

Policy Paper On The Rights Of Patients

The Hungarian Civil Liberties Union advocates legislation under the individual may freely decide matters that affect her person and life. Decisions on medical treatment are as personal as anything can be. When an individual makes such a decision, she expresses her conception of the good life, of the adequate level of health, of the way she wishes to look, and of her views about bodily suffering. We cannot feel secure in our right to self-determination regarding medical treatment unless it is the case that the law provides for our rights in the context of medical treatment and for the conditions which are necessary for the exercise of these rights. By the term “patient rights”, we do not understand special rights of people under medical treatment. We rather understand these rights as applications of general human rights to the particular context of decisions regarding medical treatment. The rules related to the rights of patients are meant to ensure that you should be able to exercise your human rights even during the period of your life when you are subjected to medical treatment.

What are the basic rights of patients?

It is the patients’ most basic right that they receive medical treatment, and that their human dignity be respected during treatment. Both medical efficiency and human rights require that patients should remain in possession of their right to self-determination.

Successful treatment presupposes as one of its necessary conditions a patient-physician relationship where the patient obtains sufficient information from the physician, and makes an autonomous choice. Patients who actively participate in making choices about their treatment options are more likely to follow the physician’s instructions.

The rights of patients that have been included in the relevant legislation – such as the right to informed consent, the right to freedom of choice of a provider, the right to confidentiality of medical records, etc. – aim at ensuring that the choices patients make about their treatment options should become an essential part of their medical treatment, and that everybody should be able to exercise this right during the entire course of medical treatment.

Are there international standards on patients’ rights?

Since the 1970s, several international declarations have been created that cover the principles of patients’ rights. Issued by the World Health Organization, the Council of Europe and the World Medical Association, these international documents demand that the human rights should be observed in medical treatment. They spell out the rights that must be ensured for the people during medical treatment so that they could exercise their right of self-determination. These international documents have offer a starting-point where from each country’s legislation can engage in creating laws that recognize and assert these rights.

Let us call attention to two such documents that are of key importance in this field for European countries:

- Declaration on the Promotion of Patients' Rights in Europe, adopted in Amsterdam in 1994 at the initiative of the WHO (we will refer to it in this document as Amsterdam Declaration of WHO)

- Convention on Human Rights and Biomedicine, which the Council of Europe adopted in 1997.

The Convention adopted by the Council of Europe has been the first major international instrument on the rights of patients with a binding force. It is an update on similar other documents as it provides safeguards for human rights in the domain of advanced medical techniques, such as modifying the human genome, doing research on embryos and the use of human organs and tissues. An increasing number of countries have been receptive to this new approach to the rights of patients. The signatories include former Soviet bloc countries such as Estonia, Lithuania, Latvia, Moldova, Rumania, Slovakia as well as Slovenia. For the convention to take force, it has to be ratified by at least five of the signatories.

Why legislation on patients' rights is important?

In case the rights of the patients are stipulated by law, it is mandatory for all to avoid violating them. Moreover, institutions may be created to ensure the enforcement of the law. According to earlier practice, patients' rights have been treated as part of the ethical requirements health care providers were supposed to follow, mostly as part of the physicians' code of conduct. Thus, e.g., the confidentiality of the patient-physician relationship was protected by the code of ethic of the medical profession. Now that the rights of patients have gained increased importance, that issue is defined as the patients' legal right to informational privacy. Accordingly, such rules are not left to the code of conduct of the medical profession but they are being made part of the law.

The right of the patient to make her choice about treatment options is often discussed by the general Health Care Act. Legislators in Hungary, Slovakia, Bulgaria, Poland, Croatia and Georgia have followed this way. Under another arrangement, specific medical interventions – as for instance, the transplantation of organs and tissues – or medical research are covered by separate laws, which in turn include provisions related to the rights of patients in that field.

Incorporating the rights of the patients in a charter is another way of earning formal recognition for these rights. Federations of hospitals or a chamber of physicians may issue such a charter, for instance. A document like this may have jurisdiction over specific institutions, a region or a country. Countries that have issued a charter of the rights of patients include France (first in 1974 and then in 1995), San Marino (in 1989), the United Kingdom (in 1992) and the Czech Republic (in 1992).

The HCLU is convinced that the most efficient way of ensuring patients' rights is for the individual countries to incorporate them into a separate law. A law that covers all the aspects of the rights of the patient and does not deal with any other issues than these can define unequivocal rules both for the health care provider and the patient. As it forms a single legal instrument, it is readily accessible and transparent. When the rights of patients are spelled out in a separate law, that acknowledges the importance of the issue. The following countries have opted for that technique:

- Finland: Law on the legal status and rights of the patients, 1992
- The Netherlands: Law on medical contracts (including a discussion of the rights of patients), 1994

- Israel: Law on the rights of patients, 1996
- Lithuania: Law on the rights of patients and damage done to patients, 1996
- Iceland: Law on the rights of patients, 1997
- Denmark: Law on the rights of patients, 1998

A list of the most important patients rights

1. Right to health care
2. Right to freedom of choice of a provider
3. Right to be treated with dignity
4. Right to information
5. Right to informed consent
6. Right to make an advance directive
7. Right to refuse treatment
8. Right to leave the health care institution
9. Right to informational privacy
10. Right to die in dignity
11. Right to complaint
12. Right to participation in decision-making in health care

What does the right to health care mean?

The point of departure is the principle, which was defined fifty years ago in the Universal Declaration of Human Rights: “Everyone has the right to a standard of living adequate for the health of himself and his family, including ... medical care...” (Article 25). Several other international documents have since defined it to be a duty of the state to ensure for all of its citizens health care of an adequate standard.

It is the conviction of the HCLU that everybody has *the right to* an adequate *health care* without discrimination, irrespective of their capacity to pay for that service. It is, however, subject to further deliberation, what should be defined as the “minimum required service”, and what are the additional “optional” services, which represent such a high costs that they can be legitimately withheld from a patient unless

- she buys a specific insurance, or
- she is willing to pay an increased sum of health care contribution.

Sooner or later each country has to make a decision about those issues for the following reason: the number of chronically ill persons is on the rise, new forms of costly medical interventions appear, the demand increasingly exceeds the available resources.

The right to medical care involves that the health care establishments should be easily accessible, and that the patients should be able to use their services continuously. *Freedom of choice* in the context of the health care provision means that patients should be able to choose the health care establishment and the physician they address in order to receive medical treatment. In the countries of the former Soviet bloc that right is relatively new as under the previous regime one could only turn to the physician assigned to their neighborhood (district physician). There was no freedom of choice concerning either a surgeon for an operation or a family doctor.

There can be objective limitations to the freedom of choice: e.g., the medical intervention sought may not be carried out in the preferred establishment, or the establishment chosen may not be able to admit the patient in the given moment. As far as medical intervention requiring limited resources – such as organ transplantation or heart surgery – is concerned, health care establishments must keep a *waiting list*. Ranking on that list should be made according to impartial criteria. The patients should be informed about the way the limited medical resources are distributed – which also determines their chances of recovery.

Patients must be involved in planning of, and checking on the quality of health care. The *right to participation in decision-making in health care* is a collective right of patients. It enables patients to articulate “consumer” interests (see Article 5.2 of the Amsterdam Declaration of WHO) either within hospital committees or in the framework of national councils. Accordingly, patients must have the right to express their views at all levels of health-related decision-making on what kinds of care they deem necessary and what problems they encounter with regard to the workings and quality of their treatment.

Must patients be told about their illness?

Patients must be given all the available information concerning their state of health even if they do not ask for it. Recognition of the *right to information* means that patients must get information in plain language – free from unfamiliar technical terminology –, and their attending physician must answer whatever questions they may ask. Whenever a new medical fact emerges in the course of treatment, when, for instance, another intervention becomes necessary, that information must be shared with the patient.

In exceptional cases the physician may withhold some of the information when, in her view, information about the illness would impose an unbearable burden on the patient, so that it could be the source of further harm. (This is called *exception based on therapeutic reasons*.)

Patients have the right not to receive further information about their state of health or illness. They may even refuse to be informed at all. (*The right not to get information*.) Patients have the right to choose who should be informed on their behalf.

In addition to their right to ask and obtain information from their physician, patients have the further right to get access to their medical records. *The right to access to medical records* means that patient must have the opportunity to read those documents, if she so desires, and to ask for a copy of them. That right may be exercised provided the institutions that handle the medical files of the patient keep them for a certain period.

In addition to information on their state of health, patients have the right to ask for, and get information on the following affairs:

- health services: what health care establishments they can turn to;
- what is the order of functioning of the health care establishment concerned: what kind of departments it has, and what are its rules and regulations;
- the name and position of the health providers who attend to them;
- the rights of patients;
- institutions that protect patients’ rights; for instance, whether there is a patient advocate at the establishment concerned; how can complaints be submitted.

A summary of the Convention on Human Rights and Biomedicine

1. Interventions in the health field, including research, require free consent, which can be given only with knowledge of their purpose and nature, their consequences and risks.
2. The respect for private life and the right to know and not to know information about one's health must be warranted.
3. Any form of discrimination on ground of genetic heritage is prohibited.
4. Test which are predictive of genetic diseases, of carrier status and of a genetic predisposition may be performed only for health purposes, and their results can be passed on only for the same purposes.
5. Interventions in the human genome aimed at modifying the human genome of any descendants are forbidden.
6. Medical selection of a future child's sex is not allowed, except very serious hereditary sex-related disease is to be avoided.
7. Scientific research shall be carried out freely, subject to provisions of this convention and other legal provisions ensuring the protection of the human being.
8. The creation of human embryos for research purposes is prohibited.
9. Organ and tissues transplantation from a living person may be carried out solely for therapeutic purposes.
10. The human body and its parts shall not, as such, give rise to financial gain.
11. Every state may in its own national legislation impose stricter regulations in order to grant a wider measure of protection.

Gian-Reto Plattner's (rapporteur to the Parliamentary Assembly for the Committee on Science and Technology) summary on the core content of the Convention. Hastings Center Report, January – February 1997. pp. 21-22.

Is it allowed to begin treatment of patients upon giving information to them?

It is not sufficient to provide patients with information. Their consent must also be obtained. Medical interventions made without the patients' consent is against the law even if they are otherwise justified and would exert a favorable effect. Exceptions to this rule are cases when the medical action must start without delay: e.g., when life-saving intervention needs to be made immediately, or when emergency treatment is needed and the patient is unable to express his will.

The right to informed consent is part of the individual's right to self-determination over her body and life in the context of health care. Today that right is the cornerstone of the patient-physician relationship in every democratic country. In order to be valid, the consent must satisfy the following legal criteria:

- it must be given voluntarily,
- it must be based on appropriate information,
- the patient must have the required competence to decide.

When patients only give their consent to medical intervention because they are threatened by dismissal from the institution unless they agree to it, then they act under duress. Consent is not freely given either when patients are not provided with proper information about the intervention and do not exactly know what to expect. Information is deemed appropriate if it

includes the following pieces of information:

- the patient’s state of health and diagnosis,
- results of the medical tests,
- the recommended medical intervention: the way it is expected to take place, its risks and advantage,
- alternatives to the recommended intervention, including their risks and advantage,
- the consequences of not making the recommended intervention,
- the expected course of convalescence and rehabilitation.

Consent given by the patient after receiving information is valid if and only if she is capable of understanding the information and of making a considered decision. In case a patient is incompetent either because of her illness – for instance, disorientation or mental disorder – or because of her age (being a child) – then she cannot give a valid consent. In such cases decision about the treatment may be brought in one of the following ways:

- Before becoming incompetent, the patient made a statement on his medical treatment. *The right to make an advance directive* enables citizens to put down their will in advance as preparation for the case if they lose their decision-making capacity. In such cases the future patient names the person who has the right to make the necessary decisions on his behalf. The previously expressed wishes may include the listing of those treatment types that the patient would not undergo under any conditions.
- The patient has a legal representative – for instance, a parent or a guardian appointed by a court – who is authorized to make a decision about treatment.
- In all the other cases, the health care establishment must initiate the appointment of a surrogate decision-maker.

When patients are incapable of making a decision, the best way to honor their right to self-determination is giving them treatment that fit their will and their values. The optimal procedure for securing this is when the person concerned makes an advance directive in which she states in advance who should make a decision about her treatment. This way it can be ensured that the person appointed as the patient’s representative is someone she trusts, someone who knows her and her views, someone she can tell how she thinks about this or that treatment or about tolerating pain. Physicians must follow the advance directive. In our view surrogate decision-makers are supposed to make decisions according to what they believe the patient would prefer to happen to her and not according to what they would prefer to happen to themselves.

The right to informed consent involves the right freely to withdraw consent at any time. (Convention on Human Rights and Biomedicine, Article 5) Consent of the patients is the precondition, in addition to treatment, of the following activities:

- the preservation and use of all substances of the human body,
- scientific research,
- clinical teaching.

In the case of minor interventions, oral consent of patients is sufficient. For certain types of medical interventions, it may be sufficient that the patient’s conduct reveals the fact of agreement (implied consent). For instance, a patient joins the queue that is waiting for inoculations or he offers his arm when blood sample is taken. However, under no condition can it be taken as a valid sign of consent to surgical operation that the patient is told that an

operation has been planned for her and she remains silent. It has become established practice to ask for the patient's written consent in all cases of operations and of involvement in medical research projects. As for treatments where oral consent is sufficient, the content of the information given and the fact that the patient has given his or her consent has to be recorded among the medical documents of the patient.

May the patient refuse the recommended treatment at any time?

The patients' *right to refuse treatment* may be exercised at any stage of the treatment provided that the patient is competent. In more and more countries, patients have even the right to refuse to get life-sustaining treatment. That right may be exercised when patients having a terminal illness do not wish to continue suffering on the verge of death, and ask for stopping the life-sustaining interventions. That is in harmony with the right to humane terminal care and the *right to die in dignity* (Amsterdam Declaration of WHO, Article 5.11)

There are states where patients may both opt for refusing life-sustaining treatment and – if the above conditions are there – may ask for active medical assistance for dying. In 1994 in The Netherlands legislation was adopted that specifies the conditions under which a physician who actively assists the death of an incurable patient can be excepted from prosecution. In the State of Oregon, USA, a law was adopted in 1997 permitting physician assisted suicide. In some cases medical assistance may be justified by the fact that stopping life-sustaining treatment will end efforts to lengthen life but fail to ensure death without suffering. In such cases a very painful dying can only be avoided if a physician uses medication to accelerate the death.

In the opinion of the HCLU, patients with terminal illness need have the right to choose to die in dignity according to their conviction. That would involve

- the right to refuse life-sustaining treatment, and
- the opportunity to medical assistance in ending life.

The rules on refusing life-sustaining treatment are stricter than those which regulate other decisions of the patient. E.g., they require that the statement be made in a written document of a particular form. In other cases, it is enough for the attending physician to make a record in the patient's documents on that he has refused a recommended treatment.

Patients may refuse treatment and may even express their will to leave the health care establishment. *The right to leave a health care establishment* is not restricted by the fact that the patient's state of health would justify her further treatment in the hospital. If such is the case, the patient has to sign a statement to the effect that he left against the physician's recommendation. It is against the law to bar patients from leaving a health care establishment. Exceptions to this rule are patients whose mental state is directly dangerous to other people. Such patients may be kept from leaving, but only as long as a court decision is made whether or not psychiatric treatment may be continued against the patient's will.

It would violate a patient's right to self-determination if decision were made on her transfer to another health care establishment without her knowledge. When a health care establishment finds it justified to transfer a patient to another facility, that may only occur after informing the patient and obtaining her consent.

Is the ancient rule that medical information must be treated confidentially still valid?

As in the past, there are rigorous rules that protect the confidentiality of the patient-physician relationship. The medical profession's code of conduct compels physicians to treat information that they obtain in therapeutic relationship as confidential. Current health care regulations include safeguards for the confidential treatment of medical records. Patients have *the right to privacy* concerning their medical files. This right includes that the health care establishment may not disclose their personal and medical data to third parties without their authorization.

The right to the confidential handling of data requires that the patients' medical records should be treated in such a manner that no third party could have access to them. When a physician is legally obligated to disclose medical records to others – for instance, information has to be given on certain epidemic diseases, or a court requests data in a crime case – then the patients concerned must be informed on what of their data have been sent, to whom and with what purpose.

Thanks to modern medical techniques and advanced information technology, the amount of medical information produced has multiplied. Moreover, the various administrative agencies have become highly reliant on working with a large amount of information. This explains why the protection of medical records has been one of the most controversial issues in the field of the rights of patients. As in the past, information on the history of the patient's family, the patient's way of life, occasionally including most intimate elements as related to the physician by the patient, continue to be of essential importance when the diagnosis and treatment are determined. Nowadays such information is not recorded on carefully guarded individual paper files. Instead, information fed into computerized databases. Consequently, measures need to be taken to ensure their confidentiality.

Access to medical data must be ensured for those persons who take part in the treatment of the patient. As for any other persons, access can only be allowed if the patient gives her consent. According to the position of the HCLU, the patients' right to informational privacy requires the observation of the following rules:

- who from among their relatives should get information is a question that must be decided by the patients themselves,
- the patients' personal and medical data may only be disclosed with their consent,
- the data must be stored in such a manner that they do not get destroyed and that they are protected from unauthorized access,
- the patients must be informed (on what kind of information was disclosed, to whom and with what purpose) even if their data are disclosed in a legitimate manner,
- when data are to be disclosed with the aim of promoting public health or criminal investigation, the obligation to disclose personal and medical information should be given the narrowest possible reading (the disclosure must serve some legitimate aim, the information disclosed must be necessary to reach that aim, the cost to the individual of his data being disclosed must not exceed the benefit expected from the disclosure, etc.),
- patients should be able to request the destruction of such data about themselves that are mistaken, are based on misunderstanding or are irrelevant.

The patients' right not to know certain information must also be part of their right to informational privacy. As we explained above, patients should be able to ask not to be informed about an issue at all or only in part.

The right not to be informed is gaining in importance now that science is capable of discovering more and more about the human genome. Genetic tests can reveal numerous diseases that do not produce symptoms at the time of the examination. It is impossible to tell in advance whether or not that disease would actually appear and, if so, whether it will appear in the near future or only decades later, and whether, at the time of the disease's making its appearance, it will be curable or not. Under such conditions, it is increasingly important for the individual that she be protected against an employer's, an insurance company's or a would-be spouse's demand that she subjects herself to a genetic test as a precondition for employment, health insurance or marriage.

The HCLU's standpoint is that the right to informational privacy mandates that the individual must have the right to refuse unwanted genetic testing. The ultimate decision must lie with her whom others want to subject to genetic screening. Nobody should be obliged to get information about his or her life prospects and state of health that he or she does not wish to know.

Does a health care establishment stand under the obligation to make an inquiry when a patient puts forward a complaint?

The patients' *right to complaint* is confirmed by the relevant international documents. The law must provide for a fair investigation into the patients' complaints. The right to complaint involves an obligation for the health care establishments to abide by the legal regulations regarding the complaint procedure, that is, to ensure that an appropriate forum for complaints be available.

Ensuring the right to complaint has multiple benefits, such as

- protecting the rights of patients in cases when they are violated and protecting patients in cases when they do not receive appropriate care,
- contributing to an improvement of the standards of the health service,
- seeing to it that a conflict between a patient and a health care establishment is settled on the lowest possible level (in order to have this effect, the complaint procedure must be easily accessible, fast and capable of generating a decision about the case that is complained about).

The complaint procedure must fulfil the following functions:

- it must ensure information for patients about the procedure and their rights,
- it should offer assistance for submitting the complaint in writing,
- it should be a mediating mechanism between a patient and a health care establishment in the effort to clarify the cases,
- it should involve a decision on whether or not the patient's complaint is well founded,
- it should involve a recommendation on how to resolve the contentious cases,
- it should come forward with initiatives on how to prevent such cases in the future.

The principal task of the patient advocate is to help patients know and exercise their rights. The patient advocate plays an important role also in the course of the complaint procedure. A patient with a complaint can rely on the patient advocate's assistance in the first place. The advocate may help patients obtain the medical documents they need and have a copy about them; and she may help patients submit their complaint. In case the patient advocate succeeds in mediating between a patient and the health care providers, there will be no formal complaint at all. The patient advocate has a lot to learn from the complaints because various lessons can be drawn from them about the operation of the health care establishments.

What are the objectives of the HCLU with respect to the task of making the patients' rights recognized and respected in Hungary?

- We consider it desirable that the Parliament revisits the rights of patients whenever a shift occurs in the international norms. In Hungary, the patients' rights have been incorporated into the Health Act as a separate chapter. As information technology and medicine make further advances, there is a need for further legislative action, following international norms.
- We consider it necessary that Hungary ratifies those international conventions – as for instance, the Council of Europe's Convention on Human Rights and Biomedicine – which define the principles of the rights of patients.
- We deem it important that meaningful relations be established among the East-Central European public interest law organizations that focus their activities on patients' rights so that they could exchange information and take joint action.
- We express the need for publications, training programs and public information services that educate the public on the rights of patients.
- We support the claim that consumers of the health services should get the opportunity to play an effective role in decision-making in the health-care system.
- We urge for the creation of institutions that protect the rights of patients.
- We consider it indispensable that whenever the rights of patients are violated, citizens should get access to legal counseling and representation.