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Perinatal and post-partum infections in times of Coronavirus: are compliance with cautionary measures and safety protocols key factors in staving off litigation?

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ABSTRACT

Several factors have been associated with increased risk of maternal and fetal peripartum and postpartum infections, including pre-existing maternal conditions (e.g. malnutrition, diabetes, obesity, severe anaemia, bacterial vaginosis, and group B streptococcus infections) and unexpected or iatrogenic conditions during labour and childbirth, such as prolonged rupture of membranes (PROM) multiple vaginal examinations, manual removal of the placenta, and cesarean section. As such, the strategies to reduce maternal and fetal infections and their short- and long-term complications have been largely directed at preventive measures where such risk factors exist. In many cases of maternal and fetal infections, medical negligence may have played a role. In fact, a given infection may not have been detected during examinations, or proper treatment may not have been implemented in a timely fashion. In fact, some infections may become more severe if they are not properly treated as quickly as possible. The Authors have aimed to shed a light on the most common, and feared, childbirth-related infections, by means of a wide-ranging analysis of medical databases (Scopus, Pubmed, Embase, Research Gate, Web of Science), legal archives (Justia, Leagle, Lexis, Casetext) and recommendations issued by medical and scientific institutions (United Nations, World Health Organization, Centers for Disease Control and Prevention, National Health Service, etc...), spanning the 2004-2020 period. The inability on the part of physicians to thoroughly document the appropriateness of their interventions and the compliance with guidelines and best practices often results in claims being filed by damaged patients and/or their legal heirs. Litigation is typically complex in such cases, and likely to result in substantial compensatory damages being awarded to damaged patients. Currently, a higher standard for cautionary rules should be applied by practitioners and medical facilities to minimize the risk of claims being filed, particularly in tort courts. As a

SOMMARIO

Numerosi fattori sono stati associati ad un maggiore rischio di infezioni materno-fetali peripartum e postpartum, tra cui condizioni materne preesistenti (ad esempio malnutrizione, diabete, obesità, anemia grave, vaginosi batterica e infezioni da streptococco di gruppo B) e condizioni inattese o iatrogene che insorgono durante il travaglio o al momento del parto (ad esempio rottura prolungata delle membrane, esami vaginali multipli, rimozione manuale della placenta e taglio cesareo). Pertanto, le strategie per ridurre le infezioni materne e fetali e le loro complicanze a breve e lungo termine sono state in gran parte rivolte ad implementare misure preventive in presenza di tali fattori di rischio. In molti casi di infezioni materne e fetali sono addebitabili a condotta colposa dei sanitari. Infatti, in alcune fattispecie, l'infezione potrebbe non essere stata rilevata durante gli accertamenti diagnostici previsti o qualora anche individuata, si potrebbero configurare casi di ritardato trattamento della stessa, che determina in molti casi un aggravamento del processo infettivo. Gli Autori si soffermano sulle infezioni peripartum considerate più comuni e pericolose, mediante un'analisi di banche dati mediche (Scopus, Pubmed, Embase, Research Gate, Web of Science) e di archivi legali (Justia, Leagle, Lexis, Casetext) effettuata per un arco cronologico compreso fra il 2004 e il febbraio 2020. Gli Autori hanno altresì analizzato le linee guida e best practices emanate da istituzioni mediche e scientifiche nazionali e sovranazionali (Nazioni Unite, OMS, Centri per il controllo e la prevenzione delle malattie, Servizio sanitario nazionale, ecc ...). Al verificarsi di eventi avversi in sala parto con conseguenze sfavorevoli alla madre e/o al feto/neonato, la condotta dei sanitari può essere chiamata in causa se i medesimi non sono in grado di comprovare il rispetto delle regole cautelari e che gli eventi in questione non siano riconducibili al loro operato. Da tali situazioni deriva un numero sempre crescente di contenzioso, di cui gli Autori hanno riportato esempi significativi, nell'ambito

matter of fact, the current global setting of Covid-19 pandemic crisis has engendered unique conditions. Hence, specifically targeted measures are needed in maternity centers in order to stave off the contagion of healthy patients, while at the same time providing the best possible care for Covid-19 positive parturients and their newborns. Compliance with directives and regulations issued by health care authorities, aimed at the implementation of adequate diagnostic pathways, isolation protocols and protection requirements, is undoubtedly crucial for preventing malpractice allegations and liability.

del quale è sempre più difficile dimostrare l'estraneità della condotta dei sanitari al prodursi dell'evento infettivo e delle sue complicanze. Attualmente in tutto il mondo sono richiesti standard più elevati di misure cautelative per evitare addebiti di malpractice. Una condizione del tutto peculiare è quella del contesto epidemico attualmente vissuto in relazione alla infezione da Covid-19. Specifiche misure sono richieste nei punti nascita al fine di evitare il contagio di donne sane e di ridurre i danni per le partorienti infette e i loro neonati. L'aderenza alle disposizioni delle autorità sanitarie in termini di predisposizione di adeguati percorsi diagnostici, procedure di isolamento e sistemi di protezione è considerata decisiva per evitare addebiti di responsabilità.

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INTRODUCTION

Neonatal infections may be characterized as congenital (i.e. those which were present at birth and likely acquired in the maternal womb) or perinatal, that is acquired later in pregnancy or upon delivery. Outcomes for the neonate after infection can vary widely based on the organism involved, the time during gestation when infection occurs, and whether the mother has any protective antibodies that can provide the fetus with passive protection, reducing the disease severity for the infant. Transplacental spread of maternal infection is the common route by which the fetus acquires infection. Placental infection is often associated with systemic illness in the neonate; thus, molecular, microbiologic, and pathologic examination of the placenta is important in the critically ill newborn. In the perinatal period, acquired early-onset infection (before 72 hours) is almost always caused by organisms acquired in the maternal birth canal. After this period, most infections are acquired through close contact with members of the baby's environment and through human milk. The manifestations of infection vary with the infecting organism. The mechanism and dynamics relative to damage and response by the host and the stage of the pregnancy, determine the effects on the neonate. Some pathogens can trigger harmful effects throughout gestation. Fetal organogenesis is usually complete by 12 weeks gestation; thus, damage incurred during this period will likely result in anomalies (1). The mother does not transfer T-cell specific immunity, crucial in the control of many viruses, to the fetus. As for maternal Immunoglobulin G (IgG) antibodies, they are transferred to the fetus and reach one-half the normal serum concentration by approximately 30 weeks' gestation, and more normal values at term. Furthermore, the transferred antibodies need to have a certain degree of concentration to be protective. In some bacterial infections, the mother might not have enough antibodies in her system, and this factor is complicated by the newborns inability to rely on an antibody response to polysaccharide antigens, such as those found on bacterial capsules such as those of group B Streptococcus. Newborns who experience a sufficient period of antigenic stimulation (usually 7-14 days) will exhibit an identifiable and measurable Immunoglobulin M (IgM) response to some viruses and parasites, which has diagnostic value. Moreover, antigen-specific T-cell responses are significantly reduced or delayed in neonates, and this also contributes to delaying B-cell and antibody responses. Still, it is worth stressing that the pathogenesis of neonatal infection is not yet fully understood (2). Globally, the most common intervention for preventing morbidity and mortality related to childbirth infection is the use of antibiotics for prophylaxis and treatment. However, the misuse of antibiotics for obstetric conditions and procedures that are thought

to carry risks of maternal infection is common in clinical practice. Such inappropriate use of antibiotics among women giving birth has implications on global efforts to contain the emergence of resistant bacteria strains and, consequently, on global health. The WHO global strategy for containment of antimicrobial resistance underscores the importance of appropriate use of antimicrobials at different levels of the health system to reduce the impact of antimicrobial resistance, while ensuring access to the best treatment available. Therefore, appropriate guidance for health professionals and policy-makers on the need for antibiotics and the type of antibiotics for the prevention and treatment of maternal peripartum infections would align with the WHO strategy and, ultimately, improve maternal and newborn outcomes (3,4).

Various definitions and terms have been proposed for childbirth-related infections, but none are used universally. A WHO technical working group has outlined the concept of puerperal sepsis as infection of the genital tract, happening any time between the onset of rupture of membranes or labour and the 42nd day postpartum; two or more of the following signs are observed: pelvic pain, fever, abnormal vaginal discharge, abnormal smell/foul odour discharge or delay in uterine involution. While this definition captures well the characteristics of infections related to giving birth, the use of the term puerperal suggests that the onset of infection is only limited to the puerperium. Patients are at a higher risk of urinary tract infection during the post-partum stages, and such complications might be linked to risk factors such as prolonged catheterization (catheters should therefore be promptly removed immediately when no longer needed), epidural anesthesia and operative delivery; a study has found the incidence to be 2.8% after CS and 1.5% after vaginal birth (5). In addition, studies have pointed out that women with diabetes mellitus are at a higher infection risk, of the lower genital tract; significantly, those with poorly controlled diabetes appear to run the highest risk of contracting genital infections (6,7). It is worth noting that subclinical intraamniotic infection could lead to postpartum cardiovascular collapse and disseminated intravascular coagulation; such developments may be erroneously ascribed to other conditions, such as amniotic fluid embolism (AFE) (8), unrelated to infection. Patients diagnosed with AFE may therefore have infection/systemic inflammation instead, a study has found. These observations have implications for the understanding of the mechanisms of disease of patients who develop cardiovascular collapse and DIC, frequently attributed to AFE (9).

RISK OF LITIGATION ARISING FROM COVID-19 CASES AMONG PARTURIENTS

Pregnant women and their fetuses are undoubtedly high-risk population segments when outbreaks spread. Scientific studies have reported the outcomes of 55 pregnant women and 46 neonates who contracted COVID-19; still, no conclusive proof of vertical transmission has been found 10-11. Exposure and susceptibility to infections is affected and increased by pregnancy-related physiological and mechanical changes; that is particularly significant in Covid-19 cases: if the cardio-respiratory system is affected, such a scenario may lead to a rapid progression which can potentially trigger respiratory failure in pregnant patients (12). It is also worth noting that the pregnancy bias towards T-helper 2 (Th2) system dominance, which protects the fetus, could leave the mother more exposed to viral infections. Moreover, it is of utmost importance to put in place comprehensive safety measures based on principles such as consistent social distancing, workplace segregation, containment of cross-infection to health care providers, sensible and timely use of personal protective equipment and telemedicine (13). A rapid review has found that preterm delivery in 47% of women hospitalized with COVID-19 in the United Kingdom, which may put the nation's neonatal services under severe pressure, should the UK's reasonable worst-case scenario (80% of the population being infected) become reality (14). On 18th March 2020, the Royal College of Obstetricians and Gynaecologists (RCOG), in consultation with RCM, RCPCH, RCOA, OOA, issued guidance for delivery and neonatal care in COVID-19 affected pregnancies; among the recommendations, it is stressed that the delivery mode should be primarily determined by obstetric indication and that the separation of affected mothers from their babies is not advisable (15-17).

In addition, one of the most meaningful recommendations is that all patients who are admitted to maternity wards should receive screening for Covid-19, if they have distinctive symptoms, and

all women with symptoms should be considered potentially Covid-19 positive.
Evidence pointing to clusters and co-infections within households has led to the request for the implementation of preventive measures such as consistent hand hygiene and use of respiratory masks for asymptomatic family members who wish to access maternity units to attend delivery, whereas partners who tested positive are required to comply with quarantine protocols, and are therefore banned from the facilities.
The Royal Colleges also recommend that whenever gravidas are hospitalized due to the worsening of symptoms and suspected or confirmed Covid-19 infection, multidisciplinary assessment examinations must be carried out in a timely fashion, ideally with the involvement of infectologists, obstetrician/gynecologists, midwives, and delivery anesthesiologists. All such proceedings and their conclusions should be discussed with the patient, with a close focus on care priorities, the most suitable location (e.g. intensive care units, isolation rooms within infectious disease wards or elsewhere), the medical specialists who contributed to the process, the medical team's concerns about specific pregnancy aspects, particularly fetal conditions. Elective cesarean section is not recommended by currently available scientific evidence in such cases. All prescriptions about pregnancy and delivery progress as well as fetal health are therefore advisable (18). On the other hand, water birth ought to be advised against, due to evidence pointing to possible the possibility of a faecal–oral route of Covid-19 transmission. No scientific evidence currently recommends augmentation of labor in Covid-19 positive patients, and any decision to resort to peridural anesthesia should be discussed and agreed upon with all delivery team members (gynecologist, obstetrician and midwife), based on maternal and fetal clinical conditions. Access to obstetrical wards is not allowed to Covid-19 positive partners, who must abide by quarantine protocols. Such indications have been transposed into regulations by health care authorities in many countries. In Italy, for instance, the Ministry of Health issued a Covid-19 set of directives on 31st March 2020 ("Indicazioni per gravida-partoriente, puerpera, neonato e allattamento") (19). In the decree, the Ministry has codified the need for pregnant women to gain admission to "Punti Nascita" (Birth Centers) hubs, also denominated 2nd level birth centers, which must be set up by regional governments or autonomous provincial authorities based on population demographics for each specific area. The new regulations mandate that each birth center be tasked with outlining pathways aimed at the proper management of obstetrical care during labor and delivery for suspected or proven Covid-19 cases, for any situation in which patient transfer is contraindicated. Specifically, tenable procedures must be laid out for obstetric care in vaginal delivery or cesarean section and puerperium, which need to include thorough protective measures for all health care operators.
In cases of SARS-CoV-2 positive gravidas, strict measures need to be put in place in order to avoid the accidental transmission of the infection, either airborne or through contact with respiratory secretions. Newborns, the other hospitalized patients and health care personnel all must be safeguarded at all times. Confirmed Covid-19 cases should therefore be able to rely on single, negative-pressure isolation rooms whenever possible, with independent bathrooms and ideally, adjacent anterooms. Should such services be unavailable, confirmed cases should anyway be hospitalized in single rooms with bathrooms, to be transferred as soon as possible to facilities with higher safety standards. All procedures that could give rise to aerosol emissions have to be carried out in negative-pressure isolation rooms. Health care staff members who came into contact with suspected or confirmed Covid-19 cases must wear all proper Personal Protective Equipment (PPE), i.e. FFP2 respirator masks (FFP3 should be used for aerosol-generating procedures), facial protection, water-proof vests, gloves. The issuance of regulations by national health care authorities has a profound legal impact in terms of possible liability of health care operators and hospital management, when Covid-19 transmission is found to have occurred, as it would happen in any epidemic outbreak. As a matter of fact, the margin of appreciation granted to doctors, obstetricians, neonatologists and anesthesiologists is rather small: all procedures will in fact have to be carried out in strict compliance with official protocols, as laid out in policy papers issued by each regional health care bureau. Individual operators will be held liable only in cases of blatant failure to abide by the regulations issued by health care authorities (from which negligence liability may arise). Within the epidemic framework, hospital management may be called to answer for its acts as well, in light of its role as guarantor of in-

frastructure suitability, the implementation of adequate proceedings, the constant compliance with all measures aimed at the protection of patients and staff, and with the standards set by health care authority provisions. Although no jurisprudence has developed yet with regard to Coronavirus cases, precedents set in similar circumstances seem to show that the choice on the part of hospital managers or personnel to operate in conditions of substandard care does not rule out possible liability; such a choice is in fact bound to entail risks for professionals and patients alike.

Delivery room malpractice: potentially catastrophic fallout

Congenital and perinatal infections are undoubtedly major factors in determining permanent disability among children all over the world. Linked together by the acronym TORCH, denoting Toxoplasma gondii, rubella virus, cytomegalovirus, and herpes virus, congenital infections can result from only a modest number of human pathogens that cross the placenta and infect the fetus. Although congenital rubella syndrome has been eliminated in the Americas by immunization, no effective immunization exists yet against several pathogens, which cannot even be effectively treated by currently available antimicrobial drugs (20). Although expecting parents certainly experience great joy at the thought of their child soon to be born, quite frequently the path to motherhood entails risks that can result in damages and injuries to mothers and infants. As a matter of fact, several changes occur in the mother's system and body during pregnancy; The maternal immune system is complex and governed by multiple metabolic and hormonal factors, and during pregnancy, it adjusts in order to protect the mother, as well as her unborn child, from disease (21). During this process, some parts of the immune system are suppressed, while others are enhanced. This can put the pregnant mother at a higher risk of bacterial infections. The death rate of viral and bacterial infections is higher in pregnant women compared to non-pregnant women. The constant monitoring of women throughout pregnancy, and particularly delivery, is therefore extremely important in order to promptly identify any infection throughout pregnancy (22). Any failure on the part of doctors to identify infection in time and to select and administer suitable antibiotics in a timely fashion can jeopardize the lives of mothers and unborn children alike. Such development can result in medical negligence litigation. Affected families can file lawsuits against the doctors involved if any malpractice is suspected (**table I**).

PROVIDING PATIENTS WITH THOROUGH INFORMATION IS KEY TO STAVING OFF LITIGATION

The provision of thorough information to patients is undoubtedly a key factor. A 2009 survey of 606 Collaborative Ambulatory Research Network (CARN) members of the American College of Obstetricians and Gynecologists (sampled to demographically represent ACOG) found that a 67% majority agreed that informing pregnant patients about infection risk during pregnancy was prioritized in their practice. Still, although many specialists routinely counsel their patients on preventing toxoplasmosis (87.7%), hepatitis B virus (78.8%), and varicella-zoster virus (60%), less than half reported counseling patients on preventing less common conditions such as CMV, LCMV, and Bordetella pertussis infections. The majority reported counseling typically occurred at initial prenatal exams (30). Furthermore, throughout the process of communicating with the patient as well as the public at large, it is essential to tailor health messages to the appropriate literacy and language level. Hence, in order to tackle and minimize that issue, use of understandable, simplified language should be consistently encouraged on written documents, such as consent forms and patient instructions and in face-to-face counseling conversations. Moreover, patients and their families/legal guardians must be informed on any views or convictions held by their doctors, which may lead to a refusal, on conscience-related, religious or moral grounds, to provide certain forms of health care interventions (e,g. abortion procedures or administration of emergency contraceptives); a prompt referral to a non-objecting provider should be made in such instances, so as to make it possible for patients to undergo the procedure that they need or request within the bounds of the law (31,32). It is worth stressing that it is the patient's choice to have any tests or procedures performed. First and foremost, she needs to be provided with the tools to make a sensible and well-informed decision. All discussions of informed consent should be appropriately documented by the health care professional. If test-

Table I. *Instances of childbirth infections and legal aftermath.*

Patient, date and location	Course of events and type of infection	Medical consequences	Legal outcome
Unnamed patient, May 5, 2004, Monmouth County, Freehold, NJ, USA	The child's mother was admitted to CentraState Medical Center in labor on May 5, 2004. The defendant obstetrician ordered Pitocin to augment the labor and the delivery of the baby. Plaintiffs' experts maintained that over the course of several hours, the obstetrician failed to appreciate evidence of a hostile uterine environment and fetal distress on the electronic fetal monitoring which should have prompted her physician to discontinue the Pitocin and call for an immediate emergency cesarean section earlier than she did. Plaintiffs' experts opined that the delay in calling for an emergency cesarean section resulted in the infant sustaining an acute asphyxic event in the minutes before his birth which left him with significant brain damage.	A neonatology expert for the defense also argued that the Plaintiff's neurological injuries were not caused by an acute asphyxic event, as the Plaintiffs' experts had argued, but by prolonged exposure to maternal chorioamnionitis, an infection of the placenta.	Attorney D. L. Z. obtained a multi-million settlement on behalf of a 6 year old boy with hypoxic ischemic encephalopathy and cerebral palsy. A portion of the settlement is being used to purchase an annuity, making the total value of the settlement $3,715,000–$9,625,000[23].
Unnamed patient, August 2006, Brigham and Women's Hospital, Boston , MA	In August 2006, then 30 weeks pregnant plaintiff's mother was admitted to Newton Wellesley Hospital (NWH) for high blood pressure and preterm labor. After a 5-day admission, she was transferred to Brigham and Women's Hospital (BWH) because her labor was progressing. On admission to BWH, both babies had normal heart rates. Shortly after admission, the mother spiked a temperature to 102.3 and the babies' heart rates became tachycardic, ranging between 170-200 bpm. The babies' heart rates remained elevated for the next 3 hours. The defendant nurse notified the defendant OB/GYN resident and the defendant attending OB/GYN. After an examination, they determined that the mother had a kidney infection. The defendants planned to start antibiotics immediately, but they were not given for over an hour and a half.	Later that afternoon, the babies' heart rates started to show decelerations. The nurse called the resident, but the patient was not evaluated. Fifteen minutes after the first call, the nurse called the resident regarding an abnormal lab value, concerning for bleeding. Yet again, the resident did not evaluate the patient. Shortly thereafter, the patient started to shake and tremble. She then began to visibly bleed, an indication of a placental abruption. The defendant doctors were notified and delivered the twins by emergency cesarean section within 10 minutes. At delivery, the plaintiff was blue, limp, and did not have a heartbeat. The baby was admitted to the BWH neonatal intensive care unit (NICU) for 10 days, then transferred to the NWH NICU. At both hospitals, the plaintiff was noted to have normal neurological exams. At 23 days of life, the plaintiff was diagnosed with a blood infection. The infection was treated, but returned weeks later. At 4 months of age, the plaintiff was diagnosed with meningitis. At 8 months old, the plaintiff had an MRI that showed periventricular leukomalacia (PVL), a brain injury associated with prematurity. At 10 months of age, the plaintiff was diagnosed with cerebral palsy.	At trial, the defense claimed that the plaintiff's injuries were caused by prematurity and the multiple infections that the plaintiff had after delivery. After 11 days of trial, the case was settled for $4,000,000.00 before closing arguments[24].
Ms. H.C., August 18th 2011, St. Francis Hospital, Columbus, OH, USA	The newborn was infected with Group B Streptococcus, after the doctors failed to test the mother for the bacterial infection, which is quite frequently found in the vagina of gravidas. According to the family's argument, the standard of care applied to obstetricians requires Group B Streptococcus (GBS) culturing in the management of a pregnancy at that particular point in time. The mother was discharged after two days in the hospital, having received multiple courses of antibiotic treatment (Ampicillin, an antibiotic known to effectively treat GBS). A few days later, the mother went in for a routine prenatal appointment with Dr. D. E., another obstetrician employed by St. Francis Hospital, during which Dr. E. cultured her for Group B Streptococcus. The test came back negative, but despite that, the mother had been "colonized" by GBS: she had the infection, but the doctor's test failed to catch it.	Two weeks later, the woman went back to the hospital in labor. The medical operators, however, concluded that there was no need for antibiotics during labor, in light of the fact that GBS culture had been found negative. The child was delivered that evening, apparently healthy. A day later, the baby's temperature had alarmingly risen. Lab tests indicated the neonate to have an infection, and subsequent blood and spinal fluid tests confirmed that Gracie contracted Group B Streptococcus at birth, leading to meningitis. The child has since been diagnosed with cerebral palsy, cortical visual impairment, and generalized developmental delay	The family's attorneys argued that having knowledge of the fact that the patient had recently received antibiotics, Dr. E. should have figured out that a culture performed on that date could not be trusted to accurately reflect her GBS status. Case settled for an undisclosed amount[25].

Patient, date and location	Course of events and type of infection	Medical consequences	Legal outcome
Ms. H.N., 29-year-old woman, August 2013, Boston Hospital, Bangor, Maine, USA	The patient was admitted to Eastern Maine Medical Center on Aug. 1 2013 and gave birth to a baby girl 20 hours later. Her pregnancy had been uneventful till then. The woman underwent an episiotomy to expedite the childbirth. Once discharged, she experienced pain and swelling, which got worse overnight, so the first-time parents returned to the hospital the next day.	The mom contracted necrotizing fasciitis, a rare and quick spreading bacterial infection, and passed away on August 8th, 2013.	The patient's family decided not to push charges against the doctors or the facility[26].
Ms. O., 2015, United Kingdom	Ms O gave bore her daughter in June 2011. An instrumental delivery turned out necessary, which led to the patient suffering a torn cervix. Her doctor subsequently repaired the tear, inserted a vaginal pack and ensured that Ms O was administered antibiotics. Still, that did not prevent an infection from setting in. Hospital staff erroneously ascribed her symptoms to sciatica, although she had never suffered from it before. Blood cultures grew Group B Streptococcal bacteria.	Ms O started experiencing intense pain in her back, waist and buttocks, making her unable to walk. Ms O was then sent home, albeit she was by then unable to walk on account of the pain and unable to take care of her newborn baby. At home, however, she only got worse. She was only checked on by community midwives, but not referred to her general practitioner or back to the hospital. Ten days following delivery, the patient was again hospitalized with sepsis and renal failure. She was transferred to an Intensive Care Unit, but she was still in great pain with multi-organ failure. She was diagnosed as having suffered a reactive arthritis due to the severe infection, which had caused the pain, swelling and stiffness in her limbs and joints, particularly her left knee. X-rays showed that the reactive arthritis had resulted in rapid deterioration in her knee joint and severe osteoarthritis; she would need a total knee replacement, despite her young age. Due to the reactive arthritis, deterioration of her knee joint and mobility problems Ms O gained a significant amount of weight in a short time, adding to her musculoskeletal pain.	The patient could not go back to work as a cleaner and required care and help with any daily activity. The patient's attorney appointed a commission of experts to analyze the care that Ms O received. The expert witnesses pointed to the failure to administer antibiotics after repair of the cervical tear, the delays in identifying an infection and starting antibiotics and the decision to discharge Ms O from hospital in light of her state at the time. The hospital management made partial concessions: breach of duty related to the failure to administer antibiotics and prematurely discharging the patient. In addition, it was acknowledged that with the timely administration of antibiotics the infection would not have grown out of control. Two months before trial was due to begin, a settlement for £750,000 was negotiated[27].
Unnamed patient, 2016, North Central Bronx Hospital, New York, USA	The pregnant woman was admitted to North Central Bronx Hospital for labor and delivery. The mother was full term, with no prenatal complications and had a spontaneous rupture of membranes while at home. For 50 hours, her labor failed to progress and she contracted an intra-amniotic infection (chorioamnionitis), due to prolonged rupture of membrane.	Despite the failure of her labor to progress, the presence of infection and repeated signs of fetal distress, Defendant hospital failed to perform a timely cesarean section. As a result of that failure, infant Plaintiff suffered a stroke and was subsequently diagnosed with cerebral palsy.	A settlement was reached on behalf of the Plaintiff for $6,000,000[28].
Ms. Doe, April 2017, Roe Hospital, Michigan, USA	Doe was admitted to a hospital in pre-term labor at 29 weeks gestation. During her 39-hour admission, she received medication to prevent a premature delivery. The hospital staff then discharged her. One day later, laboratory results revealed that she had an E-coli urinary tract infection and that she was positive for Group B strep.	Within a week, she went into labor and delivered her baby by CS. The infant has been diagnosed with brain damage, resulting in cerebral palsy, developmental delays and learning disabilities. The untreated infection spread to D.'s uterus and caused premature cervical dilation. The defendant countered that antibiotic prophylaxis was not necessary.	The parties settled for $5 million before the start of the trial[29].

ing is declined by the woman, additional counseling should be offered to dispel any doubt and answer any other questions or concerns without ever resorting to coercion or pressure.

Rates of hand hygiene compliance vary in different parts of the world; 19.6% and 20% compliance have been reported from an Italian and a Spanish teaching hospital, respectively approximately 32% from an internal medicine ward of a University Hospital in Turkey, and 34% in health care workers from a Pediatric Hospital in Rio de Janeiro in Brazil. A study from Southeast Iran regarding compliance of HCPs working in hemodialysis centers revealed a hand washing adherence rate of 58.7%, while a study from Mashad, Iran, reported a hand washing rate in the health staff of a general hospital as 8.5%. A systematic review on hand hygiene compliance by the HCP reports a median compliance rate of around 40%, with the lowest rates found in ICU settings (33). The main aspects that make hand hygiene complex during delivery, especially if a birth attendant is attending alone, is that both the woman and her infant are in need of care at the same time, which can pose challenges in terms of effective infection prevention. Finally, a delivery involves large quantities of blood which easily contaminates the hands of the health care provider and the environment. Hand hygiene at the time of birth is especially important before a cesarean section or any other minor invasive procedure, such as an episiotomy. These are very direct routes for infection because hands are so closely in contact with patient blood (34). Cesarean sections are currently rising and in many countries account for as much as 50% of deliveries (35). Much of the global focus on preventing HCAIs has concentrated on hand hygiene. This is an essential intervention but needs to be accompanied by a hygienic physical environment in order to break the transmission chain of infection. This is particularly important for clinical areas caring for patients at higher risk, and with vulnerable sites, such as delivery beds. In addition, the importance of the disinfection practices of health care personnel, instruments and patients has been evidenced by cases of legal relevance that have involved health care personnel and the problem of infections transmitted in the delivery room (36). A crucial enabling factor in the physical environment is the basic requirement for water and sanitation – a requirement that in low-income countries is inadequate compared to high-income countries. The reliance on visual cleanliness as a substitute for 'safety' is currently widespread; national and international guidelines often view visual cleanliness and frequency of cleaning as indicators of the extent to which IPC standards are met. Still, visual assessment of cleanliness on maternity units alone is an insufficient basis on which to determine safety, in terms of the possible presence of potential pathogens. Therefore, improving the availability and knowledge of hygiene protocols, supervision and feedback, and initiatives aimed at quality improvement could be useful methods to improve compliance and cut maternal/neonatal infection rates. If infections do occur, it is extremely important to promptly and properly identify their symptoms and provide medical care. Most infections can be treated with relatively low risk of further complication, provided that they are quickly diagnosed.

CONCLUSIONS

From a medico-legal perspective, not every case where a physician failed to diagnose a maternal infection will necessarily rise to the level of medical malpractice. In light of the considerable difficulties in demonstrating how the infection was transmitted, health care facilities are the most likely to be held liable. In fact, legal statutes in most countries, particularly under tort law, tend to prioritize protection and redress of those who suffered damages, by the application of "presumptive" criteria (such as the *res ipsa loquitur* legal principle, which infers negligence from the very nature of an accident or damage, even in the absence of direct proof as to how the defendant acted). Thus, the prevalent legal standard, which has become well-established in most judicial frameworks, indicates that any claimant who suffered damage due to an infection deemed to have been preventable, should be awarded compensatory damages, following a retrospective evaluation. Preventable infections, which were however not prevented due to organizational failure or individual errors by one or more operators, would generally result in compensatory damages for injuries or (wrongful death) for the plaintiffs. However, it is often quite challenging to identify when the failure/error took place, and who was liable for it, among the health care crew members; various care-related activities in fact have a potential to create a context in which infections may arise for any hospitalized patient. The most suitable and

broadly-applied standard for determining whether an infection was preventable is probability-based (preventability higher than 50%). It is safe to say that in cases of vertical infection transmission, from mother to fetus, courts will likely be more inclined to consider such outcomes as not preventable, thus unavoidable. Nonetheless, malpractice charges within a pandemic context constitute a different scenario altogether, such as the one that health care systems and operators have been fighting against worldwide. Any activity within such a setting is in fact regulated by provisions issued by national governments, legislatures and health care authorities. Still, such factors do not fully shield health professionals from malpractice allegations. Any proven failure to comply with regulations or inappropriate clinical decisions, which might have exacerbated the patient's conditions or caused his/her death, will predictably still lead to claims under criminal and civil law statutes.

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