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Article Commentary

Healthcare-acquired Sars-Cov-2 infection: A viable legal category?

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Abstract. In the context of the Sars-Cov-2 pandemic, according to the various periods of emergency and the rate of infections, hospitalized subjects also contracted the infection within the ward, sometimes with the development of disease (COVID-19) and sometimes with permanent damage. The authors wondered if Sars-Cov-2 infection should be considered on a par with other infections acquired in the healthcare setting. The non-diversified diffusion between the health and non-health sectors, the ubiquity of the virus and the high contagiousness, together with the factual inability to prevent it by the health structures, despite the adoption of entry control, practices of isolation of positive subjects, and staff surveillance, lead to consider COVID-19 in a different way, in order to otherwise burden health structures in the face of unmanageable risks, clearly also dependent on exogenous and uncontrollable factors. The guarantee of care safety must, in the pandemic, be able to compare with the real capacity for intervention according to the asset of the current health service, requesting State intervention with alternative instruments, such as *una tantum* compensation, for COVID-19 damage reparation occurred in the health sector.

Keywords: Sars-Cov-2 infection, COVID-19, hospital acquired infection, health professional liability, reparation

1. Introduction

In the broad debate on Sars-Cov-2 infection, two recent opinion papers have led to urgent reflections on the profiling of Sars-Cov-2 infection as a healthcare-acquired infection (HAI), focusing on - relevant - juridical and medico-legal repercussions, in a system that looks at the safety of care, but also at the sustainability of the health system, under the fire of the subsequent litigation [1,2].

Some very initial hints have already been proposed [3,4] but it is necessary to make further and more precise critical considerations with respect to the definition *tout court* of infection *related* to

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assistance, and to the professionals responsibilities: those of single health professionals, those of the healthcare management, in case of organizational-health deficit, and those of the facilities *per se*. The aim of this commentary is to illustrate the presence and imponderability of a residual risk in healthcare activity, even more in emergency condition, and therefore the non-collectability of conducts, beyond a reasonable caution and diligence, established by science and following good practices, with the consequent considerations on compensation systems.

2. Hospital-acquired infection and causal assessment

The concept of hospital-related infection was created to broaden the term hospital infection and include all those adverse events to the patient's health attributable to treatment and healthcare assistance. The term hospital-acquired infection extends it even more since it causally leads it back to the mere presence within a health facility, and therefore leads it back to a legal criterion of liability for pure damage to third parties. Should be put Sars-Cov-2 infection in this category if acquired in a healthcare facility?

Within a structure whose obligation is to protect health, at least guaranteeing the non-worsening of the patient's condition, in comparison to the entrance condition, such a definition accomplishes the tuzioristic attitude towards the user, typical mainly of civil law.

However, even in the wake of the recognized medico-legal criteria on the causal link, the definition of hospital-acquired/related infection, at least historically, was not only linked to the times of onset, that is to the symptomatic manifestation following access into the area of assistance and healthcare, to determine the causal attribution; but also on the characteristics of the pathogen itself - a sort of phenomenological-topographical criterion- since some pathogens were specifically attributable to healthcare setting, i.e. Escherichia coli or Klebsiella pneumoniae [5,6], and in any case on the exclusion of other causes, for which their identification in the user supported the hypothesis of contagion occurring within the structure, because it was not reasonable that it would happen otherwise.

However, these definitions remain vague for Sars-Cov-2, considering that therefore the concept of health care assistance should be extended, in the wake of the Italian Gelli-Bianco Law, no. 24/2017, to the "health sector/area", and therefore to the simple presence in the structure, looking at health personnel as an infectious vector, and at three levels of filter - physical, administrative and personal protective equipment- to Sars-Cov-2 [7]. An even more valid consideration in this pandemic era, with the restrictions and controls on the flow of health personnel, visitors and families within the health facilities themselves. We should really talk about responsibility in the "health sector" as suggested by the Gelli-Bianco law.

A vision of global risk prevention necessarily comes out, along with the Enterprise Risk Management, where the workers safety and health, together with hygiene and public health policies, intersect and reverberate on the facilities clinical risk, understood in the restrictive sense, and on the management of Sars-Cov-2 care-related infection claim.

Especially in light of the very recent considerations published in the Italian Journal of Legal Medicine by the Italian Association of Professors of Criminal Law, on allowed risks and the role of Clinical Risk Management: "A part of the risk cannot be eliminated, and therefore allowed - from which the ground elements of the same professional activity- that no organizational dedication - after a severe reference to the precise governance of Risk Management - will never be able to eradicate; to reiterate, at least in the criminal field, a certain tolerance in the face of an unavoidable risk" [8].

3. Critical issues

In the first instance, the difference between asymptomatic Sars-Cov-2 infection should be pointed out - considering, however, the renowned difficulty of identifying the asymptomatic and therefore its uncontrollable and frequent role as a vector, and symptomatic Sars-Cov-2 infection (COVID-19). Then, having ascertained the causal relationship in the event, the subsequent demonstration of the consequent damage, up to the death due to COVID-19. In fact, like an epidemic flu, in the absence of *sequelae* after transient symptoms, nothing should be compensated. Attention must also be paid to simple lung anatomical damage, without functional relevance, and to those systemic reactive immune activations, linked to Sars-Cov-2, which have yet to be examined by scientific literature.

As for the significance of COVID-19 as an infection related to assistance, we could take as an example the comparison with the classification of pneumonia, divided into community and related to assistance, according to the distribution in the environment of the specific pathogen. For Sars-Cov-2 the only parameter that would lead to the attribution to the structure, would be the only occurrence within it, since the risk is equally present and widespread both in the community and in the hospital environment - obviously according to the pandemic phases.

Certainly, relevant in function of the guarantee position assumed by the structure - and its hospitalization obligation-, but to be strengthened the effective possibility of prevention, containment and management, which is certainly made more complex, if not almost insuperable, by the equal diffusion outside the facility, with respect to the claimed high levels of safety of care. An excessive rigor would be imposed on the structure, not practicable on a real-life level, to the limit of the non-attributable impediment, since otherwise the absolute isolation of the subject would be necessary, even from the health staff, incompatible with the exercise of the health activity itself, necessarily tangent to psychophysical integrity. The same hospital rooms, in order to prevent possible transmission between patients, cannot totally be converted to single use, since we would have an impracticable reduction in hospital healthcare offer, with an inevitable economic unsustainability of the model.

Some also contest the correct use of personal protective equipment and antisepsis practices, but it is also necessary to consider staff work overload and psychophysical stress. Furthermore, given the staff shortage, due to poor human resources programming in the NHS in recent decades, to fill work shifts and maintain minimum requirements in minutes of assistance, for hospital accreditation, as well as avoid social isolation - even prolonged given by the SARS-CoV-2 infectious risk containment legislation - healthcare personnel are sometimes discouraged to undergo regular health surveillance. In fact, the staff is not obliged to undergo health surveillance with nasopharyngeal swab, in absence of symptoms, so making harder for the health company the interception of many vectors as possible of healthcare-related infections.

4. Foreseeability, special difficulty and licit impediment

The considerations regarding civil liability and foreseeability/preventability of damage are also very true, with respect to the fact that the requirement of the foreseeability of the damage, related to the psychological element of it (Article 1225 of the Italian Civil Code), is applicable to contractual responsibility, to measure compensation to the degree of *culpa*. On this point, demonstrating, with respect to *probatio diabolica*, correct and applied procedures, could lead to a downsizing of the *quantum respondeatur*, also from a transactional point of view, thinking of an indirect system of civil shield, through an equitative

evaluation, if not frankly reductive, of accounting law, of the civil judge, based on the context and specific case.

In assessing the fault, the context of absolute emergency and absolute disproportion between the number of patients and the resources available, cannot be ignored. But is this assessment legitimate and fair with respect to the same damage in another context? It is possible to think of the special technical difficulties referred to in Article 2236 of the Italian Civil Code, since it is truly extraordinary management and in the absence of specific scientific literature? Or the exemption of fortuitous events, which cannot be remedied without extraordinarily superior precautions to those of the qualified diligence, required to the healthcare professional? Obviously, to be declined according to the various situations and according to the epidemiology of the pandemic [2].

It should be noted that this approach, if correctly understood, does not end up restricting beyond measure the possibility of being exempt from liability for the structures. In fact, they need always to demonstrate in trial the exact fulfillment of the organizational obligation that is being discussed, though the highest standard of care, as an alternative to the fact that the non-fulfillment was determined by an objectively unpredictable impediment and unavoidable [9]. It is therefore essential, however, to avoid an excessive and unjustified extension of the responsibility in question, to proceed with a precise perimeter of the services due by the hospitals and the value of guidelines and/or good practices to evaluate their actions. In any case, and certainly starting from an essential fixed point: a high level of safety and health protection, and the acceptance of minimal risks by the users [10].

Although we always fall back to that question that illustrious judges have posed: the occurrence of the HAI demonstrates the failure of preventive mechanisms - here incorrect use of the FFP2 mask *aliunde* improper disinfection of the surgical site? - therefore identifying single, minimal and multiple negligent attitudes [11,12]. But when does diligence qualify as high and above average, and when instead as above concrete possibilities? Because otherwise the health care model must be drastically revised, before - absolutely - health care and structures liability law reformation.

Another non-minor aspect is the incubation times of Sars-Cov-2 compared to the 48 hours of the doctrine on bacterial infections: an incubation time between 2 to 14 days and an average of 5–6 days is a too variable period of time, and a very high contagiousness, is not easy to find a *praesumptio hominis* of existence of the causal link, pursuant to Article 2727 of the Italian Civil Code.

5. Responsibilities

It is assumed lying on the structure, certainly not of the individual healthcare professionals - because in any case it cannot be traced - but not even of the health management with respect to the organizational-health deficits of the doctrine.

We could, at least initially, also refer to the functioning *superordinate* to the same structure, dependent on the enormous disproportion recorded between requests for assistance and current resources availability, as well as the novelty of the virus and its variability. Therefore, once the presence of hygienic procedures of virus management, one again would have to look at the fortuitous event, or at the boundary between it and the *factum principis*, as the reparation for COVID-19-HAI could be contested in face of the governability and controllability criteria that are regularly due. Moreover, looking at article 7 paragraph 3 of the Italian Law n. 24/2017 on the care safety and health related responsibility on the role of guidelines, it was stated that "the medical-health litigation for damage from COVID-19 will have as main protagonists the hospitals belonging to the National Health Service and will revolve around the possibility of charging them, in order

to see their civil liability affirmed, structural and organizational deficiencies", but these deficits are really in the hands of the structures or should look further beyond the health policies, in terms of last decades health financing, first of all in systems for care safety and adequacy [10,13].

In fact, it was also – and in an authoritative way- stated that "the possibility of intervening to adopt measures to contain the contagion belonged to a plurality of subjects variously entitled to provide of different territorial areas concerned" [14].

6. Conclusion

The conclusions that can be drawn are that the case of COVID-19 must not be legally treated as a classic HAI and, first, it must be contextualized according to the period of the pandemic emergency. For a correct damage assessment, specific ascertainment are required on Sars-Cov-2 prevention and management systems of health facilities "not only the identification of specific preventive operational recommendations but also, first of all, their rigorous implementation" [7] depending on the specific situation and case. Therefore, litigations deflation systems and reparation remodeling systems must be envisaged, at least in terms of the modalities. If the indemnity does not appear to be a sufficiently suitable tool to respond and *compensate* the damage caused by COVID-19, as already discussed regarding other HAIs, equitative assessment methodologies must still be considered, even if these too are not perfect. In our opinion, in fact, equitative evaluation is more correct in the face of objective responsibilities, where the structure must respond for those events resulting from that irreducible share of risk that every complex system has. This, it is worth reiterating, depends on the claim of conduct that is not concretely sustainable and feasible, as a function of that emergency that has reverberated on every decision-making and organizational and dispensing functioning, and which would now fall otherwise, and again, only on substances - human and economic- of the health service.

The occasional acquisition of the infection, which is difficult to prevent and control, leads to reparative considerations of the *una tantum* type and to systems that, albeit occurring "in the health sector", look to the canons of classic civil liability.

Having discussed numerous points still under study and absolutely controversial, the COVID-19 infection must be looked at and restored with an undoubtedly renewed eye, from a period that has changed, with the interruption of regular health activity and with the omnipresent spread of the pathogen, many constructs of health law and more.

Conflict of interest

None to report.

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