



## Commentary

## COVID-19 and medical liability: Italy denies the shield to its heroes

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Since early June 2020, several Public Prosecutors at the head of the most important Italian Judicial Districts started to conduct penal investigations on physician behaviors concerning the prevention, diagnosis, and treatment of citizens affected by SARS-CoV-2. The main issue under scrutiny is the actual possibility to avoid or, to better say, to mitigate the pandemic risk in both public and private healthcare institutions. As well known, Italy is one of the Countries in a worldwide context more severely affected by the SARS-CoV-2 pandemic and some of the northern regions paid the highest price in terms of deaths among health care workers (HCWs). The 'Istituto Nazionale Assicurazione Infortuni sul Lavoro' (INAIL), the Italian public insurance body that protects workers in the event of accidents and occupational diseases, reported that 40% of the 236 filed fatal cases involved HCWs [1]. On the other hand, the statistics of the 'Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri (FNOMCeO)', the national federation of Italian medical doctors and dentists, counted higher figures (171 deaths among those registered at 27.06.2020), regardless of whether or not a complaint was filed with INAIL [2].

In a few weekstime frame, HCWs went from heroes to potentially 'negligent' health professionals, while lawyers and prosecutors want to put their decisions and treatments under examination [3,4]. While several liability protection or pandemic-related immunity schemes have been proposed and adopted worldwide, in Italy ordinary laws still rule this extraordinary event. The legal cause of action is dual: multiple manslaughter and negligent epidemic. While in the first case Prosecutors have to prove the causal relationship between a putative professional misconduct and the cause of death of the plaintiff, in the other scenario it could be sufficient, to convict the attending

physicians and/or the ones in charge of hospital clinical governance, to prove that among the huge amount of the sick (241.419 infected – 2.1% of world and 8,7% of Europe - and 28.710 deaths – 6,5% world and 19.5% Europe) a relative number of infection (even if a residual percentage) could be somehow prevented [5,6]. The prompt adoption of general measures such as universal use of protective masks, social distancing in the wards, the forbidding to assisting relatives in the hospitals and nurse facilities, a generalized testing for SARS-CoV-2, and COVID antibodies testing for all HCWs, are today considered as mandatory actions to be implemented in everyday clinical activities. Although necessary, none of these precautions – alone or in combination – are sufficient to set the risk to zero. From a negligent pandemic point of view, this may mean that if the hospital – even a no-COVID one - does not provide for all these measures, and one or more cases of SARS-COV-2 positive patients are detected in the healthcare facility, a presumption of liability may be enough to pursuing a negligent pandemic crime (article 452, Italian penal code). This crime requests as its main features the existence of the risk of a pandemic diffusion of an 'infectious agent' to be avoided ('risk offence') and, as its consequence, the event of one or more affected individuals ('event crime').

The starting point of view of medicine and legal system does not always overlap and the final goal may differ. The actionable goal of medicine, although unattainable in concrete terms, is an in-depth knowledge of causes of a disease, its treatment and/or its prevention, being the acceptance of the illiteracy an essential part of our scientific method (*error scientiae*).

The judicial system may not wait for the best clinical explanation of a 'new' phenomenon. It needs in each circumstance the identification of a 'crisis standard of care'. And sometimes, as it is now happening in Italy, the easiest path to follow as prosecutor is to contest the crime on the basis of a breach of the duty to protect. The assumption is that, even in time of uncertainty, HCWs always have an answer, knowing how to behave to protect the health of the other citizens, using universal measures of prevention or treasuring previous knowledge. But the SARS-CoV-2 taught us that it is not always so. We are facing a biological threat whose boundaries change day by day. All the scientific efforts put into play by international community seem to be ineffective, due to SARS-CoV-2 infectivity and transmissibility, to knowledge gaps in the comprehension of the basic biology of the infection, to the Achilles' heel represented by a- and/or

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pre-symptomatic individuals. No clear procedures are at the moment available to eradicate the risk of infection and in all the Italian hospitals or in the nurse facilities a certain number of infections, sometimes even relevant in magnitude, may have been related to a source of viral contagion potentially avoidable.

Concluding, Italian physicians and managers of health facilities are likely to face a new 'tsunami-like' event, i.e. the judicial one. The latter, unless an intervention by the legislator, will be without the protection of a "penal shield". Waiting for it, healthcare workers are 'sitting on the dock of the bay, watching the tide roll away'.

### Contributions

EdA, MN, GF and PEN conceived of the presented idea. EdA, MN and RD developed the theory. EdA wrote the manuscript in consultation with MN, PEN, GF and MF

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The authors declare that they have no conflict of interest.

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