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Liability of Health Care Professionals and Institutions During COVID-19 Pandemic in Italy: Symposium Proceedings and Position Statement

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Background: On May 12, 2020, a symposium titled "Liability of healthcare professionals and institutions during COVID-19 pandemic" was held in Italy with the participation of national experts in malpractice law, hospital management, legal medicine, and clinical risk management. The symposium's rationale was the highly likely inflation of criminal and civil proceedings concerning alleged errors committed by health care professionals and decision makers during the COVID-19 pandemic. Its aim was to identify and discuss the main issues of legal and medicolegal interest and thus to find solid solutions in the spirit of preparedness planning.

Methods: There were 5 main points of discussion: (A) how to judge errors committed during the pandemic because of the application of protocols and therapies based on no or weak evidence of efficacy, (B) whether hospital managers can be considered liable for infected health care professionals who were not given adequate personal protective equipment, (C) whether health care professionals and institutions can be considered liable for cases of infected inpatients who claim that the infection was transmitted in a hospital setting, (D) whether health care institutions and hospital managers can be considered liable for the hotspots in long-term care facilities/care homes, and (E) whether health care institutions and hospital managers can be considered liable for the worsening of chronic diseases.

Results and Conclusion: Limitation of the liability to the cases of gross negligence (with an explicit definition of this term), a no-fault system with statal indemnities for infected cases, and a rigorous methodology for the expert witnesses were proposed as key interventions for successfully facing future proceedings.

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As of May 25, 2020, in Italy, the COVID-19 pandemic has resulted in 230,414 cases of infection and 31,546 deaths, with 27,439 cases among health care professionals (HPs).[1] Considering these numbers, it is highly likely that, in the near future, a significant share of these cases will evolve into criminal and civil proceedings for medical malpractice. Italy has a Civil Law system in which the legal principles are derived from statute laws and their interpretations provided by Supreme Court rulings. Italy is one of the few countries globally where physicians can be criminally prosecuted.[2] Nevertheless, if the experimentations conducted in Maine, Minnesota, Florida, and Vermont in the 1990s in the United States are not considered,[3] Italy is the first Western country to develop a "safe harbor system" for criminal liability of HPs. In fact, Law No. 24/2017 states that an HP who commits an avoidable technical error can be considered not guilty if full compliance with proper national guidelines/protocols is proven and it is not a case of "gross negligence" (a term that is not explicitly defined by any law). Moreover, this law states that, in civil proceedings, the burden of proof is on the plaintiff if the litigation involves an HP who works in a health care institution, whereas it is on the defendant if the lawsuit is directed against a health care institution or private practitioner. Although many other revolutionary changes have been made by this law (e.g., in the field of hospital risk management), the aforementioned principles have had the widest and strongest impacts on the medical community.[4–6]

On May 12, 2020, a symposium titled "Liability of healthcare professionals and institutions during COVID-19 pandemic" was held by the Università Cattolica del Sacro Cuore and Fondazione Policlinico Universitario Agostino Gemelli IRCCS (one of the main national referral centers for the diagnosis and treatment of COVID-19 cases). The main scope of the symposium was to assess whether current Italian laws on HPs' liability are adequate to face the very likely future inflation of legal proceedings on this matter and to allow the judges to consider all the issues and particularities of having operated during a pandemic.

METHODS

Before the symposium, the organizers selected 5 points of discussion, choosing the main issues related to the liability of health care institutions, hospital managers, and/or HPs that could have been discussed by criminal, civil, and medicolegal perspectives. Experts in medical malpractice law, legal medicine, and hospital and clinical risk management were invited to participate in the symposium. Each participant was asked to discuss the 5 issues from his own perspective. At the end of the symposium, because there were no points of disagreement, the moderator summarized

and combined the views expressed by the participants and underlined the legal interventions that had been proposed. The contents of the summary report and the position statement were unanimously approved.

ADDRESSED ISSUES

There were 5 main points of discussion during the symposium:

A. How to judge errors committed during the pandemic because of the application of protocols and therapies based on no or weak evidence of efficacy
B. Whether hospital managers can be considered liable for infected HPs who were not given adequate personal protective equipment (PPE)
C. Whether HPs and institutions can be considered liable for cases of infected inpatients who claim that the infection was transmitted in a hospital setting
D. Whether health care institutions and hospital managers can be considered liable for the hotspots in long-term care facilities/care homes
E. Whether health care institutions and hospital managers can be considered liable for the worsening of chronic diseases

DISCUSSION

A. *How to judge errors committed during the pandemic because of the application of protocols and therapies based on no or weak evidence of efficacy*

Italy has been one of the first countries to face the COVID-19 pandemic and one of the countries with the highest number of COVID-19–related deaths consistently. Hence, for a very long time, physicians have had to make clinical decisions and operate without guidelines, scientific evidence, or expertise in this field —an issue that has necessarily led to off-label drug use and experimentation of new technical approaches.[7] Currently, several national and international recommendations have been published on the management of COVID-19 cases, but they should only be considered as "emergency guidelines" because they are based on rudimentary and rapidly growing knowledge on this new infectious disease. Furthermore, young (and then relatively inexperienced) physicians and residents have been working on the "front line" since the outbreak of the pandemic. In normal circumstances, all these patterns of conduct would be considered imprudent, but they have been and continue to be necessary to compensate for the national and regional health needs. Finally, ethical dilemmas regarding crucial legal implications have arisen. For example, priority assignment in the case wherein the number of critical patients exceeds the capacity of the intensive care unit (ICU) is a very complex and sensitive issue. The Italian Society of Anesthesiology, Analgesia, Resuscitation and Intensive Care has published some recommendations in this regard, stating that, during the pandemic, when the number of critical patients exceeds that of ICU beds, giving priority to those with higher life expectancy (the younger) could be considered as an alternative to the "first come, first served" criterion.[8] The Italian National Bioethics Committee advises against using these criteria, stating that such decisions should be based on the therapy's chance of success rather than on only the patient's age.[9]

B. *Whether hospital managers can be considered liable for infected HPs who were not given adequate PPE*

Since the outbreak of the pandemic, Italian public health policymakers and health care managers have been facing many critical issues, particularly regarding the allocation of resources (e.g., PPE) and the exceptional volume of cases to be treated in hospital departments and ICUs. Bed capacity of national hospitals (particularly of ICUs) and physicians' supplies have also been limited because of the continuous cuts to public health spending and proven inadequacy of the national prepandemic preparedness planning. Hence, the pandemic has pushed hospital resources near the breaking point. These factors have caused HPs to face very stressful psychological conditions and have exposed them to significant (and avoidable with proper equipment) health and safety risks in many health care facilities.

C. *Whether HPs and institutions can be considered liable for cases of infected inpatients who claim that the infection was transmitted in a hospital setting*

The high contagiousness of the disease (and, in some cases, poor organizational decisions and shortage of PPE) could have led some HPs to unwittingly infect their patients. Moreover, many patients could have been exposed to the virus in emergency departments and hospitals in which COVID-19 cases were not isolated. Under these circumstances, the COVID-19 disease should be considered a hospital-acquired infection. Hospital-acquired infections represent one of the most common causes of malpractice claims and, at the same time, one of the most complex classes of medicolegal issues.[10,11] Whether a health facility can be considered liable for an hospital-acquired infection or not mostly depends on the demonstration that (i) the infection was the actual cause of death, and alternative hypotheses can be excluded; (ii) there were effective preventive measures the operator should have adopted; and (iii) the operator did not fully comply with the health and safety standards. However, point (i) is limited by the fact that many centers are performing very few or no clinical autopsies,[12,13] whereas points (ii) and (iii) are relatively weak because there is general consensus on the efficacy of very few preventive interventions, and in a legal proceeding, it is difficult to prove whether they (e.g., handwashing) were adopted or not. Furthermore, in both criminal and civil proceedings, the so-called but-for test must be applied before taking a decision on liability—but for the hospitalization, how likely is it that the infection would have occurred? This test must validate the hypothesis beyond any reasonable doubt in criminal proceedings and with a preponderance of evidence in civil proceedings.[2] This is an interesting point because in many cases (especially in cases of infected HPs), it is nearly impossible to prove that, during a pandemic, a SARS-CoV-2 infection was transmitted in a hospital rather than in any other indoor or outdoor setting.

D. *Whether health care institutions and hospital managers can be considered liable for the hotspots in long-term care facilities/care homes*

Hospital foci can easily become catastrophic, as they jeopardize the health conditions of COVID-19 and non–COVID-19 patients and reduce the HPs' supply (and thus the volume of patients that can be adequately treated). Hospital managers and health policymakers had to (and have to) plan and adopt all interventions to contain the risk of hospital foci occurrence. Nevertheless, it is likely that many future proceedings would be based on the claim that these hotspots were caused by organizational errors. Consider this example: the Regional Council of Lombardy (the most affected Italian region) deliberated that half of the beds in care homes (Residenze sanitarie assistenziali) must be reserved for COVID-19 cases. After this decision, the death rates in these institutions increased dramatically.[14]

E. *Whether health care institutions and hospital managers can be considered liable for the worsening of chronic diseases*

Because of the relevant and rapidly growing volume of COVID-19 cases, health care institutions have radically reconfigured all hospital services and aspects of care, focusing on providing services for infected patients. In several cases, surgical elective procedures have been avoided to reserve anesthesiologists, transfusions

of blood products, and ICUs for COVID-19 patients and other particular cases (e.g., those recovering from emergency surgeries and victims of car accidents).[15,16] Without these changes, the Italian public health system would not be able to treat and contain the disease. However, despite the severity of the pandemic, patients who have chronic diseases still need therapies and regular clinical/radiological evaluation. For many of them, the pandemic can represent a limitation to secondary prevention interventions (e.g., diabetic and cardiopathic patients have been limited in terms of outdoor physical activities) and a bigger health hazard than the COVID-19 itself in case of clinical mismanagement. Moreover, it should be noted that, despite this unprecedented and severe pandemic, cardiovascular diseases and cancer remain the primary causes of death.

During the pandemic, a 50% reduction in hospitalizations for acute coronary syndromes has been noted. This anomaly has been explained by several concurring factors, such as patients' fear of going to hospitals because of the risk of infection and the exceptional workload burdening all services and HPs.[17,18] Even cancer care has been strongly affected: Spicer et al[19] noted that, during the pandemic, some cancer symptoms such as dyspnea could easily lead to cases of missed diagnosis or misdiagnosis (suspecting COVID-19 without adequately excluding alternative diagnoses). Moreover, these authors underlined that access to surgical procedures, brachytherapy, ventilatory support, proper palliative care, and even medical attention can be highly limited by the redeployment of resources for COVID-19 care.

POSITION STATEMENT

When the pandemic ends, it is highly likely that the current grief for the loss of many people who died with or of COVID-19 or the injuries caused by the disease will convert into anger and, in some cases, greed. The likely future economic crisis caused by the pandemic could inflate the number of claims and criminal/civil proceedings for suspected malpractice during the COVID-19 pandemic. Up to now, to the best of our knowledge, no study has been published on this matter, although this issue is likely to affect the entire world. In Italy, both the National Bar Council (Consiglio Nazionale Forense)[20] and the Italian Society of Legal Medicine[21] have recommended their members not to speculate on these tragic events. These positions are important but not enough, because hospitals and HPs are making extraordinary and unprecedented efforts to contain and treat the COVID-19 disease, and their sacrifices during these emergency and catastrophic conditions should not be forgotten when the pandemic ends.

During the symposium, 2 legal interventions were individuated to properly cope with and face the likely future scenario:

i)Regarding criminal law, HPs should be considered liable for avoidable errors occurred during the pandemic only in cases of gross negligence. Gross negligence should be clearly defined by law to avoid heterogeneous and arbitrary interpretations. The principle expressed by Ruling No. 8770/2017 ("Sentenza Mariotti"), a landmark decision of the Italian Supreme Court, should be systematically adopted. In this ruling, it is affirmed that an article of the Civil Code (2236 cc) can also be applied in criminal law. Article 2236 cc states that an HP who operated under unusual and complex circumstances can be considered liable only if the misconduct was intentional or characterized by gross negligence.

ii)Regarding tort law, compensations are "transfers of wealth," and thus, an abnormal volume of civil proceedings could further exacerbate the effects of the likely future economic crisis. In other words, civil proceedings for facts occurring during the pandemic could jeopardize the economic stability of public/private hospitals, citizens (patients and HPs), and insurance companies. For these reasons, a "no-fault system" is needed: set compensations for injuries caused by the COVID-19 disease in hospital settings (paid for by the State) instead of variable compensations obtained via lawsuits. Italy has already successfully experimented on this model in 1992 with Law No. 210, which disposed indemnities for those who had contracted the HIV, hepatitis C virus, or hepatitis B virus infections because of mandatory vaccinations or infected blood transfusions. It is clear that the cost of this type of compensation system would be considerably high, and thus, access to it could be restricted to HPs who have been infected.

Moreover, the role played by expert witnesses could be very important. In Italy, in any criminal or civil proceeding for medical malpractice, the involvement of (at least) one expert in legal medicine is mandatory. In future proceedings on facts concerning the pandemic, as recommended by the Italian Society of Legal Medicine,[21] these experts should help the judges, prosecutors, and lawyers contextualize any fact, giving a clear and detailed insight into all the pieces of evidence on the disease and on guidelines that were available at the time of the error.

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