THE COVID-19 EMERGENCY AND THE PROFESSIONAL LIABILITY OF HEALTHCARE PROVIDERS: THE SITUATION IN ITALY

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ABSTRACT

The manuscript concerns the problem connecting to how can the current law on the professional liability of healthcare providers be reconciled with the activities that physicians are substantiall yforced to do in the emergency to care for COVID-19 patients. The Italian healthcare system I sworking in catastrophic conditions of urgency. In the face of this dramatic situation, advertisements for "legal studies" have begun appearing in some newspapers and social media outlets, offering free consultations to represent claims for damages against subjects, physicians and healthcare structures involved in caring for COVID-19 patients. Italian healthcare workers, especially those on the front lines assisting COVID-19 patients, have a compelling need for this amendment in order to be able to work serenely without fearing future penal and/or civil suits against them. In this context, LAW no. 76 of May 28, 2021, containing "Urgent measures for the containment of the COVID-19 epidemic, in the field of SARS-CoV-2 vaccinations, justice and public competitions" was issued. The Italian situation on the relationship between medical liability in the coronavirus emergency and malpractice claims and the solution being proposed in Italy to reduce the problem are also of interest to the global medical community.

Keywords: COVID-19 Emergency, Professional Liability, Healthcare Providers, Health Policy, SARS-Cov-2 Vaccination

INTRODUCTION

In Italy, as well as in other countries, healthcare providers are called to answer for the consequences of their actions in contexts of civil law, penal law and professional association regulations. In addition, if they are employed by government structures, they can be subject to disciplinary proceedings and administrative liability.

In 2017, Italian Law No. 24/2017 (law n. 24/2017) established regulations for various aspects of professional activity in healthcare. The law focused primarily on the professional liability of physicians and healthcare professionals in the context of ensuring the provision of quality healthcare, and indicated possible sanctions to be adopted in cases of negligence on the part of healthcare professionals and organizations. It stated that safety in healthcare is part of the right to health guaranteed to citizens by art. 32 of the Italian Constitution, and indicated that this safety is achieved through a set of activities that all personnel must complete, characterized by a multi-disciplinary framework that embraces structural, technological and organizational resources. Thus, the vision has expanded from the repercussions for a healthcare professional whose actions harm

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the patient, to organization-wide liability of the national health directorates, whose efforts to increase patient safety must include a central focus on the professional liability.

The content of art. 5 of this law on the choice of medical treatment and compliance with guidelines are of particular interest in this discussion. The article requires compliance with specific guidelines for professional healthcare practices or, in the absence thereof, with good clinical practice guidelines. It calls for specific guidelines to be produced and implemented according to a structured procedure organized into several successive stages. In the absence of guidelines structured according to the specific provisions of the law, doctors must adhere to "good clinical practices."

While the definition of this concept is far from simple and is interpreted differently by various authors, it clearly includes professional practices to protect health, as based on scientific evidence, and the behavior recommended in documents, provided they are consistent with scientific evidence and processed with a stated methodology that can be reconstructed.

PROFESSIONAL PRACTICE STRATEGIES OF HEALTH CARE FACILITIES

How can the current law on the professional liability of healthcare providers be reconciled with the activities that physicians are substantially forced to do in the emergency to care for COVID-19 patients?

As a premise to answering this question, it is to be recalled that the first COVID-19 case was officially recorded in Italy on February 18, 2020. Since then, the Italian government has progressively imposed social isolation on the population, and in parallel, sought to provide for the healthcare needs of the enormous influx of symptomatic infected patients, including some minors (Fedeli, 2021).

In the first month, healthcare structures faced logistical problems (Rosenbaum, 2020), such as the insufficient number of beds in intensive care, the inadequate number of specialized staff, and the insufficient supply and quality of protective clothing, gloves, masks, etc. for workers. Equally inadequate was the treatment regimen for infected patients, absolutely not authorized (Nicoli, 2020). The only extant scientific literature was the series of articles published by Chinese physicians, which, however, provided no indications for standard therapy. In addition, the Chinese 4th edition guidelines (Guidance, 2020) and those of the WHO guidelines (Guidance, 2020) present significant differences.

Italy's Scientific Society of Internal Medicine (Scientific Society of Internal Medicine, 2020) defined clinical phenotypes and proposed criteria for identifying and managing them. However, spontaneous groups of physicians organized through social media have shown that the manifestation of the disease varies from subject to subject.

Even current experiments authorized by the Italian Medicines Agency (AIFA) originated with empirical considerations formulated by physicians, outside any authorized experimental protocol. One example is the use of Tocilizumab, a drug authorized for treatment of rheumatoid arthritis that seemed to counter the production of IL6 in COVID-19 induced pulmonary fibrosis.

Hospitals, scientific societies and even the WHO have formulated proposals for treatment, incorrectly terming them "protocols" when they are actually simple management itineraries for a pathology whose etiological agent has been identified, but whose pathogenic modalities of action within the human body we have only begun to understand in the first ten days of March 2020 (Guo, 2020).

In other words, COVID hospitals are using exclusively off label treatments, most likely justified by the state of necessity or with the spoken consent of the patient, which for that matter does not comply with Italian law, which requires documented consent "in written form or through video recording" (law n. 219/2017).

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The Italian healthcare system worked in catastrophic conditions of urgency; it has had to re-organize the healthcare structure, converting hospitals to exclusive use of COVID-19 patients in the arc of 24-48 hours, staffing intensive care units with unspecialized personnel not properly trained for the purpose, and accepting international "help" in the form of Cuban, Chinese, Russian and Albanian physicians. Thus, we have hospitals with wards speedily equipped in terms of logistics, structures, and staff, with the inevitable operative insufficiencies that must ensue (Santacroce, 2020). Unfortunately, these deficiencies have also regarded prevention of contagion, leading to a notable number of infections and deaths among healthcare workers as of September 19, 2021, 361 physicians have died.

THE CURRENT HEALTH POLICY AND LEGAL SYSTEM IN ITALY

In the face of this dramatic situation, advertisements for "legal studies", have begun appearing in some newspapers and social media outlets, offering free consultations to represent claims for damages against subjects, physicians and healthcare structures involved in caring for COVID-19 patients. Even though many groups, including some bar associations, have taken a stand against these initiatives (Anelli, Lettera al CNF, 2020; National Bar Council, Letter to the Presidents of the Councils of the Bar Association and the Presidents of the District Discipline Councils, 2020), the problem posed by the current set of regulations does exist (Parisi, 2020). Thus, healthcare workers feel "crushed" not only by a sense of powerlessness, lacking suitable weapons for fighting the infection, and witnessing daily the deaths of many of their patients (Ingravallo, 2020), or by the fact that they themselves are exposed to the concrete risk of contracting the infection, which could be lethal for them as well, but also by the risk that in the future they may be caught up in civil and/or penal proceedings for failing to have assisted patients correctly.

These factors have prompted a group of physicians to propose that the "Cura Italia" Decree (law n. 18/2020) be amended to contain safeguards about the civil and penal liability of healthcare workers: the following substantially captures the content of the various drafts that given the new and exceptional nature of the healthcare emergency caused by the spread of COVID-19, in relation to damages caused by it, the civil liability of government or private healthcare and social/healthcare structures, and of healthcare professionals as defined in Law n. 24 of March 8, 2017, article 7, is limited to cases in which the damage was caused by grave fault or malice; grave fault is defined as clear and unjustified violation of the basic principles that govern the healthcare profession and the protocols or programs established to face the emergency.

Italian healthcare workers, especially those on the front lines assisting COVID-19 patients, at that time had a compelling need for this legislation in order to be able to work serenely without fearing future penal and/or civil suits against them. There may be a great number of such suits, not only given the high number of patients who have died, but also because it would not be difficult to document damages from presumed incorrect healthcare services due to behavior not in line with the current legislation about informed consent and good clinical practice. In addition, an increased number of claims for malpractice damages might be advanced by the heirs of those who have died of COVID-19, driven by their own financial straits in the current and forecasted future economic crisis caused by the pandemic (Statista Research Department, 2020; Williams, 2020).

Several authors (Caputo, 2020; Roiati, 2020) have suggested applying art. 2236 of the Civil Code in criminal judgments for medical malpractice in emergency contexts such as those related to the COVID-19 pandemic. Reference is made to judgments that have recognized that the difficulty coefficient of a medical service, however apparently simple "on paper", can increase due to organizational factors or the presence of emergency situations, thus legitimizing recourse to the "rule of experience".

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The pandemic scope has imposed dramatic choices on physicians (Siaarti, 2020), has forced them to work even with "off label" treatments, according to emergency organizational modules and with scarce resources available.

In addition, it has further highlighted the link between inauspicious events and organizational modules, introducing in a predominant way the theme of "managerial" responsibility in the medical field (Caletti, 2021).

It is therefore understandable that health professionals have expressed the need for protection and containment of responsibility, which, however, has not been followed by specific organic legislation, except for Decree Law No. 44 of April 1, 2021, which introduced the "criminal shield" for manslaughter and culpable personal injury "occurred due to the administration of a vaccine for the prevention of SARS-CoV-2 infections, carried out during the extraordinary vaccination campaign in implementation of the National Plan" (art.3). The rule provides that punishment is excluded when the use of the vaccine is in accordance with the indications contained in the marketing authorization issued by the competent authorities and circulars published on the institutional website of the Ministry of Health relating to vaccination activities.

This pronouncement was followed by art. 3b is, introduced with the conversion law 76/2021, which states that in case of death or serious injuries suffered by the patient, caused by the emergency situation, health workers will be punishable only for cases of gross negligence.

The judge, in order to establish cases of gross negligence, must take into account, among other things, the limited scientific knowledge of the pathology and COVID treatment, the scarcity of available means and resources, and in conclusion, the overall situation of extreme difficulty (both objective and subjective) in which healthcare workers operate.

In the Italian legal system, the principle of "favor rei" is in force, according to what is stated in our Constitution (art. 3) and in the penal code (art. 2 co 4), therefore, a criminal regulation of favor towards the accused, such as art. 3b is L. 76/2021, must also be applied to facts that occurred prior to its coming into force, and therefore from the first declaration of the state of emergency, (on January 30, 2020), until its end (December 31, 2021).

However, the regulations introduced are limited to a few cases and, in any case, require the beginning of investigations or a trial against the healthcare worker. A specific legislative intervention is desirable; this, if on the one hand it could represent an adequate recognition for the efforts made by health professionals, on the other hand it could represent an incentive to involve insurance companies, which are addressed by Law No. 24/2017 (Romagnoli, 2019), that could otherwise permanently abandon the health risk market.

CONCLUSION

In such similar contexts, legislation enacted in urgent situations is not always marked by high quality; in the very delicate sphere of protection of rights, there needs to be a correct balance between the patient’s right to receive proper care and to share in decision-making about treatment, having been provided correct information as the basis for valid consent, and the healthcare provider’s right to attempt to do as much as possible for the patient, without risking subsequent accusations of incongruous conduct for those very choices that in the emergency seemed justified.

In this phase of emergency, such a balance is essential so that the perverse mechanisms of defensive medicine that cause so much damage will not be triggered, to the detriment of the patients, so desperately in need of treatment.

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