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The highly complex phase of intrapartum management: when clinical and medico-legal aspects overlap

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ABSTRACT

Objective. Some intrapartum obstetrical practices, such as episiotomy or Kristeller Maneuver, are highly controversial within the scientific community, from the ethical, political and social perspectives. Guidelines or recommendations for the management of intrapartum care, revolving around a thorough informed consent process, can be decisive to avoiding deeply conflicting situations, where the phrase "obstetric violence" has unfortunately become relatively widespread.
In this paper, the authors aimed to highlight how the use of intrapartum obstetric practices is, at times, necessary and instrumental in ensuring the well-being of the mother as well as the foetus.
Materials and Methods. A broad-ranging search has been conducted, using the scientific search engines PubMed, Google Scholar, Medscape, Medline Plus and Scopus, via the following search string: "obstetric violence", "gender violence", "intrapartum care", "episiotomy", "caesarean section", "Kristeller", "childbirth", "informed consent", taking into consideration the articles from 2015 to February 2021.
Results. Results of our research point to the fact that the woman's need for information on obstetric procedures is often not adequately met by health professionals, and the informed consent process is therefore not thoroughly implemented.
Conclusions. The authors argue in favour of adopting an informed consent model to be submitted to the pregnant women regarding any intrapartum obstetrical procedure that may become necessary before and during labour, in order to make professional conduct more transparent and protect health care personnel from claims and lawsuits arising from unwarranted practices.

INTRODUCTION

The birth of a child is an extraordinary event in the life of a woman, one which deeply impacts the sociorelational and emotional life of both parents.

As stated by the World Health Organization (WHO) in 2018, the greatest expectation of every pregnant woman is to have a "positive childbirth experience". That notion includes a continuity of care and services provided by specialized and well-trained health personnel, as well as the reasonable expectation and prospect of giving birth in a safe and comfortable environment that does not expose either the pregnant woman or her offspring to any sort of risk. The hope and reasonable expectation of being able to have a positive childbirth experience include the desire for a natural, physiological and painless labour and delivery [1, 2]. As shown by data provided by the WHO, physiological childbirth also has a long-term impact on the well-being of the family unit: "the health and well-being of a mother and child at birth largely determine the future health and well- being of the family as a whole" [3].

A fundamental aspect that falls well within the category of a positive childbirth experience certainly entails the absence of adverse physical effects related to the birth event, which can damage a woman's quality of life, undermine the possibility of further pregnancies or jeopardize the newborn's health and well-being.

Childbirth may sometimes result in complications during labour or delivery, hence the need to resort to obstetric-gynaecological practices sometimes perceived as "violent", although the aim is to prevent a negative outcome for both the mother and the foetus/newborn.

Most of the adverse events may concern perineal lacerations and/or uterine complications [4]; for the newborn, trauma can result from difficult extractions. A higher risk of trauma has been observed in cases of foetal macrosomia (sometimes associated with maternal diabetes) or in cases of breech delivery or any other abnormal foetal presentation, especially in a primiparous woman.

Nonetheless, delivery through caesarean section (CS) is not risk-free for both the mother and the foetus.

Although delivery by CS is associated with lower rates of urinary incontinence and pelvic organ prolapse [5], it does entail higher risks of fertility [5], morbidity adherent placenta placenta previa (MAP) complicating future pregnancies, ectopic pregnancies [6] as well as major risk for long-term infant conditions such as asthma and obesity [5].

In our study, we aimed to assess prevalent opinions in the scientific community regarding intrapartum obstetric manoeuvres, in light of an updated review of the literature on the subject, and how measures such as informed consent should be implemented in order to prevent litigation and claims arising from the warranted use of practices potentially deemed violent and inadvisable.

MATERIALS AND METHODS

The authors have conducted an extensive search of relevant scientific literature on multidisciplinary databases such as PubMed, Google Scholar, Medscape, Medline Plus and Scopus, in order to gain a thorough understanding of both the official positions of various international scientific societies, with a close focus on the legal and medical feasibility of such procedures, and court data and filings of any litigation related to alleged obstetric violence from 2015 to 2020.

Ultimately, using the word string (Kristeller OR uterine fundal pressure OR episiotomy OR caesarean section) AND (obstetric violence OR informed consent OR consent OR obstetric complications) the research has produced 5,349 on PubMed, 128 on Scopus, 3,130 on Google Scholar and 804 results on Medline. Papers published over a seven-year period have been included, ranging from 2015 to February 2021.

Studies on the subject have highlighted the difficulty of establishing a linkage between maternal-foetal damage and the use of certain obstetric-surgical manoeuvres in the delivery room. The authors therefore decided to also include in their research articles of purely legal relevance, in which litigation arising in the obstetric-gynaecological field was clearly highlighted; moreover, in order to assess the degree of sensitivity to the issue of obstetric violence among Internet users, the web search has been broadened by using generic search engines (Google). Such a search included articles in which women reported a lack of adequate information and perceived as unnecessary interventions such as: use of vacuum or forceps, use of enemas, frequent obstetrical vaginal evaluations, Kristeller Maneuver (KM), episiotomy, CS.

Thus, the existence of a considerable number of forums has emerged, where the problem is dealt

with and addressed from a psycho-social and legal perspective, which has enabled us to figure out the scope of the dispute relative to damages and injuries induced by and/or linked to intrapartum care management.
In fact, an apparently growing number of claims and lawsuits has been arising in that setting, especially in light of Resolution 2306/2019 [7], adopted by the Council of Europe General Assembly on 3rd October 2019, which has urged Member States to devise and put in place legal mechanisms for enabling complaints stemming from alleged acts of obstetric and gynaecological violence.
The authors have also analysed the guidelines and best practices issued by national and international medical and scientific institutions, such as United Nations, WHO, National Health Service. If adverse events in the delivery room lead to unfavourable outcomes for the mother and/or foetus/newborn, the conduct of healthcare professionals may be called into question, especially if they are unable to prove compliance with the precautionary rules, and that the adverse outcomes occurred regardless of their actions.

RESULTS

Our analysis of the research findings has highlighted that there is no universally acknowledged approach regarding the management of intrapartum phase, and some manoeuvres frequently used in the obstetric-gynaecological field could be perceived from the women as dangerous on the psycho-physical integrity of the pregnant women and unborn children [8-16].
However, some of the authors [4, 15-20] believe that universally recognized guidelines are needed in order to provide guidance and legitimize the activity of the obstetrician in intrapartum management. In fact, if a valid informed consent process is not implemented, there is a high risk of health care claims arising from the use of practices considered inappropriate, unwarranted, and even "violent".
The guidelines recommend avoiding certain manoeuvres in case of shoulder dystocia, including the exertion of excessive traction on the foetal head and the application of fundal pressure [21, 22].
In Japan, the study conducted by Hayata *et al*. supports the empirical efficacy of fundal pressure and the need to comply with the 2017 guidelines by the Japan Society of Obstetrics and Gynecology (JSOG) [23], which stresses how clinical practice and experience are necessary to achieve an informed consent model structured in adherence with said guidelines.
A retrospective survey study conducted in Spain between January 2018 and June 2019 [24], which excluded from the survey those women who had given birth at home or outside Spain, shows that 48.6% of women reported having undergone unnecessary and/or painful procedures (during childbirth assistance at public facilities), 58.4% during assistance at a private facility, and 27.1% at government-backed private facilities. Of all the women surveyed, 74.3% claimed that they had perceived their experience as violent. As emerged from an analysis of relevant scientific literature on the subject, KM is performed in 25% of all vaginal deliveries in Spain. Other interventions, such as frequent vaginal check and shaving of the genitals are sometimes performed, without medical records.
In many European countries, a propensity on the part of healthcare professionals to perform delivery by CS has emerged, even for those pregnancies in which such a procedure was not strictly clinically indicated, with a percentage of 15% in Spain and up to 79% in the United Kingdom [17], with the questionable motive of trying to reduce peripartum pain [25].
In Brazil, over the last 30 years, health strategies have been put in place to improve the quality of care and reduce the rates of deliveries by CS, as well as neonatal mortality. A policy of dissuasion in the use of KM is currently in place in the South American country, as there is insufficient scientific evidence as to its effectiveness to support its routine use, given the high risk of perineal lacerations. Furthermore, in these countries the use of KM is deemed to fall within the category of "obstetric violence" [26], since it is classified as a procedure that is not only useless but also harmful, in that it may give rise to both physical and psychological trauma.
Consequently, in Latin America there is a tendency to increasingly reduce obstetric practices such as KM, with rates as high as 55.4% before the health care reform, and 9% after it. Furthermore, some of these studies have found that methods such as KM are performed on 37.3% of women at normal risk and in 33.9% of high-risk ones [27]. Such findings indicate that these procedures are not practiced on pregnant women in strict correlation with particular maternal or foetal conditions.

In such countries, episiotomy is also considered a method that must not be routinely carried out [28-30]. Such a strong stance is based on scientific evidence pointing out how episiotomy often proves harmful, even if sometimes linked to reduced perineal trauma [31, 32]. Reported complications are pain, dyspareunia, laceration of the anal sphincter or rectal canal, vaginal prolapse, recto-vaginal fistulosis, infections, profuse bleeding, dehiscence of the surgical wound [33], in addition to constituting a violation of the sexual and reproductive rights of women [26]. Such conclusions likely arise from considering episiotomy a surgical procedure performed on healthy patients, in the absence of a proven benefit, without previous local anaesthesia and, in some cases, without patient consent [34]. However, the WHO guidelines do not go so far as to prohibit episiotomy altogether, but rather they recommend a moderate use, *i.e.*, not exceeding the 10% cut-off in healthcare facilities [1].
It is a reasonable option when the clinician believes that enlarging the birth outlet to facilitate delivery of the foetus will benefit the mother or baby, ultimately outweighing the risk of potential adverse outcomes associated with the procedure.
Ideally, information about perineal lacerations and episiotomy should be disclosed to women as part of their prenatal care.
The incidence of such procedures is quite high in Italy. In our country, the rate of CS deliveries is around 32.8%, with a greater propensity to resort to CS in private facilities (52.5%) than in public hospitals (31.9%); the episiotomy rate is 54.24%, with 21.2% of deliveries perceived as violent and traumatic. Still, there are no official guidelines in Italy governing the use of KM, UP or CS, despite their widespread use [35].

DISCUSSION

Is obstetric violence tantamount to traumatic delivery?

In 2014, the World Health Organization issued a statement titled "The prevention and elimination of disrespect and abuse during facility-based childbirth", denouncing a rapidly spreading phenomenon called "obstetric violence" [36].
The statement includes a detailed list of the main forms of procedures and conducts felt as abuse and disrespect towards women during labour and childbirth, carried out within health facilities around the world: physical abuse, serious humiliation, verbal assaults, forced implementation of medical treatments or procedures and/or lack of informed consent by women with respect to such procedures, refusal to administer pain medication despite the woman's request; serious violations of privacy; refusal of admission to health facilities; negligence and recklessness during care possibly leading to avoidable and life-threatening complications; the detention of women and their children in the facility after birth due to their economic inability to cover the costs of medical procedures.
The declaration concludes by urging governments, research bodies, scientific associations and health and legal professionals to undertake concerted efforts and initiatives aimed at preventing abuse and disrespect during the childbirth.
What prompted the WHO declaration is the inadequacy of protocols and good medical practices, albeit consistent with prevailing scientific evidence, as opposed to the 1985 WHO Recommendations, later updated [37], which has laid out the recommended approach to provide assistance during labour, childbirth and postpartum. The WHO recommends the use of methods other than merely medical-surgical ones, in order to promote relaxation of the pelvic floor and the prevention of trauma and/or lacerations of the pelvic floor [1]. Especially in spontaneous birth, due to the pressure of labour and/or delivery, trauma to the genital tract and lacerations can occur, possibly involving both the anal sphincter and the mucosa, causing major issues for the parturient. However, the effectiveness of these procedures is not absolute. The only certain evidence points to episiotomy as the only obstetric intervention capable, when necessary, of preventing severe perineal lacerations [4].
Another extremely controversial method routinely used in intrapartum is KM, *i.e.*, the exertion of pressure at the fundus level by pressing on the abdomen of the parturient towards the birth canal, in order to favour progression through the birth canal and delivery.
To date, no decisive evidence exists that such intrapartum methods may be dangerous and ineffective; on the contrary, it would seem that under certain conditions, they can favour the second stage of labour, especially when foetal distress occurs resulting from uterine hypokinesia with ensuing slowdown in the expulsive phase, or in some selected cases such as vaginal birth after caesarean section [38].

However, it has become a common opinion that the use of certain procedures can be harmful to both the physical and mental health of the woman and the newborn, therefore the number of complaints against health professionals who resort to manoeuvres such as episiotomy, CS or KM, has been steadily growing. Several courts both in the United States, Latin America and the European Union have ruled against the indiscriminate use of such obstetric-gynaecological practices, establishing over time a trend in favour of the presumption of guilt for health care professionals who rely on such methods during childbirth [39]. This is also due to the current legal scenario, in which the protection of inalienable individual rights and the notion of protection of innate human worth have been extended from the unborn child to the embryo and foetus which, "although still *in utero*", must be equated with the newborn throughout labour and delivery.

Some authors [39] have put together a collection of meaningful civil and criminal liability claims, in which evidence suggests an increasingly widespread awareness of the linkage between the use of KM and possible harm to women's health. Legal trends and jurisprudence established in Italian and American courts seem to acknowledge the dangerous nature of a widespread use of KM. UK courts have confirmed such an approach, deeming FP an inappropriate practice, although unlike the Italian and US courts, they require higher evidentiary standards to prove its real application. A mere statement on the part of women is therefore not enough to prove it.

Although episiotomy and fundal pressure manoeuvres are currently widely applied procedures and considered "acceptable" by most obstetrician-gynaecologists, midwives and probably patients themselves, trends appear to be evolving, both in the scientific community, which has taken a position against the routine adoption of such practices for "prophylactic" purposes, and in the public opinion. Such techniques have in fact been linked to a wide array of complications such as infections (both affecting the parturient and the foetus), amniotic fluid embolism (AFE) [40, 41], and even uterine trauma [42, 43], which can result in uterine factor infertility for which new solutions are being developed and experimented, such as uterine transplantation [44, 45].

Recent research findings have shown that sudden and intense struggle during childbirth is associated with an increased risk of post-partum haemorrhages, chorioamnionitis and consequently an increase in admissions to neonatal intensive care, especially in nulliparous women [46].

In delivery rooms around the world, there are many conditions and risk factors for contracting a maternal and foetal peripartum and postpartum infection. Such a risk, in the current context of the COVID-19 pandemic, has been tackled through the introduction of new rules. Therefore, specifically targeted measures are needed in maternity centres to prevent the contagion of healthy patients, while at the same time providing the best possible care to COVID-19 positive women in labour and their newborns [47, 48].

The prevention of complications arising from infections is essential. Healthcare professional must be able to figure out an appropriate timing for all those investigations aimed at preventing infections to which both the mother and the foetus are differently exposed during gestation and at birth. In fact, any failure to put in place and abide by such precautions can have major medico- legal implications [49, 50].

Obstetrics and gynaecology, as research unequivocally shows, are medical specialties that entail a high risk of adverse events resulting in claims and litigation.

Hence, concepts such as "risk-based practice", "adverse risk practices" or "precautionary approach to risk management" have been developed in order to outline the effective management of pregnancies and births [51, 52]. "Risk" is hereby akin to the concept that aims to anticipate and control the future, reducing uncertainty through probabilities. From a practical standpoint, this should translate into a wider use of preventive medicine strategies aimed at shielding health professionals from claims [53]. According to this line of reasoning, therefore, even low risk pregnancies should be closely monitored to reduce the risk of complications, however infrequent [54].

Those dynamics have in turn led to a growing trend towards the medicalization of childbirth, even of what is normally defined as spontaneous or natural. In fact, what is commonly defined as "spontaneous birth" (totalling 64.7% of cases), is not in itself "natural", *i.e.*, without any medical intervention. On the contrary, the intervention of the obstetrician during labour and delivery is frequent and takes the form of several procedures that are not always considered reliable or advisable by the scientific community.

As far as our study was able to determine concerning the practice of episiotomy, currently available scien-

tific evidence is inconclusive and cannot therefore warrant its routine use in patients in labour. Given such uncertainty, episiotomy should be limited to those circumstances in which a precise clinical need has to be met. For instance, if there is evidence of risk for the foetus or the mother, and therefore delivery needs to be expedited, or in cases of objective clinical reasons: shoulder dystocia, need to facilitate the execution of internal manoeuvres or other elements that could foreshadow serious perineal or rectal damage. Nevertheless, as various studies have proven, the unnecessary use of episiotomy increases the risk of blood loss and maternal morbidity, as well as pelvic pain in the post-partum period and dyspareunia [30]. According to some reports [54, 55], women undergoing episiotomy and episiorraphy have characterized the experience as highly stressful and painful. The World Health Organization in its guide to obstetric care published in 2018 [1] recommends a more restrictive approach to the practice of episiotomy, arguing that "Routine episiotomy or its extensive use is not recommended for women who have a spontaneous birth". WHO has admitted that episiotomy can be considered truly justified only in 5-20% of births (*i.e.*, up to 1 out of 5 births). Similar remarks have been made in reference to KM: according to the WHO, the exertion of fundal pressure in labour is one of the options for which there is insufficient evidence of efficacy to warrant a recommendation, and which therefore should be used with caution, at least until further research is conducted [1]. From a critical review of the literature, it can be assumed that the real indications for its use today are: secondary uterine hypokinesia and foetal suffering in an advanced expulsive period in association with extraction by forceps or vacuum.

The use of these manoeuvres often occurs with short notice to the woman or under emergency conditions, which detracts from the quality of doctor-patient counselling. This can negatively affect the experience of childbirth.

A positive pregnancy experience could be defined as the preservation of physical and sociocultural integrity, such as the positive perception of a healthy pregnancy, for the mother and the foetus/newborn (which includes the prevention or treatment of risks), the realization of an effective transition to easy labour and delivery, and the achievement of a positive motherhood experience (which has to include self-esteem, competence and autonomy).

However, the quality of childbirth assistance and the completion of a non-traumatic natural birth do not solely depend on the adoption of valid operational protocols at an institutional level but, above all, on the quality perceived by the pregnant womenas to the level of care received [1].

Delivery rooms almost all over the world are often understaffed, overburdened, and the organizational challenges thereof make it harder to put in place good practices and effective "one to one", patient-tailored approaches [56].

According to various scientific studies [8-11, 26, 27] within the delivery rooms of some so-called developed countries, several obstetric/surgical practices considered "routine" are perceived as violating the woman's body. For example, KM is almost always described as painful and linked to a negative childbirth experience, capable of adversely affecting the mother-child bond and possibly even resulting in major difficulties in breastfeeding, inhibition of the bonding process, and even the total ruination of the childbirth experience as a whole.

In addition to the psychological aspect, KM's bad reputation stems from its being a method that often goes completely unreported in medical records [29]. From a medico-legal standpoint, thoroughly documenting any medical procedure is essential in terms of legitimizing the medical act. As a consequence, it is very difficult to perform a statistical analysis as to the actual prevalence of KM, since it often goes undocumented, nor is it a required field for filling in the birth assistance certificate (CeDAP). This may become problematic if the aforementioned manoeuvres give rise to harmful effects on the foetus/newborn and/or the parturient, in the absence of adequate and documented information. In fact, an established principle in jurisprudence is that informed consent embodies the synthesis and integration of two fundamental human rights: the right to self- determination and the right to health [57]. Therefore, any intervention not expressly allowed by the patient, or different from that for which consent was granted, may entail both a breach of contract by the doctor and a prejudice to the patient's psychophysical integrity. Nevertheless, our study has found that currently, obstetric manoeuvres considered routine but "violent" are frequently performed without informed consent [28]. It is therefore necessary to promote the dissemination of thorough information among obstetricians, in order to raise awareness as to the need for a more restrictive approach to the use of these practices, in light of the close association be-

tween them and the risk of lawsuits and possible compensatory damages.

While the medicalization of childbirth is desirable in order to reduce the risks associated with pregnancy and childbirth itself, on the other hand the indiscriminate use of surgical procedures aimed at reducing vaginal deliveries - and therefore the timing of childbirth - may cross the line into a sort of "hyper-medicalization" not devoid of negative implications.

Italy, for example, is the European Union country with the highest number of caesarean deliveries: the rate was 36.3% in 2013, more than double that recommended by the WHO, and higher than the European average by almost 10 points (EU-27: 26.7% in 2011) [58]. The Italian High Institute of Health [59], along with the Ministry of Health, issued guidelines in 2010 and 2012 to set standards for CS use, while in the years 2011-2013 the National Health Plan set the goal of limiting CS to below 20% of total births, in an effort to reduce the risk of transforming birth from a natural event to a surgical one [60].

While the use of CS is supported by evidence pointing to a reduction in the risk of maternal pelvic disorders, such as urinary and faecal incontinence and pelvic organ prolapse, and stillbirth and neonatal morbidity [61, 62], there are now numerous studies claiming that operative delivery can put both the mother and the newborn at greater risk of adverse outcomes than planned vaginal delivery [18, 62]. In Nova Scotia, delivery via CS without labour has been found to be associated with an increased risk of puerperal infections. Other observational studies conducted in Canada have linked CS to higher rates of severe maternal morbidity, including haemorrhagic events, hysterectomy and uterine rupture, as well as reduced fertility with the risk of ectopic pregnancy, spontaneous abortion or placenta previa and placenta accreta spectrum disorders. Therefore, women contemplating a planned delivery via CS should be aware of the potential complications of the procedure such as bladder injury, and it would be advisable that this information be considered in the context of perinatal risk [63].

Unfortunately, in Italy as in many other countries, there are currently no universally recognized guidelines for the management of intrapartum that can provide guidance and solidly consistent standards for medical and obstetric personnel, and could protect health professionals from legal actions resulting from complications possibly linked to CS, episiotomy or KM.

The only references available consist of various recommendations and directives from different scientific societies which can be invoked in the event of a legal claim, such as: Public Health Agency of Canada [64], The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) [65], the Mid Essex Health care facilities, compiled by the British National Health Service (NHS) [66], American College of Obstetricians and Gynecologists (ACOG) [67], Royal College of Obstetricians and Gynecologists (RCOG) [5], and ISUOG [68].

Some events of great relevance have taken place since the publication of the latest RCOG guidelines in 2011:

1. the Montgomery ruling which underlined the importance of informed consent;
2. several criminal convictions for involuntary manslaughter arising from gross negligence, which highlighted the real risk of criminal conviction if non-compliance and malpractice can be proven in the medical care provided to a deceased patient. In the 2020 recommendations of the Royal College of Obstetricians and Gynecologists (RCOG), the doctor-patient relationship is of considerable importance, as is the level of information to be provided to the pregnant woman and the fact that this communication must be laid out and available for consultation in the medical record. In the case of assisted vaginal delivery, the health records must include detailed information on the assessment, the decision-making process and the procedure (including the possibility of procedures including episiotomy), a plan for postnatal care and sufficient information to counselling in relation to subsequent pregnancies [69].

Consent to undergo an operative birth should be obtained upon admission to the delivery room, when there is still enough time to explain and ensure that it will only be performed in case of an emergency and with certain procedures. That arguably constitutes a turning point with respect to the common practice of administering consent during the critical phase of labour, a scenario far from desirable. In fact, although informed consent is a crucial process for providing solid obstetric care, in over 50% of cases, pregnant women are not asked for consent to undergo one of these procedures. In cases where a consent form was used, the information provided to patients about the procedures seemed non-specific and rather vague, thus failing to elaborate on the risks and complications inherent in the specific procedure.

This is because very often these controversial manoeuvres are considered by health professionals as strictly related to childbirth, rather than procedures in their own right. Yet a legal review containing American and British malpractice sentences showed that just having applied KM, even in the absence of uterine damage, exposed the professional to a significant risk of conviction. This also has effects in civil court if, despite the presence of valid consent, the implementation of a procedure that was not indicated is demonstrated, as that will likely be viewed as a failure to provide necessary information. In such instances, compensation may be awarded if temporary and/or permanent biological damage is incurred, which will be compensable together with the related intrinsic suffering and any so-called existential impairment linked to socio-relational repercussions (no longer being able to be or do) [70].

CONCLUSIONS

A fundamental question to ask in light of the Italian and international legislative scenario is whether the key to avoiding legal repercussions is to provide adequate and thorough information, especially given the absence of universally recognized guidelines on intrapartum management. In Italy, the Code of Ethics for Midwives clearly specifies the duty to provide information and obtain consent [71]. In fact, the performance of any invasive medical-surgical practice likely to cause damage, albeit formally permitted, may lead to claims for compensation, if the aforementioned procedures do not meet the required standards.
According to Italian criminal law statutes, if the obstetric procedures have not been specified and correctly expounded upon to the patient, the consent given can be null and void, because based on lacking information. Compensation can be awarded if permanent or temporary damage occurs. Not only is the damage itself considered worthy of compensation, but other related aspects are as well, such as psychological distress and possible impairment also known as "existential damage" which is linked to social and emotional repercussions such as the inability to be or to do, resulting from the damage.
In light of what has been laid out so far in our study, it appears safe to assume that the adoption of an informed consent model is indeed advisable. Such a model should be applied in cases where such risky and controversial procedures are taken into consideration, in order to protect healthcare professionals and substantiate the soundness of their work. This is particularly relevant in light of the recent UN report on "Obstetric Violence", which aims to provide valuable guidance to States so that they can fulfill their obligations in terms of human rights protection by developing targeted national legislation, policies and strategies for the sake of women's reproductive health, as well as institutional procedures for reporting alleged violations of rights. That can go a long way towards ensuring a human rights-based approach and accountability within health facilities.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contribution

F.N.: Conceptualization, data curation, formal analysis, writing - original draft, supervision. F.S.: Supervision. M.C.V.: Data curation, formal analysis, writing - original draft. G.N.: Data curation, formal analysis. I.T.: Writing - original draft, writing - review and editing. A.F.C.: Writing - original draft, supervision, validation, writing - review and editing.

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The authors declare that they have no conflict of interests.

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