.e. partially or completely deprived of physical capacity to perform legal acts, the informed consent to the surgery is signed by the patient's legal representative, which is equal according to the law [4,5]. In intellectually disabled and unable to give consent for treatment pupulation with brain tumors, there are two groups of patients in clinical practice.

The first group includes patients with brain tumors diagnosed *de novo* and previous coexisting mental disability. In these patients, intellectual limitations are not related to the brain tumor. However, this does not change the fact that legal consent is also required to undertake surgical and oncological treatment of them. These are patients with mental retardation or other severe mental dissorders. The mental retardation of these patients occurs in the course of genetic diseases, developmental disorders, chronic neurological disorders, metabolic diseases and conditions after infections in the prenatal period [3]. In clinical practice, these are people suffering from Down's syndrome, childhood autism, childhood disintegrative disorders, hyperkinetic disorders, epilepsy, cerebral palsy, congenital brain defects, phenylketonuria, galactosemia, mucopolysaccharidosis, Fetal Alcohol Syndrome, and congenital

cytomegalovirus infection [3,4]. In such patients, after brain tumor *de novo* developemnet, mental status usually deteriorates, but nevertheless, they were previously in severe intellectual disability [4]. Such group of patients is not numerous in neurosurgical practice, but it should be taken into account because such patients, especially those with genetic diseases or chronic neurological disorders, are more likely to develop brain tumors than the rest of the population [3]. It is also justified to mention elderly patients with severe dementia with brain tumors [4].

The second group consists of patients with mental disorders as a result of a brain tumor with no coexisting diseases that could cause mental disability. Brain tumors lead to impaired behavior, memory, and impair higher nervous functions [4]. It may be due to the mechanism of direct infiltration or pressure of the brain tissue or due to increased intracranial pressure. Frontal lobes tumors can manifest as behavioral and personality disorders [3]. Very often, the first symptom of such tumors are mental disorders that prevent social functioning. Historically, before the era of imaging diagnostics, it happened that patients with large frontal meningiomas were not properly diagnosed and were classified as mentally retarded or with psychiatric diseases [4,5]. It also happened that such patients, due to mental disorders and behavior, committed criminal prohibited acts and were sent to penal institutions, where they were also treated as handicapped [5]. People with aphasia also constitute a group of patients with brain tumor. Aphasia is a deficit neurological symptom consisting in impaired speech and word understanding. This makes verbal contact difficult. Although such patients often have a preserved mental clarity, and only the speech function is damaged, also in some cases judgment -ordered consent decree must be adjudicated [4,5]. High intracranial pressure occurs in large tumors with severe brain edema. It is life-threatening and emergency state in neurology and neurosurgery [3]. Increased intracranial pressure causes disturbances in logical contact, the patient is then drowsy and, also due to reduced mental abilities, is not able to decide about himself and does not have a correct assessment of reality. This situation in the case of brain tumors is the same as in patients with severe brain injuries, hemorrhages and brain strokes [5].

**Factual and organizational condition**

In 2019, 115 patients with brain tumors were operated in Department of Neurosurgery in Collegium Medicum in Bydgoszcz, Nicolaus Copernicus University in Toruń. These patients included 35.65% gliomas, 31.30% cancer metastases, 24.35% meningiomas, 4.35% pituitary

adenomas, and 4.35% vestibular schwannomas. The mean age of the patients was 54.43. In 98 patients (85.22%), written informed consent was obtained for surgery. In our center, patients sign extensive forms of informed consent, approved by lawyers, which specify the essence of the operation and list possible complications or adverse events. The consent is signed upon admission to neurosurgical department. The patient reads the form each time, asks questions and has an exhaustive conversation with physician. Such a procedure requires full mental ability and clear awareness. In 17 patients (14.78%), consent could not be obtained due to impaired consciousness and intellectual functions. Among patients unable to give informed consent, 25.52% of them (4 patients) were people with chronić mental retardation who additionally developed brain tumor. In two of these patients, an application was filed with the family judgment for consent to the procedure, and two such patients were incapacitated and the consent was signed by a legal representative. In patients whose consent was given by the judgment, the family member was the probation officer in the legal proceedings. The average time from the application to the court's decision on surgical treatment was 6.38 days.

In 76.47% (13 patients), the mental disturbances and the lack of logical contact resulted from the progression of the brain tumor. Cognitive disorders were its main symptom. It should be emphasized that 92.31% of such patients (12 out of 13 patients) were people with gliomas, and in one case there was a meningioma. Out of this group of patients, in four cases (30.77%) the decision was made to perform urgent surgery for immediate indications. It was decided by two neurosurgery specialists after a thorough examination of the patients and the analysis of neuroimaging. The reason for this therapeutic decision was progressive, life-threatening increased intracranial pressure. In such cases, the time delay could result in the patient's death. In three cases, family was informed about it, and in one case, the operated patient was lonely and there were no relatives. After the life-saving surgical treatment had been performed, the operating physicians had legally informed the judgment anyway to accept such procedure. This is in accordance with applicable law (*pro futuro*) [7]. In 9 patients (69.23%), due to the relatively good neurological condition, the lack of high intracranial pressure, it was decided to refer the case to judgment for consent for surgery. In each such case, a representative of the family was appointed as the guardian of the proceedings. In 5 cases, judgment consent was obtained after an average of 7.45 days, and in 4 cases, while waiting for the judgment's consent, without obtaining it, it was decided to perform immediate surgery. The reason for this was the progressive increased intracranial pressure, which prompted him to make such a decision. This decision was made by two neurosurgery specialists, based on the patient's

condition, after careful examination.

To summary- based on the clinical material of patients operated on at the Department of Neurosurgery, Collegium Medicum in Bydgoszcz, patients undergoing neurosurgical procedure for brain tumors constituted 4 groups of patients, as shown in Figure 1:

- Operated after obtaining informed consent
- Operated under the consent of judgment
- Operated on urgent indications due to a serious condition from the beginning of hospitalization
- Operated on urgent indications, who waited for judgment approval, but due to the deterioration of the condition it was necessary to decide on an urgent operation

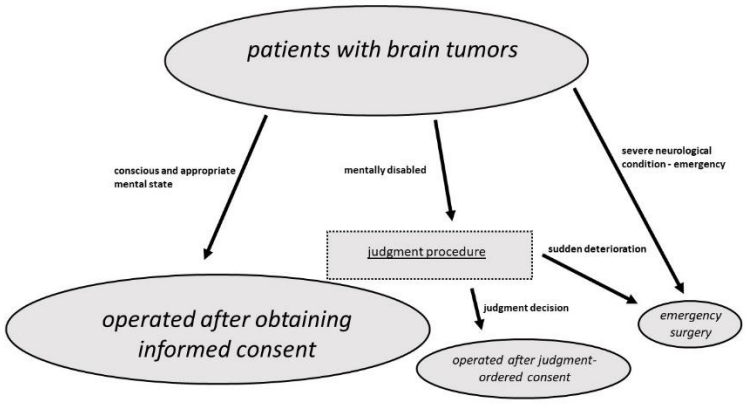


Fig. 1. Algorithm for dealing with patients with brain tumors in terms of judicial consent

**Discussion and legal point of view**

In the legal system of the Republic of Poland, there are 3 normative legal acts regulating the issue of informed consent to medical procedures:

1. The Act on the Medical Profession *(pol. Ustawa o Zawodzie Lekarza)*
2. The Code of Medical Ethics *(pol. Kodeks Etyki Lekarskiej)*
3. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine known as *European Bioethical Convention*

With reference to the Act on the Medical Profession *(pol. Ustawa o Zawodzie Lekarza)*, it allows the physician to act without the consent of the patient (or other authorized persons) or the court in two cases:

1) in immediate medical assistance. The decision undertaken by physician should, if possible, be consulted by another physician [6].

2) surgery creates an increased risk for the patient when the delay caused by the procedure for obtaining consent would pose a threat to the patient's life, serious injury or serious health impairment. In such a case, the physician is obliged, if possible, to consult another physician, possibly of the same specialty. The doctor immediately notifies the representative, actual guardian or the court about the activities performer [6,7].

Thus, the legislator distinguished two situations. The first includes activities that do not pose a higher risk for the patient (Article 33), but the patient requires immediate medical attention. The second situation is related to activities which, if omitted, would seriously endanger the patient's life or health. Therefore, it is not about every medically justified activity, but about activities involving a higher risk [6-8].

With reference to The Code of Medical Ethics *(pol. Kodeks Etyki Lekarskiej)*, according to Article 15, paragraph 3 of this document, initiation of diagnostic, therapeutic and preventive proceedings without the patient's consent may only be allowed in exceptional cases in which the life or health of the patient or other persons is at risk [6-8]. The patient's consent to treatment is subject to many legal regulations, which are not necessarily consistent with each other [7]. The article focuses on those contained mainly in the Act on the Medical Profession *(pol. Ustawa o Zawodzie Lekarza)* as well as on the rights of patients and patient advocate relating to the issue of consent, its legal nature and the requirements that ensure its full legal effectiveness [7,8]. In the constitutional context, it is important to present the evolution of basic constitutional values and to derive from them the right to self-determination, which is important in the discussed topic [8]. It is worth considering what shape this law should take due to the specificity of medical law. It will be helpful to illustrate the two opposite views on the nature of the patient-doctor relationship developed in the doctrine - a paternalistic and autonomous model, in order to finally lead to a compromise that most fully corresponds to the requirements of medical reality, allowing for the distribution of responsibility for treatment to both parties relatively equally and partnership model [8,9]. Another aspect discussed will be the regulations protecting the patient against unlawful interference with the right to self-

determination, contained in Art. 192 of the Criminal Code. An analysis of the extremely vague and imprecise features of the type of prohibited act will be carried out, which may lead to real problems in its application [7].

The institution of *pro futuro* declaration in the Polish legal system has still not been legally regulated [7]. The reason for this fact is its social controversy, as well as the ideological conflict of values between the absolute recognition of the autonomy of the individual's will and the principle of protection of life [7,8]. In medical practice, the pro futuro declaration is a significant problem in terms of adequacy and effectiveness of the submitted declaration [7]. At the moment when the patient, due to his unconsciousness, does not have a real possibility to express his opinion on further treatment, will the doctor be obliged to respect the patient's earlier declaration not to undertake any medical procedures in relation to him? From the point of view of the legitimacy of introducing the anticipated declaration to the Polish regulation, it may be necessary to confront the *pro futuro* declaration with both the protected constitutional values and the personal rights underlying Art. 23 of the Civil Code [7-10]. Presented by the doctrine, civilian theories, identifying a pro futuro statement with a declaration of will within the meaning of Art. 60 of the Civil Code, or the institution of carrying out someone else's affairs without commission, constitute a significant stimulus for further discussion on the future, fully regulating this matter [6-10].

With reference to *European Bioethical Convention*, it is one of the conventions of the Council of Europe, concluded on April 4, 1997 in Oviedo (Spain). The convention is the basic document on the European continent regulating difficult matters bordering on medicine, ethics and law [7-9]. The convention has been in force since December 1, 1999, so far only 19 European countries (Poland is not yet a party to this convention, although it has already signed it in 1999 - ratification is still needed) [9]. It contains only the most important principles, because the intention of its authors was that it would constitute a legal framework for the application of biology and medicine, and more detailed legal solutions would be included in subsequent additional protocols [9]. The above position is of great importance in view of the overriding fact of saying that. The patient, by giving consent to medical intervention (surgery or diagnostic), allows the physician to violate the physical integrity to the extent established [10]. The patient's consent revokes the unlawfulness of the action, so the doctor cannot be charged with guilt if he acts within the limits of consent. By consent, the patient accepts the risk of the procedure and takes it over [7]. However, he does not accept the doctor's negligence or any other form of guilt [7]. However, there are exceptions to this rule,

the basis of which is, as it is defined, a state of greater necessity due to the threat to the patient's life or health, or his presumed consent and statutory authorization, or even statutory obligation. The provision of art. 8 of the Bioethics Convention stipulates that: "If, due to an emergency, the required consent cannot be obtained, medical intervention may be carried out without delay, if it is necessary for the health benefits of the person concerned" [8]. It is a very broad approach, containing indefinite phrases ("emergency", "health benefit") which require clarification in the act [9,10].

## Declarations

- Availability of data and materials: All relevant data are within the paper.
- Competing Interests: The authors declare that they have no conflict of interest.

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