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Legal Challenges for Romanian Family Medicine Practitioners in Times of COVID-19

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Abstract

The general practitioners (GPs) practice faced serious challenges as a result of COVID-19 pandemic, including from a legal point of view. In this context, a series of questions related to the GPs' professional activities might arise such as: (i) what happens if a doctor makes a mistake because he/she is exhausted, as a result of overtime² or (ii) if he/she performs medical acts outside the boundaries of his/her own specialty or without consent, as requested by his/her own conscience, by the situation, by the authorities and by his/her principal? In all these special circumstances this could mean that the doctor fails to comply with the applicable law. Moreover, because he/she breaches the law, the professional insurance policy will cease to be applicable. With new roles and responsibilities, the GPs should adjust their practice to the current conditions.

Keywords: COVID-19 pandemic, general practitioners, malpractice, legal liability, telemedicine.

Rezumat

Practica medicilor de familie s-a confruntat cu serioase provocări ca rezultat al pandemiei de COVID-19, inclusiv din punctul de vedere al respectării legislației. În acest context, cu referire la activitățile profesionale ale medicilor de familie ar putea să apară o serie de întrebări, ca de pildă: (i) ce se întâmplă dacă un medic face o greșeală din cauză că el/ea este epuizat, ca rezultat al orelor suplimentare lucrate² sau (ii) dacă el/ea efectuează acte medicale în afara limitelor de competență ale propriei lui/ei specialități sau fără consimțământul pacientului, așa cum i-au dictat lui/ei propria conștiință, situația de fapt, autoritățile statului și uneori șeful lui/ei? În toate aceste situații deosebite s-ar putea trage concluzia că doctorul nu a reușit să se conformeze legislației aplicabile domeniului. Mai mult de-atât, întrucât el/ea au încălcat prevederi legale, asigurarea de răspundere civilă profesională individuală va înceta să opereze. Cu responsabilități și roluri noi, medicii de familie sunt nevoiți să-și adapteze praxisul la condițiile actuale.

Cuvinte cheie: pandemia COVID-19, medici de familie, malpraxis, răspundere legală, telemedicină.

INTRODUCTION

Under the International Health Regulations (IHR) (2005) and following the advice coming from the Emergency Committee, on 30 January 2020, the Director-General of WHO declared the COVID-19 outbreak a public health emergency of international concern³.

Pandemics represent a significant stress test for a country's economic, political and most of all for the health systems⁴. An effective pandemic response demands a complex and multi-layered approach comprising surveillance, containment, border control, as well as various social and community measures. With the exception of border control, all these response

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measures involve the GPs' contributions in one way or another.

As a consequence, while the healthcare systems are put to a tough and difficult test⁵, it is also a critical moment that the roles and responsibilities of family doctors are assessed and recognised⁶.

Objectives of the research

- What is the role of family medicine in this pandemic times?
- Are GPs prepared to overcome the challenges of assessing health complaints without actually seeing the patient? Is telemedicine covered by Romanian legislation and fully functional so as to be included in GPs' practice?
- Are family doctors allowed to practice outside their medical specialty limits? Under what conditions?
- Excessive physical and mental stress during this period exonerates family doctors from legal liability in case of medical errors?

Findings

- Romanian health system is characterised by low funding and inefficient use of public resources, with the lowest spending per capita and as a share of GDP in the EU. There is a lack of universal coverage, although the non-covered population does have access to a minimum package of benefits. There are also inequities with regard to access to services between the rural and urban populations and for vulnerable populations⁷.
- Romanian GPs have a gatekeeper role for the public system (National Health Insurance House - CNAS), but not for the private system. This means that those benefiting from free medical services cannot access any other service unless they are seen first by their GP. Patients who choose the private system don't need to see a GP first, as they can access any medical service through direct payment.
- Most Romanian patients are registered with a GP freely chosen, without limitations regarding the area in which they live. Most choose a GP close to home and don't change the GP for many years⁸.
- According to the Romanian National Federation of Family Doctors, half of Romanian localities have no family doctors or not enough physicians⁹.
- Traditional roles have changed¹⁰.
- Pandemics represent a significant stress test for a country's economic, political and health systems.
- In the wake of the novel coronavirus disease 2019

(COVID-19) pandemic, which has now infected more than 120 million people and caused more than 2.65 million deaths worldwide¹¹, strict quarantine measures are a commonplace. As we already stated that, with the exception of border control, all these response measures involve the contributions of GPs in one way or another.

- Family medicine, dealing with both the emotional and the scientific side of medicine on a daily basis, plays a critical role in tackling this pandemic, in easing the burden on the acute-care system.

There are 11,400 GPs in Romania¹² working based on a contract with CNAS¹³, representing a third of the total number of doctors in Romania. Most GPs work in single-handed practices, especially in rural areas. In urban areas there are usually larger primary care clinics, but GPs still work in solo practices, with at least one nurse for each GP (a requirement under the agreement with CNAS). Apart from GPs who own their own practice, there are also GPs who are employees working for GPs with solo practices or for large private clinics¹⁴. The average list of registered patients is 1,800 with some practices caring for just 800 patients (minimum accepted limit for a contract with CNAS), while about 20% of practice units look after over 2,200 patients.

Roles and responsibilities of family medicine during a pandemic

- *Triage and treatment of suspected or confirmed cases.* The role aims to decrease the burden on secondary and tertiary facilities, thereby reducing healthcare costs for the authorities carrying responsibilities in this context¹⁵.
- *Resource allocation.*
- *Surveillance and monitoring.* Being the first point of contact for many infectious diseases, a network of sentinel primary care physicians could potentially serve as an early warning system for detecting sudden spikes in disease incidences or the emergence of novel strains.
- *Preventive care.*
- *Provision of affordable care.*
- *Ongoing delivery of primary care to patients with other acute illnesses and chronic diseases.*

The medical activity of GPs is strictly regulated by law and every breach of these legal rules may engage GPs' legal responsibility. We will review main aspects of the Romanian legislation related to GPs' professional activities in order to identify the legal regime related to

their liability and possible vulnerabilities for the practice as a result of changes (including legal changes, if the case) brought by COVID-19 pandemic.

I. The obligation to provide medical care

Physicians have to provide medical care to patients and cannot refuse to provide it, with one exception, regulated very restrictively by the legislation.

In order to refuse providing health assistance, the following conditions must be cumulatively met and these legal conditions have not been amended by special legislation as a result of COVID-19 pandemic:

- the reason for the refusal - the patient's discourteous behaviour;
- the patient's health condition - the patient's state of health should allow him to search another doctor having the same specialty;
- form conditions - the patient must be notified in writing at least 5 days before the end of the doctor-patient professional relationship.

Analysing the legal conditions presented above, it is obvious that the doctor's risk of getting ill and/or the risk of infecting other patients cannot represent a reason to refuse providing medical assistance, in any case. The principle of universal precautions and programs with the purpose of preventing nosocomial infections are the accepted legal solutions in these situations.

Only the patient's discourteous behaviour can trigger the procedures described in this chapter. From the perspective of the legal limits listed above, it can be concluded that doctors cannot refuse to provide medical care (regardless of the case's severity) to protect themselves against the risk of SARS-CoV-2 coronavirus infection, in the situation where the medical institution can provide the materials and sanitary equipment necessary for the medical personnel's protection.

II. Limiting medical practice to one's own specialty. Conditions for surpassing this limit¹⁶

The doctor is obliged to act within the limits of professional competence held in his specialty.

The exception to the above rule is the emergency situation when the medical staff who would have the necessary competence for the patient is not available.

Given that a large number of patients in serious condition will be presented to hospitals, it is possible/likely to have many situations in which the 3 cumulative conditions described by the legislation for performing medical acts beyond the limits of professional

competence are met. The above-mentioned conditions are as follows:

1. emergency situation;
2. there is no available doctor having the necessary specialty;
3. the initiation of the medical act cannot be postponed until his/her arrival and/or patient's transfer to another competent medical institution.

Under these special conditions, physicians can, thus, act outside the limits of their competence, being able to perform any medical acts necessary to save lives/prevent the irreversible deterioration of patients' health.

There are also bureaucratic requirements described in legal texts and applicable in such situations.

After performing the medical act (without a deadline fixed by law), it is necessary to fill in a form to document the fulfilment of the 3 mentioned conditions¹⁷.

Performing medical acts by illegally exceeding the limits of competence held by the doctor (i.e. under different conditions than the ones described above) may engage the doctor's civil liability.

The illegal exceeding of the limits of competence has an additional negative consequence - it determines that the professional liability insurance contracts cease to operate, given that the exceeding of the limits of competence constitutes an exclusion clause in most of doctors' professional liability insurance contracts ("malpractice insurance")¹⁸.

Analysing the legal context, it is clear that, in exceptional conditions, the GP is allowed to practice outside the boundaries of his/her own specialty. The pandemic showed us that „exceptional conditions” could become routine practice and the doctors should be prepared from both scientific and legal perspective.

III. Patient's Informed Consent. Refusal to consent. Medical interventions without consent

Obtaining the patient's informed consent is mandatory for any kind of medical act. It is obtained from the patient or his/her legal representative, in accordance with the law¹⁹.

If the major patient having judgement refuses²⁰ the medical act, the doctor has the obligation to respect the patient's decision and to inform him/her regarding the refusal's consequences.

Medical acts may be performed against the will of the adult patient having judgement only in two situations: based on a court decision²¹ or under conditions of involuntary hospitalization, permitted by law in the

case of patients with psychiatric disorders, in compliance with the conditions specified in the Law no. 487/2002 regarding Mental Health and protection of persons with mental disorders²².

If the patient's refusal to comply with medical recommendations may pose a danger to himself or to public health, the doctor may breach the rule of medical data's confidentiality and may notify the authorities. This exception to the rule of maintaining the confidentiality of medical data is expressly provided in the legal texts applicable to medical practice²³.

In case of a minor or a major patient without judgement and in the situation when the legal representatives of these patients refuse to accept the medical act, an arbitration commission, constituted at the level of the medical institution, will decide, in accordance with the law²⁴.

For minors deprived of liberty who do not have a legal representative, the attending physician of the detention place acts as a legal representative, exclusively for the provision of medical assistance and preventive measures, according to article 47 par. (4) of the Decree no. 195/2020 and during emergency situations, as provided by the above-mentioned Decree.

Physicians may perform medical procedures without the patient's consent, in accordance with the law, in situations where the following conditions are cumulatively met:

1. it is a medical emergency;
2. the patient cannot give his/her informed consent;
3. there is no time to obtain consent from the patient's legal representatives.

In this case, no consent will be needed and the Emergency Report will be completed later. If the medical act was performed with the exceeding of the professional competence, the report will mention the fulfilment of the 3 legal conditions that allowed this exceeding (conditions mentioned and analysed during a previous chapter).

Providing healthcare in pandemic could be challenging. Important decisions are to be made, but as long as the medical legislation was not amended as a result of the pandemic, the patients' rights must be respected. No treatment or vaccine campaign should be performed without patients' consent as regulated/prescribed by law.

IV. Telemedicine

WHO defines telemedicine as "the delivery of health care services, where distance is a critical factor, by all

health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities".

Since 2013, The Romanian National College of Physicians Code of Conduct has stated that "... any medical decision will be based primarily on the personal and immediate examination of the patient by the concerned doctor".

In March 2020 the Romanian Government issued legal norms which provide that: "During the state of emergency, the medical consultations provided in the package of basic services, respectively in the minimum package of medical services, can be provided remotely; these can be provided both by family doctors and by specialists from the outpatient clinic and can be carried out by any means of communication, within the maximum number of 8 consultations/hour" (Government Decision no. 49/2020).

In November 2020 the medical law was changed in order to regulate telemedicine in Romania (by Emergency Government Ordinance no. 196 of 18.11.2020). The procedural norms for applying the law are nowadays in public debate.

The COVID-19 pandemic brought new ways of practicing family medicine. But there are significant limits in using telemedicine. The GPs encountered difficulties when using the communication technologies due to poor quality of images, lack of patients' knowledge and experience in using mobile devices etc²⁵.

Concluding remarks

- The crisis has put family medicine at the centre of the health care system and has highlighted its strengths: patients count on their family doctor for information, advice, reassurance, forward referral, and all the other critical components of primary care more than ever²⁶.
- This pandemic has genuinely demonstrated the medical professional's need to adapt, evolve and thrive, even in these times of unprecedented crisis.
- Family doctors can and, therefore, must play a crucial role in COVID-19 research through the careful registration of all their COVID-19 patients; both survivors and the deceased, including patients who tested positive for a virus test, as well as patients

with typical COVID-19-like symptoms who were not tested – and most often were not hospitalised – but recovered at home, in isolation.

- The pandemic has created a pressure to change the focus from routine activities to critically thinking about individuals' real health needs in communities, as well as staff health and safety.
- A shift is happening from reactive curative care towards a more promotive, preventative community-based approach.
- GPs all over the world had to change the way they work in response to COVID-19. Keeping up with new protocols and guidance, responding promptly to the changing environment, and navigating uncertainty has become the new normal and at times can be overwhelming²⁷.

- The legal framework was also modified as result of the pandemic. Complying with the medical law requirements is another challenge. The medical malpractice litigation's risk should be taken into consideration even when doctors are regarded as "heroes". None is above the law.

Compliance with ethics requirements: The authors declare no conflict of interest regarding this article. The authors declare that all the procedures and experiments of this study respect the ethical standards in the Helsinki Declaration of 1975, as revised in 2008(5), as well as the national law. Informed consent was obtained from all the patients included in the study.

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8. However, patients can change GPs after a 6 months minimum period.
9. 53% of the localities in Romania have no family doctor or an insufficient number of physicians overall, according to the statistics valid of August 2019. Data available on <https://snmf.ro/en/>.
10. For example, orthopedic medical officers and ophthalmology specialists are screening people for acute respiratory symptoms, some joining nurses and community health workers.
11. Data available on <https://covid19.who.int/>.
12. Data available on: <https://snmf.ro/en/overview/>.
13. The National Health Insurance House (CNAS) administers all the funding and is responsible for planning and purchasing, through its county branches, health services from both public and private hospitals, laboratories, pharmacies, ambulatory care specialists, GPs etc.
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