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Liability of clinical oncologists and the COVID-19 emergency: Between hopes and concerns[☆]



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ABSTRACT

To contain COVID-19 spread, Italy is under a global lockdown since February 21, 2020, except for health services and food supply. In this scenario, growing apprehension concerning legal consequences is rising among health professionals due to several ethical and legal questions. Even if medical ethicists may approve patients' prioritization protocols, hospitals and health professionals remain highly exposed to liability. The so-called smart-working may be very useful, but it may harbor potential legal harms for health personnel and patients and safety. Moreover, personal umbrella policies also often exclude liability arising out of the transmission of a communicable disease, especially a pandemic state, is declared. Under the pressure of medical associations, Italian Government political forces have very recently presented an amendment to the recently released ordinances for the COVID-19 emergency aimed to reduce medical liability. Presumably, similar epidemics or other wide-scale similar events may happen again in an unpredictable future. Therefore, more articulated legal regulations are strongly needed starting from lessons learned from this epidemic.

To date, Italy is experiencing a severe outbreak of COVID-19 infection with a largely unexpected death rate [1]. As a consequence, the entire nation is under a global lockdown to contain virus spread since February 21, 2020, except for health services and food supply [2].

The sharp increase of patients with COVID-19 related severe acute respiratory syndrome (SARS) requiring in a high percentage of cases immediate hospitalization in intensive care units is rapidly saturating the Regional Health System capacity in some areas of the nation [3]. In a few days, many hospitals have generated COVID-19 dedicated units [4]. In this contest, many medical procedures have been shortened by necessity, and patients withheld or transferred with the uncertainty of correct and adequate enforcement of risk management procedures. Due to the reported health risk of cancer patients in China, the Italian Government, and the Italian scientific associations released guidelines

for the management of patients affected by solid and hematological tumors [5]. The measures taken include, among others, postponing follow-up visits and "unnecessary and non-urgent" treatments as well as social distancing and visitors limitation in hospitals.

In this scenario, growing apprehension concerning legal consequences is rising among health professionals not only in Italy but also in the USA. In a recent commentary, Cohen and colleagues [6] raise the ethical and legal issue of deciding which patient should be treated in a moment of a shortage of pulmonary ventilators and invoke urgent State Government actions. Even if medical ethicists may approve patients' prioritization protocols, hospitals and health professionals remain exposed to liability. In our opinion, this is not the only legal risk. The so-called smart-working, applied by several non-medical companies, may be very useful, but it may harbor potential legal harms for health

[☆] In honor of the numerous Italian doctors and nurses died during this dramatic time

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personnel and patients' safety. For instance, releasing prescriptions or judging patients' conditions via not validated web-based social media and or instant messaging systems may be harmful to both patients and doctors. These concerns are not unmotivated since legal claims and proceedings for malpractice in this setting are already increasing. Uncertainty about professional insurance coverage exists exacerbated by sometime necessary or involuntary violations of disease guidelines. Moreover, personal umbrella policies also often exclude liability due to communicable diseases, especially if the World Health Organization declares a pandemic state as done on March 11.

In Italy, the plaintiff may legally pursue healthcare professionals both in criminal and civil courts. A recently released law has stated that healthcare professionals should follow validated disease-specific guidelines in their daily clinical practice. Moreover, the plaintiff must prove that the defendant is guilty of the preponderance of the evidence [7]. If physicians deviate from guidelines, they may be considered negligent in case of a claim, and the plaintiff compensated for injuries and financial damages. Although malpractice claims against the at-fault party remain civil, however, malpractice may become a criminal matter, especially if fraud is suspected or conducting unnecessary procedures or complications because of the haphazard prescribing as may occur in cases of unexpected deaths or loss of chances especially when gross negligence applies. In Italy, patients or families who feel damaged may trigger the criminal process. Attorneys often use penal proceedings as a "pressure" weapon to obtain civil reimbursements since the outcome of criminal trials may affect the civil one. Even if the vast majority of claims end with healthcare professionals acquittal, however, pursued physicians, if condemned, may face administrative penalties from hospitals and sometimes the loss of their medical license and job. Nevertheless, such events affect physicians profoundly both psychologically and economically.

Under the pressure of medical associations, Italian Government political forces have very recently presented an amendment to the recently released ordinances for the COVID-19 emergency aimed to decriminalize medical liability. At present, after a few days from its presentation, the amendment is under evaluation by the Parliament. It may be reported as follows: "*Art. 13 Bis. Limitations to civil, criminal, and administrative liability of all medical institutions and healthcare professionals; during the time emergency due to COVID-19 epidemics, as indicated in the resolution of January 31, 2020, released from the Italian Government Cabinet and subsequent modifications or extensions, the medical liability of healthcare personnel, community health and public, private hospitals are limited to the fraud cases only in derogation to current laws and because of the extraordinary emergency and the awesome commitment of healthcare professionals*". Most health professionals have vigorously applauded this amendment.

Finally, the health personnel cannot be held strictly liable for

damage due to an involuntary violation of disease guidelines as may occur during the COVID-19 emergency, according to the case-law of the Italian Court of Cassation (see Judgment n. 35922, 11 July 2012). The Court stated that experts should assess "*the physicians' compliance with the guidelines in light of the concrete situation in which the professional had to intervene.*"

On a broader view, but in the absolute respect of our patients' lives and rights, the concept of damage and liability of healthcare should be revised both culturally and legally. Presumably, a similar epidemic or other similar wide-scale events may happen again in an unpredictable future. Therefore, more articulated legal regulations are strongly needed starting from lessons learned from this epidemic.

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