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Future medico-legal implications on Obstetrics and Gynaecology practice in the SARS-CoV-2 pandemic

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ABSTRACT

Since February 2020, the Italian National Healthcare System had to mitigate the possibility of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) transmission to vulnerable patients. Healthcare professionals rapidly reviewed their workflow to maintain a safe and high standard treatment, but weak scientific evidences and organizational limits resulted in the adoption of heterogeneous measures. Adherence to screening protocols and follow-up programs pregnant women and oncological patients has not been always guaranteed: this scenario could evolve in an enormous number of medico-legal actions. This context, showing the weakness of the Italian law No. 24/2017, imposes an urgent reorganization of the legal framework to homogenize the judgements to “protect” healthcare professionals involved in this epochal emergency.

SOMMARIO

Da febbraio 2020, il Sistema Sanitario Italiano ha dovuto arginare il rischio di trasmissione della malattia da Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-Cov-2) a pazienti vulnerabili. Gli operatori sanitari hanno rapidamente rivisto il loro flusso di lavoro per mantenere uno standard di cure adeguato, ma prove scientifiche deboli e limiti organizzativi hanno portato all'adozione di misure eterogenee. L'adesione ai protocolli di screening e ai programmi di follow-up delle donne gravide e delle pazienti oncologiche non è sempre stata garantita: questo scenario potrebbe evolvere in un numero enorme di azioni medico-legali. Tale contesto, che mostra la debolezza della legge italiana n. 24/2017, impone un'urgente riorganizzazione del quadro giuridico per “tutelare” gli operatori sanitari coinvolti in questa emergenza epocale.

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Key words

COVID-19; gynaecologic liability; Italian law; criminal proceeding; civil proceeding; risk management.

INTRODUCTION

Since February 2020, the coronavirus disease 19 (COVID-19) burdened Italian health institutions because of its high transmissibility. In this emergency, the National Healthcare System had to mitigate the possibility of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission to vulnerable groups, such as pregnant women, which were jeopardized by the virus. In fact, the most recent scientific evidences confirmed the increased risk of preterm birth and caesarean delivery (1, 2) and suspects a vertical transmission for pregnant women affected by COVID-19 (3).

Government-mandated social distancing and lockdown measures were found to be beneficial to limit the spread of the virus. However, they may lead to detrimental effects (in the worst case more important than virus transmission) on pregnant women and patients affected by gynaecological problems due to the partial shutdown of essential care services. For example, antenatal care units have suffered an important resource diversion, which shifted from routinely to essential care of pregnant women and increased the risk of maternal morbidity and mortality, especially for women with lower socioeconomic status (4). Thus, gynaecological and obstetrical medical negligence litigations, related to the consequence of the COVID-19 pandemic, is currently of interest for the Italian public and private health system.

The pandemic evidenced the weakness of complex laws regulating medical liability in Italy, which are structured on an ordinary framework, but inadequate during an emergency. Concisely, healthcare professionals (HPs) worked in an unprecedented setting characterized by poor instrumental and physical resources, shortage and/or contrasting scientific evidences, and overcrowding hospitals, which exposed them to criminal and civil proceedings for medical malpractice (5).

The aim of this article is to underline the background in which HPs had to work and to clarify the current Italian law status based on law No. 24/2017, which regulates HPs liability in both criminal and civil frameworks to propose a possible solution for future potential litigations.

THE EVOLUTION OF SCIENTIFIC EVIDENCES AND RECOMMENDATIONS REGARDING PREGNANT WOMEN AND NEWBORNS IN THE EARLY STAGE OF THE PANDEMIC

The advent of the SARS-CoV-2 pandemic drastically affected the Italian healthcare system, including gynaecology. In the initial phase, between January and May 2020, COVID-19 patients, affected with severe pneumonia, quickly overloaded healthcare facilities, which extremely challenged the in-hospital management of mothers and newborns ensuring an adequate healthcare service and, at the same time, protecting them from transmission. HPs rapidly reviewed their workflow to maintain a secure and high standard treatment, but lacking and weak scientific evidences resulted in the adoption of heterogeneous measures. In fact, the urgency to provide a guidance to manage COVID-19-free patients emerged with pressure during the initial phase of the pandemic. Continuously increasing ambiguous, impracticable and contrasting guidelines and recommendations lead to confusion of HPs whereas the proposed solutions were characterized by low viability from an economical and structural point of view.

On February 27th, the Italian Superior Health Institute (Istituto Superiore di Sanità (ISS)) (6), coordinated by the National Centre for Disease Prevention and Health Promotion (Centro Nazionale di Prevenzione delle Malattie e di Promozione della Salute (CNaPPS)), initiated a task force composed by members of the Italian scientific associations in gynaecology, obstetrics, midwifery, neonatology, paediatrics and anaesthesiology (SIGO, AOGOI, AGUI, FNOPO, SIN, SIMP, SIP, ACP and SIAARTI). The goal of the working group was a weekly online review of clinical practice guidelines for HPs about pregnancy, childbirth and breastfeeding according to current scientific literature on SARS-CoV-2 published on the most popular databases (PubMed, Scopus, Embase and CINAHL).

The weekly communications were essential to: 1) guarantee a continuous learning and guidance for HPs, and 2) share fast scientific evidences and medical experiences about the new virus. This weekly update continued until 7th of May, when the task force considered the knowledge about SARS-CoV-2 more stable, and the working group

decided to inform Italian HPs only in case of relevant and specific developments.

At the end of the first week of their work (February 27th–March 5th), the expert panel of the ISS confirmed the alarming state of scientific uncertainty. In fact, the task force was unable to provide any official recommendation for SARS-CoV-2 positive mothers and/or for those with clinical symptoms of COVID-19 recommending “multidisciplinary case-by-case assessment” (7).

A first document has been published by the Royal College of Obstetricians & Gynaecologists (RCOG) (8, 9) only on March 9th, which summarizes the available evidences on the effects of the SARS-CoV-2 virus on mothers and newborns. The text, for the third time updated on March 18th (10), by the RCOG in collaboration with the Royal College of Midwives, Royal College of Paediatrics and Child Health, Public Health England and Health Protection Scotland, strongly advised “to test for SARS-CoV all women who, at the time of hospital admission for delivery, have symptoms that indicate COVID-19 and to consider all symptomatic women as potentially infected”. Subsequently, the 5th version (11) available on March 28th alarmingly signalled the possibility of vertical transmission recommending indications for safe surgical management of suspected or confirmed COVID-19 pregnant women. Moreover, it underlined the prominence that HPs should use effective personal protective equipment, as remarked by the ISS COVID-19 Report No. 2/2020 (12). Up to now, 12 versions (2) of the RCOG’s report are available and the last has been published on 14 October 2020.

On March 31st, the Italian Ministry of Health issued the circular 11257 which comprehends key indications related to maternity care during the pandemic (**figure 1**), according to the recommendations contained in the interim guidance on pregnancy, childbirth, and breastfeeding published by the main international agencies (World Health Organization (WHO), Centres for Disease Control and Prevention and the UK Royal Colleges).

Finally, a “Global interim guidance on coronavirus disease 2019 (COVID-19) during pregnancy and puerperium from FIGO and allied partners: Information for healthcare professionals” (13) was published on April 4th by the International Federation of Gynaecology and Obstetrics (FIGO), which focused on the evidences available for the medical treatment of COVID-19 positive women. The manuscript

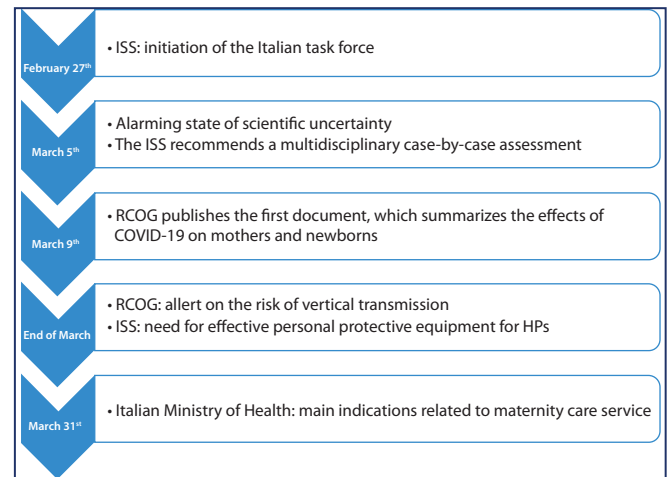


Figure 1. Preliminary scientific evidences and recommendations about COVID-19, pregnancy, and newborns in the first month of the outbreak.

aimed to “response the World Health Organization (WHO) statements and international concerns regarding the coronavirus disease 2019 (COVID-19) outbreak” and focused on four main settings of pregnancy to manage pregnant women adequately: “1) ambulatory antenatal care in the outpatient clinics; 2) management in the setting of the obstetrical triage; 3) intrapartum management; and 4) postpartum management and neonatal care” and to offer “guidance on the medical treatment of pregnant women with COVID-19 infection”.

A week later, a narrative revision (14) indicated strategies to reorganize obstetric units during the crisis based on available logistical resources to contrast the emergency and to summarize the most important evidences about the virus during pregnancy.

Additionally, anaesthesiologists offered relevant contributions:

- on April 14th, the Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) (15) proposed the second version of “Indications for the anesthesiological-resuscitation management of patients with suspected or confirmed SARS-CoV-2 (COVID-19) infection in the peripartum”.
- On April 22nd, a team of Chinese anaesthesiologists (16) schematized procedures able to reduce the risk of contagion for HPs during caesarean section of infected women.

From March 25th to April 17th, two systematic reviews have been published: the first, (17) disclosed the association between COVID-19 and higher rates

(and pooled proportions) of preterm birth, pre-eclampsia, caesarean section, and perinatal death. The second (18) revealed a favourable outcome for infected women during pregnancy but recognized the relevant adverse risks and the unpredictable fetal consequences of long-standing infections occurring in early gestation. According to the authors, limitations of the reviews regarded the limited number of analysed studies; therefore, results should be interpreted with caution. On April 17th an US narrative review (19) proposed care practices for COVID-19 positive women in pregnancy affirming that “the implications for pregnancy remain largely unknown” and “because no treatment, no vaccine and no herd immunity exist, social distancing is the best mechanism available to protect patients and health care workers from infection”. Nevertheless, in the same period different studies (20, 21) suggested no alarming maternal and perinatal outcomes for COVID-19 infected pregnant women.

Another serious global issue has been the availability and effective personal protective equipment in different obstetrical settings. The data of a retrospective multicentre study (22) conducted in the Lombardy region including 42 Italian women with confirmed diagnosis of SARS-CoV-2 infection prior to or within 36 hours after delivery, showed the occurrences COVID-19 symptoms only after delivery. For this reason, the authors stressed the necessity to strengthen safe procedures for HPs during labour assistance. They also affirmed that postpartum infection cannot be excluded, and vaginal delivery may be associated with a lower risk of intrapartum SARS-CoV-2 transmission to neonates. Kabesch *et al.* (23) shared on 20th of April the reorganization of the Regensburg University hospital birth clinic to contain HPs transmission of the virus. The measurements included massive testing of personnel, intensive active monitoring for symptomatic HPs and for their close contacts, increased hygiene measures, and adoption of facemasks and social distancing. Later, (May 1st) the American Journal of Obstetrics and Gynaecology (MFM) (24) published the guidelines edited by the Italian and American colleagues of specialists about clinical and logistics management of pregnant women during the prenatal, labour and delivery phases at the time of the pandemic.

Tips were also offered by:

- the Society of Infectious Disease in Obstetrics and Gynecology (ISIDOG) (25): “Recommendations Concerning COVID-19 and Pregnancy” (April 22nd). The clinical practice recommenda-

tions were focused on diagnosis, treatment and management of COVID-19 for pregnant women according to indications provided from the CDC, RCOG and ANZICS.

- The American Journal of Epidemiology: The “General Guidelines in the Management of an Obstetrical Patient on the Labor and Delivery Unit during the COVID-19 Pandemic” (26) (April 28th) offer potential indications for delivery with severe COVID-19 infection.

Following the numerous requests, on 24th April the Italian Scientific Societies (SIGO, AOGOI, AGUI, SIN, FNOPO) (27) presented the document titled “Pregnancy and childbirth in the COVID-19 period: practical advice” to encourage the correct management and needs of mothers, fathers, and children.

As claimed by Shalish *et al.*, in a critical review published on May 2nd, the urgent need for guidelines and protocols on diagnosis, management and infection control strategies lead to a “tremendous confusion” due to the sudden development of the disease. For this reason, authors “comprehensively reviewed the current evidence regarding COVID-19 perinatal transmission, respiratory outcomes of neonates born to mothers with COVID-19 and infants with documented SARS-CoV-2 infection, and the evidence for using different respiratory support modalities and aerosol-generating procedures in this specific population”.

Finally, on May 31st (28), the ISS published feasible clinical-care practice guidelines based on current available literature (**figure 2**). More than one month later (July 10th), the RCOG (29) proposed the last implemented version (2.4) of the “Guidance for maternal medicine services in the evolving coronavirus (COVID-19) pandemic”, which contains pragmatic advices to clinicians on the management of common medical disorders in pregnancy in times of COVID-19. Nevertheless, the negative impact on pregnancy and birth care is still considered a critical aspect as remarked by a petition (30) signed by 62 members of the European Parliament claiming the weakening of maternity services and requesting funding to avoid the closure of territorial prenatal and birth units. Moreover, the petitioners demanded adequate human, economical and instrumental resources to be employed in maternity services. Additionally, they suggested an identification of necessary protective equipment and policies to ensure the presence of a person to support the woman during labour and delivery, as recommended by the WHO.

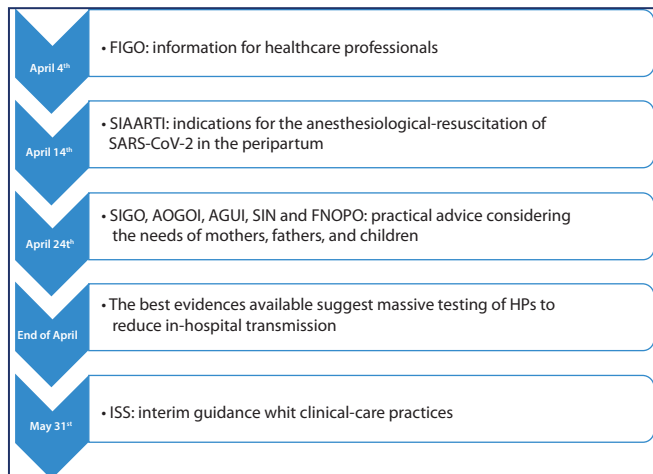


Figure 2. Scientific evidences and recommendations about COVID-19, pregnancy, and newborns from April to May 2020.

THE IMPACTS OF THE SARS-COV-2 PANDEMIC ON OTHER ESSENTIAL GYNAECOLOGICAL AND OBSTETRICAL CARE SERVICES

During the COVID-19 pandemic, resources from health system were redirected to respond to the emergency and several essential healthcare services became inaccessible. Particularly, the potential risk of in hospital transmission caused the rejection of COVID-free patients and their adherence to screening protocols and follow-up programs. Furthermore, many patients affected by tumours experienced treatment delays (*e.g.*, surgical, systemic and radiotherapeutic). This contributed to a series of medico-legal problems since the appropriate level of essential gynaecological and obstetrical services has been significantly compromised.

For instance, not all sexual and reproductive health care units, for the treatment of sexually transmitted infections (*e.g.* HIV), were available during the public health emergency. The comment document (31) realized by the Guttmacher Institute estimated that in low- and middle-income countries “10% of women who would normally have a safe abortion instead resorted to an unsafe method” in the event of “countrywide lockdowns forced clinics to close or if abortion was considered a nonessential service”. Likewise, the interruptions in regular provision of essential services exposed women and girls, living in fragile socioeconomic context, to manifest medical complications related to gynaecological problems that outweigh the potential risks of in-hospital SARS-CoV-2 transmission (32, 33). In fact, the scientific community emphasized

how the deferment dramatically affected vulnerable groups, such as women with oncological pathologies in need of oocyte collection or infertile patients with advanced maternal age and reduced oocyte reserve, underling the necessity to guarantee the access on this essential health services, often erroneously considered luxury (34).

Similarly, the SARS-CoV-2 pandemic constrained a drastically reorganization of cancer surgical recovery plans to reduce the risk of COVID-19 infection. The impact of this rescheduling of oncologic patient care is under investigation by a global expert response study (35) titled CovidSurger-Cancer Gynecological Oncology. Nevertheless, the outcomes related to cancer develop slowly, thus the negative impact of the delay of the medical support will be revealed in the next future.

Furthermore, during the first wave of the pandemic (from March 22nd to May 8th), many of the most important scientific societies of gynaecologic oncology published their recommendations about the diagnosis, treatment and follow-up of gynaecological tumours by providing advices to reorganize surgical services during a health-related crisis aimed to guarantee the high-quality care (36, 37). Despite the efforts to redistribute facilities' resources, some procedures suffered of radical changes, especially in the hospitals with a poor level of readiness to implement strategic-logistical plans and difficulty to increase medical staff. This has practically materialized in decreased care quality. For instance, in healthcare facilities unable to guarantee access to radiologically guided tissue biopsies to the totality of the patients, physicians were encouraged to fully relay their diagnosis in advanced ovarian cancer to cytology before starting chemotherapy (38).

A global predictive model (39) estimated that during the COVID-19 peak, 12 weeks of disruption caused the cancelation of about 28,505 operations for gynaecological cancer surgery (12-week cancellation rate of 39.3%), 2,175,774 for gynaecological benign surgery (12-week cancellation rate of 81.6%), and 441,611 for obstetrics disorders (12-week cancellation rate of 25.4%). The magnitude of the problem has been recognized by a recent meta-analysis (40), which demonstrated the increased risk of death in some types of tumours caused by the delay in curative cancer treatment leading to unprecedented medical-legal issues.

However, in the context of the COVID-19 pandemic, we should not forget that before, during, or after the surgery the risk of contracting the infection

in hospital has worsened outcomes in COVID-patients compared with COVID-free patients (41, 42). Given this risk, the option to wait for the end of the pandemic or postpone surgery was shared between surgeons and patients, leading to delays related to the choice of correctly informed patients and not to inadequate or weakened health facility response. Furthermore, consequences of oncological treatment delay in the COVID era cannot be considered the same as consequences of a similar delay before the pandemic: the consequences of SARS-CoV-2 infection on patients' health are known.

In obstetrics, scientific evidence of the potential adverse effects of the virus on maternal and perinatal outcomes were published (43). One of the potential explanations of this evidence is the fear of pregnant women to continue their normal follow-up programmes in a period of social distancing imposed by governments.

Similar considerations cannot be neglected when establishing the real cause of unfavourable outcomes during the pandemic. Health responsibility should change its standards following the new scenario, profoundly different from the pre-COVID era, because the pandemic upset the previous balances and paradigms. For example, cancer survival curves, valid in 2019, may not be valid anymore, as some recent studies highlighted in other field (44). Moreover, hospitals actively reorganize their pathways to ensure high quality and safety for every patient, COVID or not. This means, operatively, that necessarily two different pathways had been constructed for every type of patient: two different obstetrical pathways, one for pregnant women with COVID-19 and one pregnant women without infection; two different oncological pathways, one for oncological women with COVID-19 and one for oncological women without COVID-19 infection. One of the unavoidable consequences of this reorganization is the reduction of healthcare workers: the precedent staff was split and even if new healthcare workers were enrolled the number sometimes resulted inadequate, considering the need of strict segregation among the two equips and the need of ensuring physical distancing in the same spaces (45). Such regulation was mandatory to avoid nosocomial infection among healthcare workers and spread to COVID-free patients. Further, the need to sanitize equipment and environments poses a new limit, forcing the hospital-machinery to another slowdown.

A risk management policy that aims to reduce the burden of litigation due to this different patient

management will be successful if able to condense today's difficulties into the medical record, which is the main evidence for the court. The exponential acquisition of constantly updated scientific evidence and adapting experiences are translated daily into organizational choices, sometimes leading to a compromise. The framework that justifies such choices cannot be forgotten. patients who undergo elective surgery should be told that, despite measures to limit the risk of infection, there remains a risk of contracting covid-19 in hospital, whether before, during, or after the operation. The surgeon should explain that, if the risk eventuates, the impact on the patient's health is currently unknown but could at worst lead to complications that require intensi patients who undergo elective surgery should be told that, despite measures to limit the risk of infection, there remains a risk of contracting covid-19 in hospital, whether before, during, or after the operation. The surgeon should explain that, if the risk eventuates, the impact on the patient's health is currently unknown but could at worst lead to complications that require intensi. Another challenge we must face is using our skills to improve our organizations in general, preparing for other challenges that lie ahead.

CRIMINAL ASPECTS

Although the criminal implications of the pandemic are not yet evident and predictable, the dramatic consequences of the outbreak accounting in Italy tens of thousands of victims and more than one million of infected could evolve in an enormous number of undesirable legal actions. Likely, HPs are exposed to be accused of "an event that, even if it happened against the intention, occurred due to negligence, imprudence, unskillfulness or failure to comply with laws, regulations, orders and disciplines" according to article No. 43 of the Italian Penal Code.

The present Italian judicial system for healthcare liability is ruled by article No. 590-*sexies* introduced by articles 6 of the law No. 24/2017, called "Gelli-Bianco", aimed to guarantee the constitutionally protected right to enjoy good health providing safe and high-standard treatments based on the key role of clinical practice guidelines (CPGs) (46). Briefly, law No. 24/2017 ensures healthcare safety by the adoption of effective prevention tools, facilities, structures, technologies and risk management. Moreover, article No. 590-*sexies* clearly states that the punishment is

not practicable as gross fault (*colpa grave*, defined as violation of the basic rules of diligence and a health care below the standards of accepted medical practice) when the medical action is performed according to evidence-based guidelines published by the Italian national health system or, in absence of them, best health care practices (47) adequately adopted on the specific clinical case. This article, inspired by a legislative model called “safe harbour”, could have negative impact on the judgment of medical liability during the pandemic, because, especially at the beginning, the guidelines had a consolidated evidence-base that supported their adoption, or many items weren't evidence-based guidelines (48, 49).

At the origin, article No 590-*sexies* produced misunderstanding in proceedings (50, 51) and the United Divisions of the Italian Supreme Court promptly ruled the judgment No. 8770, known as “Sentenza Mariotti” (52) by establishing that: 1) the HPs are liable for slight fault in cases of negligence (*negligenza*), imprudence (*imprudenza*) and unskillfulness (*imperizia*); 2) medical workers could be punished for negligence and imprudence in every case of gross fault, but not if the unskillfulness is committed in compliance with the CPGs and best practices in a complex and extraordinary situation; 3) the specific risk and the special technical difficulties of the clinical case have to be considered in the circumstance of a gross fault for unskillfulness, consisting in a serious deficiency of care and/or a passive behaviour in absence of the essential precautions.

Concisely, the adequate management of a clinical case could be negatively affected by a series of unpredictable situations due to the variability of the clinical picture and the availability of the logistical resources drastically limiting the liability of HPs (49). This legal framework must be recognized in the national emergency caused by the SARS-CoV-2 pandemic.

It is worth emphasizing that Italy was the first Western country to be struck by the devastating new coronavirus. Italian HPs worked in absence of solid scientific evidences without validated, undisputable and convincing evidence-based CPGs because the pathological mechanisms triggered and, consequently, the safety of medications to contrast by the virus, were unknown. Medical workers firstly experienced off-label drug use and experimentation of innovative technical approaches. The COVID-19 outbreak rapidly overwhelmed the health system of the Northern Italy, such as in the Lombardy, one of Europe's wealthiest and most productive areas, causing a shortage of beds and medical supplies

and forcing the doctors to make increasingly critical choices. The lack of instrumental and human resources (partially mitigated owing to the extraordinary contribution of young and inexperienced HPs), and protective devices worsened the crisis and Italian first-line HPs worked in extreme circumstances.

Even HPs employed in medical divisions not directly involved in the fight against the new coronavirus found themselves in difficulty. For instance, gynaecologists and midwives faced to treat pregnant women affected by SARS-CoV-2 without exhaustive knowledge about maternal and the fetal effects of the COVID-19 disease, consequence of the disease on the delivery and possibilities of a vertical/intrapartum/post-partum transmission and their relative outcomes on newborns.

It should be stressed that the choice of adequate medical care must be based on CPGs funded on the best evidences of the topic updated at the time of the medical intervention also according to judgment No. 8770 of the Italian United Divisions of the Supreme Court. This statement clarified two capital legal aspects: 1) continuing professional development is mandatory for HPs by acquiring the knowledge, good practice, skills and attitudes useful to offer the state-of-the art treatment; 2) *ex-ante facto* principle has to be the pillar for the robust judgment; thus the judge must evaluate the liability of HPs based on the CPGs and the best practices available at the time of the fact. To date, the situation is still in a very dynamic stage: physicians and scientists daily collect a huge amount of information updating incessantly the state-of-the art about the mechanism of action and transmission of the virus, the development of new techniques of detection and the implementation of novel effective therapeutic strategies. Thus, it has been rather impracticable for medical staff and health care facilities to take the pace day-to-day with the continually improvement of the knowledge about SARS-CoV-2.

Under the above-mentioned situation, it would be reasonable from an ethical and legal point to implement a “criminal shield” for HPs involved in future litigations about their liability in cases of adverse occurrences (5). Undoubtedly, the rapid outbreak of COVID-19 and the consequent overload of the weak Italian health system, coupled with the lack of undisputable CPGs and best practices for the management of the patients affected by a new virus, drastically limited the liability of the HPs calling more attention for a modification of the legal framework by Italian institutions.

CIVIL ASPECTS

Contractual liability

The impact of the SARS-CoV-2 pandemic on the civil litigation related to medical liability could be significant for healthcare institutions (53). According to The Italian Civil Code, article No. 1218 and article No. 1228, public and private healthcare facilities are responsible for negligence or misconduct of their staff (54).

Generally, Italian public and private hospitals are called to respond not only to medical malpractice, but also to personal damage due to organisational shortcomings. In fact, according to the law No. 24/2017, a patient must receive the best standard of care. At the same time, damages related to delays, long waiting list, other pathology, or transmission liability from the HPs to the patients, could involve healthcare facilities in further civil proceedings.

The magnitude of problem is visible considering the hypothesis of hospitals as the main vector of transmission in the first phase of the outbreak. Indictments could be related to negligence or omissions of the employees. Since the early stage of pandemic, healthcare facilities had to ensure: 1) intensive care units for COVID-19 patients consisting in confined areas to avoid in-hospital transmission; 2) well-organized triage to offer suspected COVID-19 patients a satisfactory treatment; 3) adequate provision of personal protective equipment for HPs; 4) information to HPs about risk of transmission; 5) reporting of n positive and suspected new cases to coordination centres. However, potentially infectious persons, pending the result of diagnostic tests, were hospitalized in the same area of confirmed COVID-19 patients favouring transmission. In case of a civil litigation against healthcare facilities about in-hospital transmission in a non-ideal environment, with HPs and the hospitals incapable to satisfy the precautionary measures, the cause and effect link and the fact that the patient would not have been infected in an ideal environment, has to be demonstrated (52).

Considering the high contagiousness of SARS-CoV-2 and the high probability of transmission, in the next future, a significant number of civil proceedings, pressuring the Italian healthcare system (whether private or public) and overloading the law courts, is expected. A possible solution, to mitigate the serious risk of dramatic effects on healthcare costs and workload of the legal system due

to civil litigations about HPs liability, is to recognize an *a priori* indemnity for the consequences of COVID-19 directly payed by the state.

Furthermore, the COVID-19 emergency imposed to reschedule the hospitals' agenda and thousands of medical exams have been postponed or, in the worst case, cancelled. Obviously, this decreased the standard of care predictably and exacerbated the pathological conditions of the patients leading to permanent or temporal damages. Likely, it will generate in the next future a tremendous volume of claims that cannot be set in extrajudicial resolution providing a right compensation for injuries.

Extra-contractual liability

Up to now, the discussion was focused on the claims for hospital negligence, but according to article No. 2043 of the Italian Civil Code, the HPs themselves (doctors, midwives, nurses, technicians, *etc.*) could be attacked. The ultimate result is a considerable enhancement of insurance costs. One must remember that HPs working in the emergency faced an unprecedented condition in absence of convincing and adoptable CPGs based on solid scientific evidence for the management of COVID-19 patients. This is a relevant element since law No. 24/2017 declares that HPs need to act with a scrupulous attention and adequate medical preparation (diligence) complying with CPGs released on the website of the Italian National Institute of Health after a systematic and scrupulous assessment of scientific evidences.

Since the beginning of the outbreak, the efforts of medical associations have been devoted to identify effective care. To date, there is no specific treatment for COVID-19 and care is based on a symptomatic approach, providing supportive therapies with modest results (*e.g.*, oxygen therapy and fluid management). Thus, the eligibility of a claim for active or omissive professional liability cannot exist as ruled by the abovementioned law No. 24/2017. Moreover, article No. 2236 of the Italian Civil Code establishes that "if the performance implies the solution of especially complex technical issues, the contractor is not liable for damages, except in case of willful misconduct or gross negligence".

From a practical point of view, this law supports HPs working in an emergency characterized by a special difficulty to manage patient conditions. Due to the solidity of the reasons that depict the pandemic as a problem of special complexity, plausibly article No. 2236 plays a key role in the ori-

entation of the courts representing a powerful tool for a rational and ethical reduction of the risk of professional liability for HPs (55).

In that regard, article No. 5, subsection 5, of law No. 24/2017, mandates that the quantitative evaluation of the damage, in case of a tort, must be established on the "special difficulty", the complexity of the solution to the problem, not solely from a medical point of view but also based on viability of logistical resources of health facilities.

Overall, the current legal framework limits the liability of HPs in the pandemic, except for wilful misconduct and gross fault (article No. 2236 Civil Code), but its updating is necessary to avoid heterogeneous and arbitrary interpretations. To avoid doubt, legislative action is expected to exclude the liability for medical staff working during the COVID-19 emergency.

CONCLUSIONS

The SARS-CoV-2 pandemic represents a situation of special difficulty for HPs, particularly in its early-stage (56, 57). The rapid transmission of the new coronavirus caused an overload of hospitals where medical staff has treated a relevant number of patients in total or partial absence of undisputable or adoptable CPGs or good health care practices.

The milestone of judgment No. 8770/2018 of United Divisions of the Italian Supreme Court imposed a change of jurisprudential parameters in a special situation adjusting a legal standard. Thus, the case-law is to reject criminal consequences for HPs by considering the unprecedented emergency scenario characterized by the lack of scientific and medical evidences making their performance extremely problematic. In the above-mentioned exceptional circumstances, the opportunity of applying article No. 2236 of the Civil Code in the criminal process restricts the punishment to wilful misconduct or gross negligence. Moreover, an ethical assessment suggests a necessary revision of the criminal legal framework by legislator to introduce a "shield" for HPs worked in the first line against the SARS-CoV-2 virus.

In case of contractual liability, healthcare facilities are scarcely defensible because of their responsibility on the provision of protective personal devices (in order to reduce in-hospital infections) and logistical deficiencies leading to patient's injuries caused by the COVID-19 disease. Based on the well-established law No. 210/1992, *a priori* in-

demnity for the resultant law tort directly payed by the Italian State may mitigate the number of civil proceedings. Another main consequence of the overloaded healthcare system has been the delayed medical care of patients affected by different diseases. This compromised the standard of care resulting in permanent or temporal damages opening the door for future civil claims that cannot be simple resolved in extrajudicial settings.

In case of extra-contractual liability, punishment is excluded in a special situation like the SARS-CoV-2 pandemic, according to article No. 2236 of Civil Code and article No. 5, subsection 5, of law No. 24/2017.

Overall, the outbreak imposes urgent reorganization of the legal framework to homogenize the judgments in both civil and criminal processes by excluding the liability of HPs involved in an epochal emergency.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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