Covid-19 Pandemic and Medical Liability in Italy: How to Balance the Protection of Healthcare Professionals and Patients

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Abstract

The paper analyzes the impact of the Covid-19 pandemic on the medical liability regime in the Italian legal system. Italy has been one of the most impacted countries by the pandemic. Considering the huge number of infected patients and deaths, it is likely that the 'sanitary pandemic' will be followed by a 'judiciary pandemic'. In reality, the emergency may expose healthcare practitioners to several claims of culpability based on negligence anytime a medical error is judged directly related to the patient's injury, as in the event of misdiagnosis, poor treatment, or the death of Covid-19 positive people. The greatest risk is the underestimation of the complexities linked to the anomalous and unpredictable context within which the healthcare personnel have operated. The healthcare personnel faced challenges due to resource constraints and a lack of familiarity with the virus and its pathophysiology. In the absence of specific regulations to protect physicians' accountability, it is necessary to establish the definition of medical liability within the civil law domain by utilizing existing standards, including those outlined in the Italian civil code and the 'legge Gelli-Bianco'.

I. Introduction

Worldwide, Italy has been one of the countries most severely affected by the SARS-CoV-2 pandemic, with a remarkably high number of infected patients and an equally high number of related deaths upon contracting Covid-19.[1]

The huge disproportion between the increased clinical needs and the available resources resulted in a dramatic turn out of the situation. Indeed, due to the exponential increase of cases, the hospital-driven healthcare system had to provide its services to a growing number of patients despite the insufficient resources and the limited number of qualified personnel. Furthermore, due to the conspicuous cuts made to the public financing of the Italian healthcare system in recent years, the medical class was forced to face the pandemic in critical conditions.[2]

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[1] As reported on https://tinyurl.com/3dmewrzw (last visited 20 September 2023), in Italy, from 3 January 2020 to 5:35 pm CET, to 10 February 2023, there have been 25.488.166 confirmed cases of Covid-19 with 187.272 deaths, reported to World Health Organization (WHO).

[2] See Rapporto Osservasalute 2019, available at https://tinyurl.com/26w26mhp (last visited 20 September 2023).

The healthcare system in Italy exhibited inadequate preparedness to effectively manage the current emergency. The medical community has exerted substantial endeavors in tackling the pandemic, wherein hospitals, particularly intensive care units, have been strained to their maximum capacity. Healthcare professionals have also experienced arduous work schedules.[3]

Regrettably, given the significant number of infected individuals and associated fatalities, it is probable that the current 'sanitary pandemic' will be succeeded by a subsequent 'judiciary pandemic'. The emergency situation can potentially subject healthcare providers to liability claims for negligence. Medical errors, such as misdiagnosis, inadequate treatment, or the death of Covid-19 positive patients, can lead to potential legal disputes against healthcare professionals when a causal link is established between the error and the harm caused to the patient.[4]

In the coming years, the most pressing issue will be the potential underestimation of the complex obstacles posed by the unusual and unpredictable conditions in which healthcare professionals have operated.

Undoubtedly, it is imperative to consider all factors pertaining to this emergency. Several factors contribute to the challenges faced in managing the Covid-19 pandemic. These factors encompass the absence of comprehensive guidelines and a scientific comprehension of the virus and its associated pathology, the assignment of healthcare providers to Covid wards without sufficient expertise or specialization, and the conversion of abandoned hospitals into functional units to address the urgent healthcare needs arising from the pandemic. The entire Italian healthcare system has been forced to reshape itself, to master the crisis caused by the pandemic.

In recognition of the valuable role played by healthcare personnel, some countries have provided liability shields for doctors who have worked in the emergency context. These shields aim to balance conflicting interests: on one hand the social concept of the right to health, and therefore the need to protect patients affected by the virus, on the other, the need to protect doctors and, more generally, the healthcare professionals who had to deal with an unpredictable emergency scenario.[5]

For example, in the US many States provided immunity for the civil liability deriving from injury or death occurred to patients due to medical treatments provided by the State in response to the Covid-19 pandemic, and some States granted protection from criminal liability too.[6]

[3] G. Ricci, G. Pallotta et al, 'Consequences of Covid-19 Outbreak in Italy: Medical Responsibilities and Governmental Measures' *Frontiers in public health*, 8 (2020).

[4] G. Ponzanelli, 'La responsabilità sanitaria e i possibili contenziosi da Covid' *Giustiziacivile.com* (2020).

[5] A. Cioffi and R. Rinaldi, 'Covid-19 and medical liability: A delicate balance' *Medico-Legal Journal*, 88, 187-188 (2020).

[6] V. Gutmann Koch, 'Crisis Standards of Care and State Liability Shields' *San Diego Law Review*, 975 (2020).

Granting this protection should not be interpreted as a means to ease their criminal responsibility. It is indeed necessary to distinguish the damage that occurred due to the emergency situation, from the damage that occurred during the emergency, and therefore to distinguish the material causality from the mere temporal occasionality.[7] In fact, the state of emergency cannot represent a screen behind which to hide any imprudence or negligence committed by the doctors or the hospitals during the emergency.

In order to limit the criminal liability of physicians in the event of death or injury caused in an emergency situation, a criminal shield has been implemented in Italy, limiting the liability to egregious negligence.[8] The present regulation also provides specific indices to exclude gross negligence.[9]

On the other hand, such shield has not been provided for civil liability. As a matter of fact, during the conversion of the so-called Law Decree 'Cura Italia'[10] into Law, the introduction of specific rules to limit the civil liability of doctors and hospitals[11] was proposed, but the amendments suggested, were withdrawn before the discussion reached the Senate. According to these amendments, the healthcare workers would have been held liable only if the damage caused to the patient was due to misconduct or gross negligence. More specifically, the gross negligence in this case, implies an unjustified violation of the *leges artis* ie, the basic principles governing the medical profession.

In the civil law field, a provision that grants protection to the healthcare personnel called to deal with the Covid-19 emergency, seems to be amiss.[12]

Therefore, it is necessary to assess whether the in-force rules provided by the Italian legal system in this field limit, somehow, the healthcare workers' responsibility.

[7] G. Comandè, 'La responsabilità sanitaria al tempo del coronavirus … e dopo' *Danno e responsabilità*, 301 (2020).

[8] Art 3 *bis* of decreto legge 1 April 2021 no 44 - as converted with modification by Legge 28 May 2021 no 76 - states that 'the facts referred to in Arts 589 and 590 of the Italian Criminal Code, committed in the exercise of a health profession and which are caused by an emergency situation, are punishable only in case of gross negligence'.

[9] Art 3 *bis*, para 2 of decreto legge 1 April 2021 no 44 states that the judge, in order to assess the degree of negligence, may take into account 'the limited scientific knowledge on the diseases caused by SARS-Cov- 2 and on the appropriate therapies attainable at the time, as well as the lack of human and material resources available in relation to the number of cases to be treated simultaneously, as well as the lower degree of experience and technical knowledge possessed by non-specialized personnel employed to deal with the emergency'.

[10] Decreto legge 17 March 2020 no 18.

[11] See M. Capecchi, 'Coronavirus e responsabilità sanitaria: quali prospettive di riforma' *Rivista responsabilità medica* (2020).

[12] G. Facci, 'Covid 19, medicina delle catastrofi e responsabilità sanitaria' *Giustiziacivile.com* (2020).

II. The Rules of Medical Liability in Italy: The Double Compensation Track Outlined by the 'Legge Gelli-Bianco'

In the Italian legal system, medical liability is thoroughly disciplined by the so-called 'legge Gelli-Bianco'.[13]

The innovations introduced by this Law specifically focus on the prevention of health risk and on patient safety.[14]

The provision of safe treatments, which do not cause harm to the patient, in accordance with the doctor's code of ethics, is the foundation of what is considered 'good health care'.

Art 1 of the legge Gelli-Bianco defines the concept of safe treatment as a 'constitutive part of the right to health, pursued in the interest of the individual and of the community'. In the light of this definition, the right to health – a pillar of our constitutional system – is not a mere claim to psycho-physical integrity but rather, it must be considered as an aspiration to well-being in a global sense, and it is based on both concepts of freedom of cure and right to access safe health care services.[15]

The abovementioned Law means to address and solve some of the most relevant problems, such as the high number of disputes for 'medical malpractice', the exponential increase of the 'costs of compensation' as well as the widespread of 'defensive medical practices'.[16] It also aims to rebalance the relationship between the doctor and the patient.

Indeed, the legge Gelli-Bianco aims to reconcile conflicting interests: on the one hand there's the need to guarantee a better quality, efficiency, and safety of the cures to all patients, as well as a full protection for any damages caused by medical malpractice; on the other hand, it needs to guarantee the serenity of action of the health care providers.[17]

The aforementioned goals are pursued through a series of provisions that can be summed up as follows: the channeling of responsibility towards healthcare

[13] Legge 8 March 2017 no 24 'Disposizioni in materia di sicurezza delle cure e della persona assistita, nonché in materia di responsabilità professionale degli esercenti le professioni sanitarie'.

[14] According to definition by Charles Vincent, the patient safety consists in avoiding, preventing, and mitigating adverse events or damages caused by the health care itself, see C. Vincent, *Patient safety* (London: Blackwell Publishing Ltd, 2nd ed, 2010), 31.

[15] C. Coppola, 'Il nuovo sistema della responsabilità civile sanitaria' *Responsabilità civile e previdenza*, 1449 (2018).

[16] For 'defensive medicine' we refer to the set of actions and behaviors put in place by the healthcare professional in order to avoid the risk of compensation actions by patients. The prescription of diagnostic tests, procedures and visits that are not strictly necessary are known as practices of 'positive defensive medicine'. Instead, we refer to 'negative defensive medicine' in all those cases in which the doctor avoids performing certain procedures or even taking charge of the patient to protect himself from the risk of legal disputes. A clear illustration of the problems related to the defensive medicine phenomenon is given by C. Granelli, 'Il fenomeno della medicina difensiva e la legge di riforma della responsabilità sanitaria' *Responsabilità civile e previdenza* (2018).

[17] A. Astone, 'Profili civilistici della responsabilità sanitaria (Riflessioni a margine della l. 8 marzo 2017, n. 24)' *Nuova giurisprudenza civile commentata*, 1115 (2017).

facilities, which are assigned contractual liability pursuant to Arts 1218 and 1228 of the Italian Civil Code; the assignment of tort liability to healthcare professionals pursuant to Art 2043 of the Italian Civil Code; and the exclusion of criminal liability for healthcare professionals who have complied with the guidelines;[18] the application of the criteria established by the Arts 138 and 139 of the Italian Insurance Code, for the compensation for damages from medical malpractice, the provision of an insurance obligation to be paid by the hospital and the doctor, as well as regulating the direct action of the injured party against the insurance company[19]

Undoubtedly, the fulcrum of the reform of the legge Gelli-Bianco is represented by Art 7, entitled 'Professional liability of the healthcare personnel'. The Law in question makes a clear distinction between the responsibility of the healthcare facility - whether public or private - and the personal responsibility of the doctor, outlining the so-called 'double compensation track'.

In particular, the Art 7, para 1, legge no 24/2017, provides that the responsibility of the medical facility – public or private – called to provide healthcare-hospital assistance, has a contractual nature.

As a matter of fact, the aforementioned regulation, does not represent a novelty:[20] the Italian Case Law had already stated that upon accepting a patient, the hospital finalizes what is known as a healthcare assistance contract. [21]

This unconventional agreement encompasses a variety of services, including diagnostic procedures, standards for welfare and assistance, and therapeutic

[18] The guidelines are directives addressed to healthcare professionals, recommendations of clinical behavior, necessary to help doctors and patients decide on the most appropriate therapeutic approach for the specific case. In the absence of guidelines, the doctor is required to follow good clinical care practices, as expressive indications of the leges artis, even if not formalized. According to the provision of Art 7, para 3, of the legge Gelli-Bianco, the judge in formulating the liability charge to the doctor must consider the observance of guidelines and best practices, and he has to decrease the amount of the due compensation. About the role and the relevance of guidelines in the attribution of civil liability see M. Franzoni, 'Colpa e linee guida nella nuova legge' *Danno e responsabilità*, 271 (2017).

[19] G. Ponzanelli, 'Medical malpractice: la legge Bianco Gelli' C*ontratto e Impresa*, 356, 358 (2017).

[20] R. La Russa et al, 'La riforma della responsabilità sanitaria nel diritto civile: l'istituzione del «doppio binario» ed il nuovo regime assicurativo, tra obbligo di copertura e possibilità di autotutela' *Responsabilità civile e previdenza*, 352 (2019).

[21] Corte di Cassazione 26 January 2006 no 1698, available at www.dejure.it, according to which the relationship established between the patient and the healthcare structure has its source in an atypical contract, with corresponding services, from which, against the patient's obligation to pay the consideration, arises for the nursing home, a series of obligations: in fact, alongside those the board and lodging, there is also an obligation of making available the auxiliary medical and paramedical personnel, as well as the obligation to provide all the necessary medical equipment, also in view of any potential complication or emergency. Therefore, the responsibility of the healthcare facility towards the patient has a contractual nature and can arise from the non-fulfilment of the obligations directly attributed to the structure, pursuant to Art 1218 of the Civil Code, or it can arise – pursuant to Art 1228 of the Civil Code – from the negligent behavior of the healthcare professionals who operate within the structure, even in the absence of a subordinate employment relationship.

guidelines. Additionally, it imposes organizational responsibilities on the healthcare facility, mandating that treatments be administered within a suitable structural framework.[22] Therefore, the healthcare facility is required to provide a complex service, which is not limited to the administration of medical care, but includes further obligations, such supplying medical and paramedical personnel, medicines, and all the necessary technical equipment.[23]

Furthermore, the healthcare facility's contractual liability can be either a direct or an indirect one. The former is related to the non-fulfillment of structural requirements, pursuant to Art 1218 of the civil code. In this case the responsibility is a consequence of the so-called organizational deficit of the structure. The latter is, instead, related to the behavior of healthcare professionals, pursuant to Art 1228 of the Italian Civil Code. This provision states that if the debtor, in fulfilling the obligation, uses the work of third parties, he is also liable for the willful or negligent behavior of the latter. In these cases, the healthcare structure may file a claim against the professionals pursuant to Art 9 of legge no 24/2017.[24]

Consequently, the hospital, or healthcare facility, bears contractual responsibility for any harm inflicted upon the patient as a result of breaching the obligations outlined in the healthcare assistance agreement, up to the extent that the provision of services becomes impossible due to an unforeseeable circumstance.

As far as the doctor's position is concerned, Art 7 para 3 of the abovementioned legge Gelli-Bianco, qualifies the related responsibility as a tort.[25]

The current provision states that employed doctors, and more generally all those who for several reasons carry out their activity within a healthcare facility or under an agreement with the National Healthcare Service, are liable, pursuant to Art 2043 of the Italian Civil Code.

Of course, as the abovementioned Law itself specifies, the tort law does not apply to the doctor who, although operating within a healthcare facility, has acted on the basis of a fiduciary contractual relationship with the patient. In that case the doctor will be liable for the damages caused pursuant to Art 1218 of the Italian Civil Code,[26] and his qualified diligence will be parameterized to the nature of the activity performed, according to the provision of Art 1176 para 2 of the Italian Civil Code. Qualifying the doctor's responsibility as a tort, means overcoming the theory of 'qualified social contact'.

In fact, before the introduction of the legge Gelli-Bianco, the Italian Supreme Court of Cassation considered the liability of the healthcare professional as liability

[22] M. Faccioli, *La responsabilità civile per difetto di organizzazione delle strutture sanitarie* (Pisa: Pacini editore, 2018), 135.

[23] A. Astone, n 17 above, 1117.

[24] M. Hazan, 'Alla vigilia di un cambiamento profondo: la riforma della responsabilità medica e della sua assicurazione (DDL Gelli)' *Danno e responsabilità*, 75, 82 (2017).

[25] A. Palmieri, 'La riforma della responsabilità medica. La responsabilità del medico' *Questione Giustizia,* 163 (2018).

[26] ibid

for non-fulfillment through the application of the 'social contact' theory.[27]

In other words, it was believed that between the doctor and the patient there was a legally relevant relationship, which implied protective and informative obligations on the doctor's behalf.[28]

The violation of these obligations gave rise to liability for non-fulfillment, according to the Arts 1218 *et seq* of the Italian Civil Code.

The primary objective of the 'social contact' theory was to provide advantageous conditions for the claimant by shifting the burden of proof and facilitating the compensation process. Indeed, given the burden of proof framework established for contractual liability, it was comparatively more feasible for the afflicted patient to secure recompense. As per the regulations delineated by the Supreme Court of Cassation,[29] the creditor, in this case the damaged patient, only needed to prove the contract (or social contact) with the doctor and the worsening of the pre-existing pathology or the onset of a new pathology; while the doctor, as a debtor, had to prove either the correct fulfillment of his obligations or the unattributable cause. This regime ended up placing excessive burden on the healthcare professional.[30]

In the realm of medical liability, the 'social contact theory' can be deemed obsolete, as the legge Gelli-Bianco explicitly stipulates in Art 7, para 3, that a doctor, in cases where no contractual agreement exists with the patient, can be held accountable for damages inflicted upon the patient in a non-contractual manner, in accordance with Art 2043 of the Italian Civil Code.

Basically, the previous law concerning medical responsibility[31] already contained a reference to Art 2043 of the Italian Civil Code, however, it was a non-technical one and raised many doubts concerning its interpretation. The Art 7 of the legge Gelli-Bianco intended to clarify, once and for all, the doubts arisen on the nature of the healthcare professional's liability. The reform can therefore be read as an

[27] The theory of 'qualified social contact' was elaborated by the German doctrine in the 1940s and subsequently implemented by Italian doctrine. It implies the liability due to the violation of pre-existing protection and collaboration duties. These obligations descend from the qualified social contact between the involved parties, such as the relationship between the doctor and the patient. So, the source of the liability is neither the violation of the principle of *neminem laedere* nor breach of a contract, but instead the infringement of independent protection obligations. Extensively illustrated by C. Castronovo, *Tra contratto e torto. L'obbligazione senza prestazione*, *La nuova responsabilità civile* (Milano: Giuffrè, 2006), 443.

[28] Among the most important judgements on this topic, we indicate Corte di Cassazione 22 January 1999 no 589, *Corriere giuridico*, 441 (1999), which specifies that the absence of a contract certainly cannot make the doctor's professionalism fail. The doctor has behavioral obligations towards those who have relied on this professionalism by coming into contact with him. Therefore, his liability cannot be traced back to Art 2043 of the Italian Civil Code.

[29] Corte di Cassazione-Sezioni unite 11 January 2008 no 577, *Danno e respo*nsabilità, 788 (2008), commented by G. Vinciguerra, 'Nuovi (ma provvisori) assetti della responsabilità medica'.

[30] G. Alpa, 'Un bilancio quinquennale della riforma della legge n. 24 del 2017 sulla sicurezza delle cure e la responsabilità professionale degli esercenti le professioni sanitarie' *Responsabilità medica,* 167, 171 (2022).

[31] Decreto legge 13 September 2012 no 158, converted into legge 8 November 2012 no 189 (the so-called Legge Balduzzi).

expression of the legislator's will to recover the non-contractual nature of the doctor's liability.[32]

This definition holds particular relevance. In fact, in accordance with the regime of non-contractual liability, the process of obtaining compensation for the injured patient becomes more intricate. In the context of non-contractual liability, it is important to note that the burden of proof is reversed. Consequently, the onus falls upon the party that has suffered harm to establish all the necessary elements of the case. These elements include demonstrating the existence of damage, establishing a causal connection, proving imputability, and providing evidence of willful misconduct or negligence. Moreover, the entitlement to receive reparation for non-contractual harm becomes time-barred after a period of five years, as opposed to the customary ten-year timeframe applicable to contractual liability.[33]

On the other hand, considering that to the healthcare facility in itself is attributed a contractual liability, makes it easier for the injured patient to obtain a compensation from the structure in case of medical malpractice.

Therefore, the goal pursued by the legislator, through the double compensation system, seems to be that of funneling the judicial initiatives against the healthcare structures, rather than against the individual healthcare providers. The model of responsibility outlined by the legge Gelli-Bianco reform seems to be focused on the healthcare facilities, considering them as a subject capable of preventing and managing the risks that result from the provision of healthcare services.[34]

Considered that this is, in summary, the framework of the current in-force rules in the Italian Legal System on medical liability, we deem it necessary to assess the impact of the Covid-19 pandemic. In fact, in the absence of *ad hoc* provisions, it is necessary to set the current rules against the emergency scenario to understand which responsibilities can be ascribed to the doctors and which, instead, can be referred to the healthcare facilities called to operate in the delicate and unpredictable context of the pandemic.

III. The Civil Liability of the Doctors in the Covid-19 Emergency

In the context of the Covid-19 pandemic, three distinct forms of individual responsibility can be discerned and ascribed to medical professionals.

A first type of responsibility concerns the cases of misdiagnosis. A contractual or non-contractual liability can be attributed to the doctors for having omitted or having delayed the diagnosis, and therefore for not having promptly recognized the presence of the virus if the symptoms of the disease worsened due to the

[32] See C. Castronovo, 'Swinging malpractice. Il pendolo della responsabilità medica' *Europa e diritto privato*, 847, 853 (2020).

[33] R. La Russa et al, n 20 above, 358.

[34] M. Hazan, n 24 above, 82.

doctor's error.[35]

Actually, in this specific case, granting a liability protection to the doctor, doesn't seem necessary: in fact, even during the first wave of the health emergency, the Covid-19 symptoms were known and easily identifiable, and the infection was ascertainable with research methodologies considered reliable by the scientific community.[36] Therefore, it is deemed unnecessary and inappropriate to limit or exclude the doctor's responsibility for the case of misdiagnosis.

The second form of responsibility which may concern the doctors relates to the therapeutic error. This refers to the cases in which the doctor has provided an inadequate treatment to the patient affected by Covid-19, causing a damage consisting in the intensifying of the conditions, or even, in the worst-case scenario, in the patient's death. In this case, it seems necessary to delimit the doctor's responsibility.

Indeed, the health emergency was characterized since the very beginning by the novelty of the virus – as well as the novelty of the related pathology – and by its high infectivity, as well as for the absence of guidelines and best practice rules regarding the treatments to be provided to the infected patients.[37]

This said, civil responsibility cannot be attributed to the health personnel without considering all these factors. It is therefore necessary to identify the behavior required by the doctor in this delicate and unpredictable context.

As a matter of fact, in the absence of what we may refer to as a 'civil shield' introduced by the emergency legislator, the most suitable regulation fit to delimit the doctor's individual responsibility, appears to be Art 2236 of the Italian Civil Code.[38]

This Art provides a limitation of liability particularly relevant for the doctors.[39] It generally limits the responsibility of the worker to cases of gross negligence, whenever the worker is called to solve technical problems of special difficulty. The abovementioned Art is applicable not only to the contractual liability, but to

[35] M. Faccioli, 'Covid-19 e responsabilità civile sanitaria' *Risarcimento danno e responsabilità* (2021), available at https://tinyurl.com/57xex8x7 (last visited 20 September 2023).

[36] M. Faccioli, 'Il ruolo dell'art. 2236 c.c. nella responsabilità sanitaria per danni da Covid 19' *Responsabilità medica*, 2 (2020).

[37] I. Sardella, 'La responsabilità sanitaria ad un anno dalla pandemia: quali limitazioni per sanitario e la struttura?' *Danno e responsabilità*, 542 (2021).

[38] On the applicability of Art 2236 of the Italian Civil Code to define the liability of doctors in the Covid-19 emergency context see M. Franzoni, 'La responsabilità sanitaria ai tempi della pandemia' *Jus*, 91, 98, (2021).

[39] The 'Report to the Italian civil code' available at https://tinyurl.com/yhc4wz4e (last visited 20 September 2023), states at no 917 that the Art 2236 aims to reconcile 'two opposing needs, that of not mortifying the professional's initiative with the fear of unfair reprisals by the client in case of failure, and the reverse need of not indulging towards unthinking decisions or reprehensible inertia of the professional. The code found the equilibrium point in the application of the normal liability provisions, establishing, only for those cases in which technical problems of special difficulty occur, that the professional may be exempted from liability for slight negligence'.

tort liability too.[40] Therefore, this provision is useful for the doctor whether or not he or she has a contractual relationship with the patient.

The application of the present provision in Italian Case Law is predominantly observed in exceptional and extraordinary circumstances, particularly in cases that have not received sufficient analysis from the scientific community.[41]

Hence, it can be argued that this regulation is well-suited to address the exigencies of the emergency situation. In fact, one of the main characteristics of the health emergency by Covid-19, as said, has been the lack of knowledge by the scientific community of the virus – and of the related pathology – at the least as far as the first wave is concerned.

However, the Supreme Court of Cassation limits the application field of this rule to the doctor's inexperience, leaving out from its provision, what relates to the doctor's imprudence and negligence.[42]

In any case, this restrictive interpretation does not preclude the applicability of the present regulation to cases of therapeutic error committed in the context of the Covid-19 emergency. Therefore, in order to limit the doctor's liability for inadequate treatment of the patient, within the pandemic context, a civil liability shield is not necessary, as the in-force regulations – and in particular, the aforementioned Art 2236 of the Italian Civil Code – seems to be sufficient.[43]

However, it is imperative to differentiate between the initial wave of the health crisis and the subsequent stages. The latter were undeniably marked by an enhanced understanding of the virus, the pathology of Covid-19, and the appropriate treatment protocols. The determination of the doctor's liability in the subsequent phases, specifically in cases of therapeutic error, necessitates a thorough assessment by a judge.

A third and final hypothesis of individual responsibility concerns cases in which the doctor's negligent or imprudent behavior has determined the diffusion of the virus within the hospital (or the healthcare facility).

The problem here concerns the probative plan: the difficulty in these cases lies in proving the causal link between the doctor's conduct and the infection of other patients admitted to the hospital.[44] Indeed, this specific hypothesis of liability appears to be more directly attributable to the healthcare facilities.[45]

IV. The Position of the Healthcare Facilities Within the Pandemic Scenario

[40] See Corte di Cassazione 6 May 1971 no 1282, *Foro Italiano*, 1476 (1971).

[41] Corte di Cassazione 2 February 2005 no 2042, *Sanità pubblica e privata*, 68 (2005).

[42] Corte di Cassazione 16 February 2001 no 2335, *Responsabilità civile e previdenza*, 580 (2001).

[43] G. Ponzanelli, n 4 above.

[44] M. Faccioli, n 35 above.

[45] ibid

In relation to the healthcare facilities' position in the pandemic context, there are different types of responsibilities which can be attributed to them. A first form of liability concerns the so-called 'nosocomial damage'. Nosocomial infections are defined as infections contracted by patients due to their presence on the hospital's premises.[46]

In order to reduce the occurrence of these infections, healthcare facilities are required to constantly monitor the pathogens circulating inside the most hazardous wards. In addition to this, they are required to carry out operations such as the sanitization and disinfection of the environments, and, obviously, of all the instruments.

Since healthcare facilities are attributed a contractual liability, the regime outlined by the Art 1218 of the Italian Civil Code, is applied also in the case of the so called 'nosocomial infections'.[47]

This is reflected in the division of the burden of proof: the patient, who wants to obtain a compensation for the 'nosocomial damage', is required to prove the contract with the healthcare facility and the onset of the infection, as well as the causal link with the active/passive conduct of the staff working within the structure. The healthcare facility, as a debtor, must demonstrate that the professional service was performed diligently, or that the non-performance or delay was caused by an unforeseen circumstance that made performance impossible.[48]

In the light of these indications, the responsibility of the healthcare facility for 'nosocomial infection' from Covid-19 must be interpreted on a case-by-case basis.

For example, we shall analyze the case of those patients admitted to healthcare

[46] A. Bonelli, 'Responsabilità professionale ed organizzativa in materia di infezioni ospedaliere' *Rivista Italiana Di Medicina Legale*, 471 (2012).

[47] L. Cannata, L. Molinari and G. Tomei, 'La responsabilità per infezioni nosocomiali' *Danno e responsabilità*, 547, 549 (2021).

[48] In this respect, according to Corte di Cassazione 11 November 2019 no 28991, 'where the contractual liability of the medical practitioner is deduced in case of the non-fulfilment of his professional diligence, damaging the right to health, it is on the injured party to prove, also by means of presumptions, the existence of a causal link between the aggravation of the pathological situation (or the onset of new pathologies) and the conduct of the medical practitioner, while it is the burden of the debtor to prove, if the creditor has discharged its burden of proof, the unforeseeable and unavoidable cause of the impossibility of the exact performance of the service', commented by C. Scognamiglio, 'La Cassazione mette a punto e consolida il proprio orientamento in materia di onere della prova sul nesso di causa nella responsabilità contrattuale del sanitario' *Corriere giuridico*, 307 (2020).

Recalling the aforementioned principle of law, and applying it to the subject of nosocomial infections, Corte di Cassazione 22 February 2023 no 5490, ruled that 'it is on the injured party to prove the direct causal link between the infection and the healthcare service; once the burden of proof concerning the causal link has been discharged by the patient, even by means of presumptions, it is up to the healthcare facility, in order to free itself from any liability for the damages suffered by the patient, to provide proof of the specific unforeseeable and unavoidable cause of the impossibility of the exact performance of the service, the latter not being reductively understood as a mere abstract provision of medical devices potentially capable of averting the risk of nosocomial infections for patients, but as the impossibility of the exact performance of the protective service directly and immediately referable to the individual patient concerned'.

facilities for other diseases, who, during the hospitalization, have contracted the SARS-Cov-2 infection. In these cases, the liability attributable to the structures is based on the failure on their side, to take all the necessary measures to avoid the spreading of the virus within the hospital.

Undoubtedly, within the emergency context, it is imperative to consider various factors, including the disparity between patient volume and resource availability, as well as the novelty of the disease and the lack of established protocols aimed at preventing viral transmission within healthcare facilities. However, according to the Italian Case Law, the sterilization of all instruments, as well as the sanitisation and disinfection of all environments, and the isolation of the sick patients, are ordinary procedures and must be always guaranteed by any healthcare facility.[49]

Therefore, it seems difficult to outline an *a priori* exclusion of responsibility for cases of infection from Covid-19 in a hospital setting.

In any case, although there is no legal shield that can limit this liability, the healthcare facilities can always free themselves from any liability by proving that they have followed all the *leges artis* protocols regarding sanitisation and disinfection, and proving, therefore, they have adopted all the precautionary measures to avoid the spreading of the virus. Alternately, they may escape further liability by proving that the failure to fulfil any statutory obligations was caused by an obstruction that was objectively unforeseeable and inescapable.[50]

On the other hand, there can also be a responsibility for organizational shortcomings attributable to the healthcare facility as a whole, for the activities of diagnosis and treatment administration to the patients affected by Covid-19.

For instance, we can take the example of all those patients who have suffered a damage due to the lateness of the hospitalization, because of the overcrowding of the intensive care wards. In these cases, the attribution of the responsibility requires to verify if the risk related to the health emergency, was a predictable one.

In fact, the organizational problems connected to the emergency must necessarily be taken into account. In particular, the following elements must be considered: the limited number of beds in the intensive care wards, the lack of ventilators, the overcrowding of all hospital units, the reduced availability of Covid-19 test kits (swabs).[51]

It, therefore, seems difficult to impute the responsibility for an organizational shortcoming, given that the healthcare facilities – at least in the first wave of the emergency – were completely unprepared to cope with an extraordinary event such as the Covid-19 pandemic.[52]

Therefore, in the absence of specific rules, an exclusion of contractual liability can be provided through the concept of the unattributable cause.

[49] M. Faccioli, n 35 above.
[50] M. Faccioli, n 36 above.
[51] G. Ponzanelli, n 4 above.
[52] M. Faccioli, n 35 above.

Factors such as the exceptional nature of the pathology and the absence of specialized departments, along with the objective shortage of both the equipment and the number of beds in the intensive care wards, complete the reasoning behind the release of the proof necessary to exclude the healthcare facilities' liability in cases of organizational shortcomings.

However, it is worth asking whether these considerations can be applied to all the phases of the health emergency, or whether it is more correct to imagine an informal distinction between the first wave of the health emergency and the subsequent phases.[53]

V. Doctor's Liability for Anti-Covid Vaccine Damage

Another relevant issue connected to the medical responsibility related to the Covid-19 emergency concerns the doctor's liability for the damage caused by the administration of the vaccine.[54]

The efficacy of the Covid-19 vaccination has been demonstrated as a preventive measure, effectively mitigating the spread of infection, diminishing the incidence of hospitalizations, and reducing mortality rates.[55]

Of course, as any other medical treatment, it is not free from adverse reactions. Luckily, most of the reported cases present mild symptoms[56] but, the rare cases which have presented serious negative effects, could expose the healthcare providers, who administered the vaccination, to legal action. It must be noted that during the first period of the pandemic, healthcare personnel had to work under conditions of extreme scientific uncertainty in relation to the Covid-19 vaccinations.[57]

In order to support and reassure the health workers involved in the vaccination campaign, the legislator has introduced a criminal shield for them.[58]

In particular, Art 3 of the Decreto Legge 1 April 2021 no 44[59] states that responsibility for the crimes of manslaughter and culpable personal injury, as referred to in Arts 589 and 590 of the Italian Criminal Code, occurring as a result of the administration of a Covid-19 vaccine is excluded when the use of the

[53] I. Sardella, n 37 above, 545.

[54] As reported by the World Health Organization on https://tinyurl.com/3dmewrzw as of 22 January 2023, a total of 150.074.539 vaccine doses have been administered in Italy.

[55] P. Frati et al, *No-Fault Compensation and Anti-Covid-19 Compulsory Vaccination: The Italian Context in a Broad View*, 2022, available at https://tinyurl.com/sj5cdfuv (last visited 20 September 2023).

[56] As reported by Consiglio di Stato 20 October 2021 no 7045, available at www.dejure.it, the damages resulting from the administration of the vaccine for SARS-Cov-2 must be considered, given the extreme rarity of the occurrence of serious and correlated events, to be complying with a criterion of statistical normality.

[57] F. Beccia et al, 'Covid-19 Vaccination and Medical Liability: An International Perspective in 18 Countries' *Vaccines*, 10, 1275 (2022).

[58] E. Minervini, 'Vaccinazione ed epidemia da Covid-19' *Danno e responsabilità*, 600-601 (2021).

[59] Converted with amendments into Legge 28 May 2021 no 76.

vaccine complies with the indications contained in the marketing authorizations issued by the Ministry of Health.[60]

On the other hand, indemnity plans have been introduced in order to protect people harmed by the Covid-19 vaccination.

Indeed, para 1-*bis* of Art 20 of Decreto Legislativo 27 January 2022 no 4,[61] added to the Art 1 of the Law no 210/1992,[62] states that:

> 'The indemnity referred to in paragraph 1 is due, under the conditions and in the manner established by this law, also to those who have suffered injuries or infirmities, from which a permanent psycho-physical impairment has resulted, due to the anti-SARS Cov-2 vaccination, recommended by the Italian Health Authority'.

The aforementioned Law no 210/1992 provides an indemnity to people who have been harmed by the compulsory vaccination; however, over time the Italian Case Law has extended the application of this law also to subjects who have suffered injuries and/or infirmities due to the administration of non-mandatory but recommended vaccines.[63]

There is no discernible distinction between mandatory vaccines and strongly recommended vaccines: the indemnity, in essence, serves to recompense the individual sacrifice incurred in light of the benefits accrued by the community. Hence, the entitlement to compensation arises from the provisions outlined in Arts 2 and 32 of the Italian Constitution, which state respectively the principles of the 'social solidarity' and the 'protection of health as a collective interest'.[64]

As known, the vaccines against SARS-Cov-2 were initially mandatory only for the healthcare providers, while they were only strongly recommended for the rest of the population. The massive vaccination campaign, and the introduction of the so-called 'enhanced green pass', necessary for the exercise of constitutionally guaranteed rights only by vaccinated subjects, has convinced a large part of the population to be vaccinated.[65]

Given the uncertainty related to the side effects of the anti-Covid vaccines and to the potential adverse reactions, the individuals who were vaccinated have put their health at risk for the protection of a collective interest. In fact, all the

[60] About the criminal shield against vaccination damage see A. Massaro, 'Responsabilità penale per morte o lesioni derivanti dalla somministrazione del vaccino anti SARS-Cov-2: gli "anticorpi" dei principi generali in materia di colpa penale' *Rivista italiana di medicina legale,* 683-703 (2021).

[61] Converted into Legge 28 March 2022 no 25.

[62] Legge 25 February 1992 no 210 recognizes compensation to subjects irreversibly damaged by vaccinations, transfusions, and administration of infected blood products.

[63] According to Corte costituzionale 26 April 2012 no 107, available at www.dejure.it, the reason that determines the right to the indemnity in favor of subjects damaged by transfusions or compulsory vaccinations, is the collective interest in health and not the obligatory nature of the treatment, which is just a tool to pursue the aforementioned interest.

[64] Corte costituzionale 16 October 2000 no 423, *Danno e responsabilità*, 490 (2001).

[65] Minervini, n 58 above, 601.

vaccinated people, contributed to control the infection, and as a consequence, to lighten the burden of the National Healthcare System. The indemnity, therefore, aims to compensate these people for their individual sacrifice that has determined a collective advantage.[66]

Those who have suffered a permanent psycho-physical impairment as a result of the SARS-Cov-2 vaccination (whether it was required or merely recommended by the Italian Health Authority) have the right to an indemnity that is not to be considered compensatory, as it is not intended to repair an unjust damage related to a liability case, but rather has a character of social solidarity.[67]

The right to obtain the indemnity is recognized only where there is a causal link between the administration of the vaccine and the damage suffered by the person receiving the medical treatment.[68]

It is sufficient to establish the causal relationship between the injury sustained and the vaccination treatment under Art 1 of Law no 210 of 1992, despite the fact that, under Art 2043 of the Italian Civil Code, the injured party must demonstrate either the illegal act, the unjust damage, the willful misconduct, or the negligence and the causal link between the offence and the suffered damage. However, even if the indemnity is offered regardless of whether any fault exists, it does not fully restore the damage that was sustained.[69]

Anyway, nothing excludes that the injured party can also exercise a compensation action pursuant to Art 2043 of the Italian Civil Code. This can happen in the event that the patient is able to prove the subjective requisites of willful misconduct or negligence and the causal link existing between the unlawful conduct (even in the form of an omission), and the unfair damage.[70]

VI. Conclusions: How to Define Medical Responsibility in the Absence of a 'Civil Shield'

From the considerations above we can state that in the Italian legal system does not lack rules to define the civil responsibility of doctors and health facilities in the context of the Covid-19 emergency.

The individual liability of the doctors who operated in this difficult situation

[66] V. Restuccia, 'Danno da vaccino e responsabilità' *Diritto di famiglia e delle persone*, 1122, 1140 (2022).

[67] S. Foà, 'I danni da vaccino SARS-Cov-2 tra obblighi, raccomandazioni e «solidarietà irrinunciabile»' *Responsabilità civile e previdenza*, 1070, 1080 (2022).

[68] According to Corte di Cassazione 27 June 2022 no 20539, available at www.dejure.it, the injured party must only prove that he has suffered injuries or infirmities of such intensity as to have caused a permanent psycho-physical impairment, and that the damage suffered is a consequence of the vaccination.

[69] A. Iuliani, 'La fisionomia del danno e l'ampiezza del risarcimento nelle due specie di responsabilità' *Europa e diritto privato*, 137 (2016).

[70] Corte costituzionale 26 February 1998 no 27, *Foro italiano*, 1370 (1998).

could be defined through the application of the Art 2236 of the Italian Civil Code: in fact, the cases of damage caused to the patient by an inadequate treatment due to the doctor's incompetence, could be qualified as a case of special difficulty of the service provided in the emergency context, and therefore, the individual liability could be bound to a case of gross negligence.[71]

The healthcare facility, on the other hand, could be exempted from liability by proving one of the following: either that the professional obligations have been regularly fulfilled, or by providing proof of the non-attributable cause, pursuant the Art 1218 of the Italian Civile Code. The evidence of the latter can be provided in the light of the peculiar and anomalous characteristics of the health emergency.[72]

Therefore, it does not seem necessary to introduce further rules to protect healthcare professionals and healthcare structures who operated within the pandemic context.

However, it is still necessary to grant a full protection to the damaged patients and their heirs. The recommended solution to reconcile both the conflicting interest of the damaged patients and the healthcare providers, seems to be the introduction of an indemnity plan.[73]

Providing an indemnity plan means shifting the potential future claims from the level of responsibility to the level of social solidarity.[74]

The indemnity does not consist in a full reparation of the harm sustained, but it still offers an adequate consolation. Following all, the Italian Constitutional Court had previously determined that an exemption to the rule of full compensation for personal injury may be made if it is necessary to safeguard super-individual interests.[75]

Furthermore, as mentioned, the Italian legal system already has an indemnity plan in the sanitary field: the indemnity in favor of those irreversibly damaged by vaccinations, transfusions, and administration of infected blood products, provided by Legge 25 February 1992 no 210, which now also refers to the cases of damages caused by anti-Covid-19 vaccines.[76]

The implementation of a pandemic-specific indemnity scheme within the Italian legal system would contribute to achieving a balance between safeguarding the interests of medical practitioners and ensuring the well-being of patients. This scheme would provide appropriate financial compensation to affected parties, thereby avoiding undue detriment to the efforts of doctors and healthcare institutions

[71] M. Faccioli, n 36 above.

[72] G. Ponzanelli, n 4 above.

[73] B. Guidi, 'Una survey medico legale sulla responsabilità civile al tempo del Covid-19' *Danno e responsabilità*, 555, 558, (2021).

[74] G. Facci 'La medicina delle catastrofi e la responsabilità civile' *Responsabilità civile e previdenza*, 706, 722, 3 (2020).

[75] See Corte Costituzionale 16 October 2014 no 235, *Nuova giurisprudenza civile commentata*, 424 (2015).

[76] Legge 25 February 1992 no 210.

tasked with managing a worldwide crisis.[77]

The primary objective of this particular policy is to guarantee that healthcare providers are fully dedicated to patient care, without being burdened by concerns regarding potential legal actions in the future.

In light of the aforementioned circumstances, it is imperative to recognize that the entitlement to receive medical treatment should not impose an obligation of flawless performance on healthcare practitioners.

[77] The following have commented on the possibility of introducing compensation plans linked to the health emergency: G. Ponzanelli, 'Il fascino irresistibile dei piani no-fault' *Jus*, 125, 128 (2021); C. Scognamiglio, 'La pandemia Covid-19 tra funzioni della responsabilità civile e modelli indennitari' *Jus*, 132, 141 (2021).