

Legislative Considerations on Respecting Patient's Rights in the Global Context Generated by the SARS COV-2 Pandemic

Erimia Cristina-Luiza

*Lecturer, PhD, Ovidius University of Constanta, Faculty of Pharmacy, Campus Corp C, Constanta, Romania
cristinaerimia@gmail.com*

ABSTRACT: In the contemporary era, the right to health is a part of human rights and is based on one's natural rights. Hence the obligation of the states to elaborate an appropriate legislation and to implement this obligation, i.e. social responsibility in health. This article aims to analyze the way in which the rights of European patients are respected in the current global context, referring, in particular, to respecting patients' rights in the Romanian health system. The assertion of patient's rights must take into account, in particular, citizens' right to travel (freedom of movement) between the Member States of the European Union and equal opportunities, so as to benefit from quality services, in particular, to promote the implementation of these rights in all the states at regional level. In addition, the observance of these rights in the context of the COVID-19 pandemic implies changes in the daily relations between the patients and the ensemble composed of specialists and health structures. A modern healthcare system needs to be focused on the patient's needs, to have dynamic and integrated structures, adaptable to the diverse and changing health needs of the society in general and of individuals in particular and, last but not least, it must recognize the patient's role as an active partner in health policies, especially in the case of the SARS CoV-2 infection's emergence.

KEYWORDS: fundamental rights, the right to health, patient's rights, European legislation, public health, SARS CoV-2 pandemic

Introduction

Throughout the historical evolution, the patient has had many obligations, but no rights in the modern sense. For authorities, the control of the epidemics was much more important than individual welfare, this being the reason behind public healthcare. The discoveries of political democracy, along with the economic and scientific progress since those times have changed the game of power.

In the decades following World War I, the progress of citizens' rights have become the foundation for the modern patient's rights. The introduction of the popular vote and the clear definition of citizens' rights have created the basis for expressing a desire for various social services, including healthcare. In our opinion, the scientific progress between the two world wars has highlighted the potential to treat an increasing number of diseases, not just the increase in the number of patients, but also in their expectations.

In the contemporary era, when the right to health is a part of human rights and is based on one's natural rights, European countries and the European Community have addressed the issue of the rights of the people who use health services. Patient's rights are a part of human rights and aim to promote patients' autonomy in the long-term. These rights are often intertwined.

Although political statements, such as human rights, are too general and imprecise to serve as a handbook of patients' rights, their value as a source of ideological and ethical inspiration has been significant.

Theory

At the European level, the legal regulation of patient's rights had as its starting point the document "*Principles of the Rights of Patients in Europe: A Common Framework*" (WHO 1994) which set out a set of principles for the promotion and implementation of patients' rights in the European states who were members of the World Health Organization. Subsequently, the Oviedo Convention provided the patient with a catalog of rights and proclaimed his fundamental rights.

As a result of these signals, there has been an increase in national regulations regarding patient rights in almost every European country, even if in some countries there were formal laws on patient rights, applied according to political culture, such as an individual's right to take legal action if he/she is denied a right to certain functions or in cases of discrimination (Marin and Botinã 2012, 56-57) based on ethnicity or sexual orientation criteria.

In certain systems, patient rights are brought together within a general framework, while in others there are numerous specialized legislative acts.

In the context of the European Union, the assertion of patient's rights has had to take into account in particular the right of citizens to travel between the Member States and the right to equal opportunities in terms of benefiting from quality services in their countries of origin and in their host countries, and, in particular, in order to promote the implementation of these rights in all Member States.

Results and Discussions

The patient's right to be treated is undoubtedly a major achievement, but it must be considered in terms of the content of the care and the patient's position when receiving care. Today, in order for access to healthcare to be global and for individual rights to be respected, the patient must be able to navigate the healthcare system to access the best care.

The emergence of SARS-CoV-2 infection has led to the rapid spread of COVID-19 worldwide. On 30 January 2020, WHO declared COVID-19 a public health emergency of international interest, and on 11 March 2020 the pandemic was declared. By November 2020, over 56 million confirmed cases and over 1 million deaths worldwide have been reported.

The First Order of the Minister of Health regarding the action plan and the COVID-19 hospitals list established a network of support hospitals at national level, with the aim of taking over patients from infectious disease hospitals.

This order also imposed the first restrictions on the activity of all the hospitals in the country, by reducing by up to 80% the scheduled hospitalizations and scheduled surgeries for chronic patients in health facilities with beds from university centers and reducing by up to 50% the outpatient activity compared to February. These restrictions were addressed on April 14, 2020, allowing hospitals to provide diagnostic or therapeutic interventions to chronic patients and pregnant women for whom postponement could have reduced the chances of survival. On 3 April, a new Ministerial Order designated, in addition to the support hospitals, Phase I hospitals and Phase II hospitals. The initial definition of these hospitals mentions the possibility of treating other pathologies only for phase II hospitals, given the existence of completely separate circuits. The result was, therefore, a period of almost 2 months (between 3 April and 29 May) in which, at least from a legal point of view, the hospitals designated to manage COVID-19 were obligated to treat almost exclusively patients infected with the new coronavirus. During this time, the number of COVID-19 dedicated hospitals reached 134.

The inclusion on the list of hospitals dedicated to COVID-19, especially of Phase I and II hospitals, has had a dramatic impact on the usual activity of the hospitals. At the same time, the activity of non-COVID hospitals was negatively influenced both by the restrictions imposed by the establishment of the state of emergency, and by the restrictions on hospitalizations and outpatient activity imposed by order of the Minister of Health.

The number of hospitalizations at national level has dropped dramatically since April 2020, when 70% fewer hospitalizations than in the similar period of the previous year were recorded.

The right to healthcare and treatment

Every person has the right to receive healthcare appropriate to his/her needs, including preventive care and health promoting activities (WHO 1994).

Services should be available and accessible in a fair manner, without discrimination and in accordance with the financial, human, and material resources available in a given society (Wicks 2007, 20-29).

Patients have the collective right to a certain form of representation at each level of the healthcare system, in matters relating to the planning and evaluation of services, including the limits, quality and functioning of the healthcare provided (WHO 2007).

Patients have the right to a quality of healthcare characterized both by high technical standards and by a human relationship between the patient and the healthcare providers.

Although there is no absolute delimitation between acute and chronic healthcare, with many cases of exacerbation of chronic diseases, in March-August 2020 the sections dedicated to chronic patients recorded a significantly higher decrease in activity compared to the sections dedicated to acute pathologies.

In the current context of the pandemic, Colentina Clinical Hospital in Bucharest, one of the most important centers for chronic patients in the country, being transformed into a support hospital for COVID-19 management, discharged most patients and was dedicated almost exclusively to treating patients infected with the new coronavirus, thus, a decrease of over 90% in hospitalizations was recorded in April 2020 compared to April 2019.

Patients for whom there are no longer any medical reasons for admission to a healthcare institution are entitled to a comprehensive explanation before being transferred to another place or sent home. The transfer can only take place after another healthcare institution has agreed to receive the patient. However, it is not clear where and in what manner thousands of patients who used the medical services of Colentina Clinical Hospital in Bucharest were redirected every month.

Another indispensable center for chronic patients from all over the country is Fundeni Clinical Institute in Bucharest. Although it was not included on the list of COVID-19 designated hospitals, the decline in activity was considerable, especially in the first months of the pandemic, with a modest rebound in July-August 2020.

Over 16,500 people with HIV / AIDS live in Romania. In the first 6 months of 2020 alone, 159 new cases of HIV infection were detected (INBI 2020).

The medical services specific to HIV infection recorded the largest decrease of all pathologies. This is even more worrying as each case of HIV infection improperly treated can lead both to treatment-resistant forms and to new cases of infection. This is especially true for certain categories of people at risk, who need intense medical and social support in order to maintain adherence to the treatment.

In the case of the centers providing substitution treatment (STC) for people who inject themselves drugs, during the state of emergency, March 16 - May 14, 2020, no admissions of new patients to existing STC centers were accepted, which aggravated an already very difficult situation regarding access to substitution treatment in Romania [ORS 2020].

According to an analysis of the impact of the COVID-19 pandemic on the quality of the medical services and access of chronic patients to medical services (Mixich, Radu 2020), more than half of the respondents (51.7%) consider that the COVID-19 pandemic negatively affected the quality of the medical care received.

Respondents awarded grades from 1 to 10 to the quality of medical services received before the COVID-19 pandemic and during the pandemic. The grade average decreased from 8 - before the onset of the pandemic, to 4 - during the pandemic. Therefore, from the perspective of the chronically ill patients, the COVID-19 pandemic significantly reduced the quality of the medical services.

The causes for this significant decrease are multiple. The most frequently invoked is the reduction or refusal of access to the hospital where the person usually presented for treatment and monitoring. The difficulties generated by the traffic restrictions, as well as the difficult procurement of medicines are also frequently mentioned causes.

The COVID-19 pandemic has been a considerable challenge even for the most advanced medical systems in the world. A World Health Organization study carried out in 155 countries (WHO 2020) found that medical services for noncommunicable diseases were partially or completely disrupted worldwide, with the poorest countries being the most affected. 53% of the participating countries reported disruptions in the medical services for the treatment of high blood pressure, 49% for diabetes and its complications, 42% for cancer and 31% for cardiovascular emergencies. Screening campaigns (e.g., for breast or cervical cancer) were postponed in 50% of the countries participating in the study.

A study published in September by the Gates Foundation draws attention to the negative impact the pandemic has on HIV and tuberculosis healthcare (Goalkeepers Report 2020). The risk of interrupting this care is the deterioration of the health of those infected and the increase in the number of cases. Prior to the onset of the SARS-COV-2 virus, there were already 3 million unidentified cases of tuberculosis globally: infected people who did not know they had the disease, and the current limited access to diagnostic and treatment services will increase this number. The Global Fund to Fight HIV / AIDS, Tuberculosis and Malaria draws attention to the huge risk that the progress in recent years will be lost amid the COVID-19 pandemic (The Global Fund 2020). Disruptions in HIV treatment services are likely to increase the annual number of HIV deaths by more than half a million, bringing it back to the 2008 level.

Another patients' right that we intend to analyze in the light of the COVID-19 pandemic is the right to information (Marin and Buzescu, 2020, 728-730). The patient's right to information is proclaimed both in international documents (WHO's Declaration, the Helsinki Declaration of the World Medical Association, the European Charter of Patients' Rights), and in national ones (Trandafirescu 2009, 140), which constitute the implementation of the international applicable laws and of the *acquis communautaire*.

The doctor can take the best therapeutic measures for the patient, but he/she must explain them to the patient. Information about health services and about the best way to use them must be available to the public, so that all those interested can benefit from them.

One can see that, at present, citizens, especially those belonging to vulnerable groups, do not have essential information about their rights and obligations as patients. The lack of information is due, on the one hand, to the lack of activity on the part of the health system in terms of communicating minimal information regarding these rights and obligations, but also to a social inertia which has not yet determined an interest of the Romanian patient in this matter (OECD 2019). Basically, the citizens find out what rights and obligations they have in relation to the health system only when they encounter a problem in this field and end up using one or more services of the health system.

According to this principle, patients have the right to be fully informed about their health, including the medical factors of their condition, about the suggested medical procedures, about the potential risks and benefits of each procedure, about the alternatives to the proposed procedures, including the effect of non-treatment. Patients also have the right to be fully informed about the diagnosis, prognosis, and progress of the treatment.

The Ministry of Health has updated the List of specialized units which perform RT-PCR testing in order to establish the diagnosis of severe acute respiratory syndrome caused by the new coronavirus, with accredited laboratories (addresses/contact numbers), according to the legal provisions in force.

Although all the units on the List have the obligation to ensure with priority the diagnosis for the patients in the health units, suspects of epidemiological investigations, as well as the persons from the risk groups, according to the methodology of the National Institute of Public Health - National Centre for Surveillance and Control of Communicable Diseases, given the national epidemiological context, the units will decide the conditions under which they can respond to the needs for additional testing, upon request, and can determine the cost of the test.

However, some patients do not know how and do not get a medical evaluation during the disease, to know if a personalized treatment is needed or not. Although studies on the medium and long-term effects of COVID-19 already exist in the medical literature, there is no articulated program in Romania to monitoring patients and former patients infected with SARS CoV-2.

While non-pharmaceutical interventions have had the effect of mitigating the spread and effects of the pandemic and slowed down the transmission of the SARS CoV-2 infection, it is widely accepted that the rapid development, production and distribution of one or more vaccines against COVID-19 are essential for pandemic control, protecting health systems, reducing morbidity and mortality, and reviving economies worldwide.

Among the objectives of the EU vaccine strategy, a benchmark for national strategies formulated by Member States is to ensure that all EU citizens have a fair and affordable access to vaccines at decent prices.

From the point of view of patient's rights, the accessibility of the vaccines for the target groups in terms of price and of physical proximity is very important.

Among the main elements to be considered for national vaccination strategies is clear communication regarding the benefits, risks and importance of the vaccines against COVID-19, in order to instill public confidence.

Among the values and general principles of the National Vaccination Strategy is the clear communication of the benefits, risks and importance of the vaccination against COVID-19 for the entire population of Romania. The development of the communication strategy to promote vaccination at the level of the target groups is also focused on conducting information, communication, and education campaigns regarding the vaccination against COVID-19.

The declared purpose of the strategy is to inform the public clearly, completely, and factually about the vaccination against COVID-19 in order to promote the openness to vaccination against COVID-19 and to increase its confidence in the vaccination.

Although aimed at alleviating vaccination reluctance or hesitation about vaccination by clearly communicating the benefits, potential risks and operating principles of the vaccine, the information provided to the public through the national platform on vaccination against COVID-19 (<https://vaccinare-covid.gov.ro/>) is extremely technical, presenting the stages of the development of a vaccine, what the candidate vaccines are, as well as the modalities of their authorization.

Conclusions

The main responsibility in the field of healthcare lies with the states, through the obligation to ensure proper promotion and protection of public health, in order to improve the quality of life.

Transparency is a key feature of an effective healthcare system, the access to information also empowering citizens to participate effectively in the policy decisions taken at European, national and international levels.

Patient's rights are a part of human rights and aim to promote patients' autonomy in the long-term. These rights are often intertwined. Furthermore, in compliance with the principle of human rights and the values in healthcare, every citizen has the right to health protection, insofar as it is available, through appropriate measures to prevent disease and through healthcare, and to the possibility of pursuing the highest possible level of health.

Even in the current context of the global pandemic, it is necessary for civil society (Rotaru 2020, 71-82) to monitor whether the states are developing appropriate policies to promote access to health, so that individuals can have access to information about the development and implementation of public health policies, without having their fundamental rights violated.

The impact of the COVID-19 pandemic on the access of chronic patients in Romania (including users of substitution centers) to medical services and on the quality of these services is considerable. The effect will lead to a deterioration of the chronic patients' health and to a pressure increase on an already overworked medical system.

Along with the vaccination campaign, a complex program is needed to assess the sick and those who have gone through the disease, so that the costs can be as low as possible, both for the people and for the state.

Since unmonitored medium and long-term sequelae mean future costs for the health system, this is the reason why European states undertake studies and develop medical recovery programs.

If Romania does not keep one step ahead of the pandemic, the structural mistrust in the health system will deepen the vaccine-skepticism, the only thing able to restore a sense of normalcy.

References

- Goalkeepers Report. 2020. *COVID-19: A global perspective*. Bill & Melinda Gates Foundation: 2020 Goalkeepers Report. <https://www.gatesfoundation.org/goalkeepers/report/2020-report/#GlobalPerspective>.
- Marin, Marilena and Botină, Mădălina. 2012. *Specific features of the dismissal of personal assistants of disabled persons. Case Study*. Proceedings of the 2nd International Conference on Law and Social Order, Constantza, March 2-3, 2012. "Contemporary Readings in Law and Social Justice" (1): 53-61. New York: Addleton Academic Publishers.
- Marin, Marilena and Buzescu, Gheorghe. 2020. "Legal effect of the self-liability declaration during the pandemic - COVID 19. Integrity and freedom of conscience." *Journal for Freedom of Conscience*, 728-737.
- Mixich, Vlad and Radu, Constantin. 2020. *The impact of the COVID-19 pandemic on the access of chronic patients to medical services in Romania. Monitoring Report*. Romanian Health Observatory and Romanian Angel Appeal Foundation. <https://observatoruldesanatate.ro/publicatii/pandemie-bolnavi-cronici/>.
- National Institute of Infectious Diseases "Matei Balș" (INBI). 2020. *General data as of June 30*. "Matei Balș" National Institute of Infectious Diseases - Department for Monitoring and Evaluation of HIV/AIDS Infection in Romania.
- OECD and European Observatory on Health Systems and Policies. 2019. *State of Health in the EU. Romania Country Health Profile 2019*. https://ec.europa.eu/health/sites/health/files/state/docs/2019_chp_romania_english.pdf.
- Romanian Health Observatory (ORS). 2020. *Monitoring report on access in Romania to substitution treatment for injecting drug users*. Report by Romanian Health Observatory and Romanian Angel Appeal Foundation. January 2020. https://health-observatory.ro/wp-content/uploads/2020/07/ors_monitorizare_acces_substitutie_2020.pdf.
- Rotaru, Ioan-Gheorghe. 2020. "Spiritual Lessons observed through the Coronavirus Crisis." *Dialogo. Issue of Modern Man* 6(2): 71-82.
- The Global Fund. 2020. *The Global Fund to Fight AIDS, Tuberculosis and Malaria. Results Report 2020*. https://www.theglobalfund.org/media/10103/corporate_2020resultsreport_report_en.pdf.
- Trandafirescu, Bogdan Cristian. 2009. *News brought by Regulation (EC) No. 593/2008 (Rome I) and Romanian private international law*. Volume of the Communication Session "Recent Regulations in Business Law". Bucharest: ASE Publishing House.

- Wicks, Elizabeth. 2007. *Human rights and healthcare*. Portland, Oregon: Hart Publishing.
- World Health Organisation (WHO). 1994. A Declaration on the Promotion of Patients' Rights in Europe, Amsterdam, 1994: Principles of the Rights of Patients in Europe: A Common Framework Amsterdam Declaration of Patients' Rights, Endorsed by the World Health Organization European Consultation on The Rights of Patients, 28-30 March 1994. World Health Organization: Regional Office for Europe.
- World Health Organisation (WHO). 2007. *Everybody's business: strengthening health systems to improve health outcomes: WHO's framework for action*. Geneva: World Health Organization WHO Document Production Services.
- World Health Organisation (WHO). 2020. *COVID-19 significantly impacts health services for noncommunicable diseases*. World Health Organization Survey. <https://www.who.int/news/item/01-06-2020-covid-19-significantly-impacts-health-services-for-noncommunicable-diseases>.