Limitation of professional medical liability in case of emergency medical treatment according to the joint criminal divisions of the Supreme Court of Cassazione

Ann. Ital. Chir., 2019 90, 6: 485-490
pii: S0003469X19030975

Gianluca Montanari Vergallo*, Matteo Gulino**, Alessandro di Luca***, Raffaella Rinaldi*

**Department of Anatomical, Histological, Forensic Medicine and Orthopaedic Sciences, Sapienza University of Rome, Rome, Italy*
***Department of Medico-Surgical Sciences and Biotechnologies, Sapienza University of Rome, Rome, Italy*
****Department of Public Health, Università Cattolica del Sacro Cuore, Rome, Italy*

Limitation of professional medical liability in case of emergency medical treatment according to the joint criminal divisions of the Supreme Court of Cassazione

Judgement no. 8770 released on February 22, 2018 by the joint criminal divisions of the Supreme Court of Cassazione innovatively established that emergency medical conditions represent "problem of special complexity" and, therefore, it is mandatory to apply art. 2236 of the Italian Civil Code. This article provides that health care professional may be convicted only in case of willful misconduct or gross negligence.
The authors analyze the jurisprudential evolution of all those elements that are fundamental to assess health care professional liability: a) special complexity of the performance b) relation between imprudence and carelessness c) conditions that may make the healthcare liability gross.
The principles approved by the joint criminal division within the above mentioned judgment significantly expand special complexity cases' range and, therefore, the corresponding liability's limitation range is extended.
Due to the solidity of the reasons on which it is based, this sentence could permanently influence the orientation of the Courts and, therefore, dramatically diminish the risk of professional liability for healthcare staff.
There is, however, a lack of clarity in the practical applications of the distinction between unskillfulness, on the one hand, and imprudence and negligence on the other. This event risks to nullify the usefulness of the joint criminal divisions' intervention. In fact, if the Court considers the health care professional behavior to be imprudent or negligent (rather than unskilled), no limitation of liability can be applied.

KEY WORDS: Carelessness, Criminal and civil medical liability limitation, Emergency medical treatments, Gross negligence, Problems of special complexity, Unskillfulness, imprudence

Introduction

Medical liability has been having a long jurisprudential evolution. Until the 1980s, since judges were supposed to assess medical negligence with a broad range of views and comprehensively, medical liability was admitted only if the healthcare professional behavior was lacking the minimum medical skills and experience which are legitimately required for anyone who is qualified to practice medicine [1].

In this historical period, there was also the tendency to apply to the criminal medical liability of healthcare professional art. 2236 of the Italian Civil Code, according to which: "If the service requires to solve technical problems of special complexity, the employee cannot be held liable for the damages, save for intent or serious negligence". In this regard, the Constitutional Court of Italy elucidated that, in cases of special complexity, criminal liability might be excluded only in case of slight unskillfulness, not even in case of gross unskillfulness.

It is necessary to appraise medical negligence comprehensively, because in medicine evaluation mistake is always possible. On the contrary, in case of carelessness and imprudence, the health care provider can't benefit

Pervenuto in Redazione Giugno 2019. Accettato per la pubblicazione Luglio 2019
Correspondence to: Raffaella Rinaldi, Department of Anatomical, Histological, Forensic Medicine and Orthopaedic Sciences, Sapienza University of Rome, Viale Regina Elena 336, Roma, Italy (e-mail: raffa.rinaldi@uniroma1.it)

from any liability's limitation [2]. In fact, as the 1942 report of the Keeper of the Seals to the King of Italy shows, article no. 2236 of the Italian Civil Code does not have the function to legitimize careless or superficial behavior, but it has the function of not mortify the initiative of the professional with the fear of unjust reprisal of the patient in case of failure [3].
Science and technique progress contribute to make judges more severe towards health care professionals. As a consequence, this approach has reduced the amount of medical treatment that should be considered as treatment of special complexity [4].
Indeed, with the progress of the scientific medical knowledge, judges have begun to constantly assert that any ignorance or defective application of such knowledge should be criminally punished [5-7].
Conversely, in recent years there has been an increase in sensitivity both of the legislator and of the Criminal Divisions of the Cassazione. The Parliament, in fact, first approved the so-called Balduzzi Decree (Legislative Decree No. 158/2012, converted into Law No. 189/2012), then repealed by the much more organic Law n. 24/2017, the so-called Gelli-Bianco law.
In art. 6, the latter states that the doctor who adheres to the guidelines published on the website of the Istituto Superiore di Sanità is not liable for slight unskillfulness. In case of absence of guidelines, good clinical practices, as long as these are recommendations appropriate to the specific case, should be adopted by health care professionals [8].
Even the evolution of the sentences of the Supreme Court turned out to be significant. In effect these sentences, limited to cases of special complexity, returned to consider doctors responsible only for willful misconduct or gross negligence. This thesis was recently authoritatively endorsed by the joint sections, which have also clarified that situations of emergency or lack of adequate health facilities represent cases of special complexity.

Article 2236 c.c. May Also Be Applied in Case of Criminal liability

Until recently, the criminal divisions of the Supreme Court of Cassazione have always stated that art. 2236 of the Italian Civil Code could not be applied to criminal liability, because it is a rule related to the contractual relationship between patient and doctor.
Furthermore, the negligence regulation comprised in the criminal code does not contain any gaps and clearly states that the slight and gross nature of the negligence only affects the extent of penalty (article 133 criminal code).
Therefore, the fact that in the individual case the fault is slight, involves a minor sanction but can never exclude liability. Conversely, according to the latest jurisprudence, also confirmed in 2018 by the criminal joint divisions, art. 2236 contains a principle of rationality and a rule of experience which should be followed in assessing the charge of unskillfulness whether the concrete case involves the solution of the problems mentioned above, or whether an emergency situation occurs.
The criminal joint divisions enhance the principle that health care professional's behavior must be adjusted to the technical-scientific complexity of the required performance and to the context in which it is carried out [9].

Cases of Special Complexity Also Include Emergency Treatment

The aforementioned art. 2236 of the Italian Civil Code is commonly considered a limitation of liability. Consequently, in order to avoid reducing the patient's right to health protection, jurisprudence has felt the need to strictly interpret the constitutive elements of this provision.
This explains the widespread jurisprudential orientation according to which only the treatment that concretely "transcends the limits of the preparation and of the skill normally necessary for practicing a health care profession, of being an exceptional and extraordinary case for not having been adequately studied in science and experimented in practice, or for having been the object of proposals and debates in medical science with experimentation of different and incompatible diagnostic and therapeutic systems, among which to make his choice" [10].
However, this interpretation appeared to be incorrect on a medical level. Indeed, it is quite possible that a medical performance, although widely known in literature, is of particular complexity because, for example, it requires a particular manual skill, such as some delicate operations of neurosurgery [11].
Furthermore, it is possible that an adverse occurrence must be dealt with known treatments and on which there are no contrasts of opinions. Nevertheless, the rarity of the adverse event or the very low percentage of favorable treatment outcomes should lead to the conclusion that the case is of special complexity [12].
The most recent jurisprudence, attentive to these considerations, has extended the limitation of responsibility contained in art. 2236 of the Italian Civil Code. In fact, despite confirming that the evaluation parameters must be derived from the criminal laws and not from the Civil Law, it stated that: "With regard to medical professional negligence, the Civil Law principle referred to in art. 2236 of the Italian Civil Code, which assigns importance only to gross negligence, can be applied in the criminal sphere as a rule of experience to be followed in assessing the charge of incompetence, whether the concrete case requires the solution of problems of special difficulty or if the case is an emergency situation. Indeed, health care professional's negligence must be based on the technical-scientific difficulty of the requi-

red performance and on the context in which it took place. It follows that whether the cases are not difficult and can be dealt with standard performance the prerequisites for parameterizing the subjective charge to the canon of gross negligence do not exist" [13-15].

The sentence of the criminal joint divisions released in 2018 also reiterated that emergency situations must be considered as cases of special difficulty, because having to decide and act immediately makes difficult even what, otherwise, would not be. Consequently, the limitation of liability provided by art. 2236 of the Civil Code is applied.

With this statement, the joint divisions consider important the fact that the doctor's activity can be characterized by high difficulty due to an unpredictable series of factors linked to the changeability of the situation to be faced and the resources available.

The underlying problem is how to assess the negligence consisting in the violation of the guidelines or, in their absence, good clinical practices as recommended by art. 5 of Law no. 24/2017, the so-called Gelli-Bianco law. In fact, even health care behaviors that fall easily into standardized guidelines can be difficult to carry out, due to the urgency or lack of adequate healthcare facilities [9].

This orientation appears to be more consistent with one of the objectives of the reform, that is to give greater objectivity to the ascertainment of negligence.

In fact, the complexity of the clinical situation makes the identification of the right choice much more subjective and debatable and, therefore, easily exposes health care provider to sentences based more on opinion, albeit widespread and authoritative, rather than on the proof of guilt.

The issue also involves several non-surgical settings, such us Compulsory psychiatric treatment [16].

The Notion of Unskillfulness

Another constant jurisprudential orientation that has contributed to narrowing the range of application of article 2236 of the Italian Civil Code is the one according to which the limitation of responsibility concerns only cases of negligence for unskillfulness and not also those of imprudence or carelessness.

This principle appears fully logical, because a greater complexity of the case should always lead to raising the threshold of prudence and diligence, not to legitimize the -albeit slight- violation of these obligations.

Unskillfulness, consisting in the non-observance of technical rules which are necessary for the correct performance of certain activities, "results in a carelessness or in a qualified imprudence, depending on whether such violated technical rules prescribe a *facere* (to be done) or a *non facere* (not to be done)" [17].

In fact, unskillfulness can occur both in an active conduct and in an omission: in the first case, it consists of imprudence, in the second one it consists of carelessness; both, however, are qualified by the fact that they violate technical norms or rules that must be known by the people that carry out the activity to which those technical norms refer.

When, on the other hand, the diligence or prudence rule belongs to the generality of the associates, for example because it is well-known or is a rule of common experience, it does not seem possible to consider it as unskillfulness, but rather as imprudence or carelessness [18].

This boundary line between unskillfulness, imprudence and carelessness is clear in theory, but it is often disproved in practice, because judges tend to extend the area of negligence and imprudence in the sector in question, thus restricting that of unskillfulness.

This propensity reflected within the sentence that decided the case in which the death of the patient was traced to "cardiac tamponade caused by hemopericardium caused by damage to the wall of the right atrium, which occurred during maneuvers to replace the Tesio catheter, which became necessary due to the obstruction of the previous garrison, which had prevented dialysis in the patient, suffering from chronic kidney failure".

According to the Supreme Court of Cassazione, the lesion was caused by "an inadequate management of the metal guide during the cannulation of the vascular catheter to be replaced, induced precisely by the obstruction of the catheter and the attempt by the health care professional to overcome its resistance by exerting greater force which proved to be excessive".

The judges identified the negligence of the doctor in the insertion maneuver of the metallic guide of the Tesio vascular catheter, as "carried out by excessively forcing the sliding of the metal guide inside the catheter, in the presence of a highly predictable obstruction, since the lack of patency constituted the reason why it was decided to replace the catheter".

The College, despite affirming that «[the] imprudence, traditionally, consists in the realization of a positive action that is not matched in the special circumstances of the case by those precautions that ordinary experience suggests to employ for the protection and the safety of personal and others' interests, stated that excessive use of force in the insertion of the metal guide represents carelessness, not unskillfulness.

In fact the latter, including behaviors "In contrast with the technical rules of the activity that the health care providers are supposed to carry out", would not be configurable in the concrete case because: "The health care professional was not accused for the violation of the technical rules governing the insertion of the catheter, but rather he was disputed for, with an absorbent evaluation, the use of imprudent improper dexterity that totally ignores the compliance with the specific "guidelines relative to the intervention".

This confused distinction between unskillfulness, on the one hand, and negligence or imprudence on the other,

can lead to consider the use of excessive force in obstetric maneuvers as an imprudent behavior, rather than an unskillful one.
Conversely, the amount of energy to be used should also be included among the technical rules of a manual operation, since it represents a piece of information that only operators know and that is unknown to common experience [19].

When Negligence Can Be Considered Gross

The notion of gross negligence has also been the subject of considerable hermeneutical evolution. The traditional thesis, inspired by the definition of Roman Studies *lata culpa* dating back to Ulpiano [20-21] and conditioned by the conception that *lata culpa dolo aequiparatur* [22-23], applies gross negligence only in residual cases, that is, for example, when "the need to depart from guidelines was macroscopic, immediately recognizable by any other health care provider instead" [24] or when the diagnostic-therapeutic choice was based on such basic knowledge as to be obvious to all.
Even the Constitutional Court of Italy asserted that gross negligence consists in the lack of that minimum skill and technical expertise in the use of manual or instrumental means or, finally, in the lack of prudence or diligence, that every doctor must have [2]. Even recently, the Supreme Court reiterated that it is possible to configure gross negligence in the case of an inexcusable mistake, which originates when one of the following conditions occurs: failure to apply the general and fundamental knowledge pertaining to the profession or lack of that minimum and technical skill in the use of the manual or instrumental means used in the operation and that the doctor must be confident he/she can manage correctly or, finally, the lack of prudence or diligence, which should never lack in those who practice health care [19].
This automatic inclusion of negligence and imprudence in gross negligence appears to be open to criticism, because it prevents taking into account the specific features of the peculiar case. Moreover, this approach can have a penalizing consequence for health care staff: if negligence and imprudence are always forms of gross negligence, doctors who hold these behaviors must return to public and private structures the amount of money they have paid to patients as compensation for damages.
Therefore, the usefulness of the art. 9 of the Gelli-Bianco law, according to which doctors are liable to public and private structures for compensation paid to patients only in cases of willful misconduct or gross negligence, is greatly reduced. In fact, if all negligence and imprudence behaviors are considered gross negligence, it will often be possible for the structures to recoup from doctors at least a part of the compensation paid to patients.
Moreover, a sector of considerable litigation is that of health care associated infections, in which errors can easily be considered negligent, rather than due to unskillfulness [25].
The doctrine has greatly contributed to overcoming this thesis. In particular, it was pointed out that
the judgment on the seriousness of the negligent must be assessed through the following criteria:
a) quantification of the event predictability;
b) extent of collectability;
c) type of motivation, for example to commit imprudence after following an order issued by a superior colleague;
d) particular difficulty in observing the precautionary rule, as in the case of a slight sudden illness;
e) range of avoidability, in fact if the correct alternative action is useless there is no negligence;
f) extent of the divergence between proper and held conduct [17-18].
In light of these considerations, the recent jurisprudence has affirmed that, since negligence is based on the violation of an objective duty of diligence, the first parameter to consider to establish its seriousness consists in the "measurement of the divergence between the actually held behavior and the one that was expected to be observed on the basis of the precautionary provision".
On a subjective level, instead, it is necessary to determine: "Quantification of the collectability of the compliance with precautionary rules" based on the following circumstances:
a) Professionalism of the agent, because the non-observance of a therapeutic norm has a greater negative value for a distinguished specialist than for a common general practitioner. On the other hand, the reproach will be less strong when the agent is in a situation of particular difficulty such as, for example, a slight malaise, an emotional shock or a sudden tiredness;
b) the motivation of the behavior, for which a hasty and inappropriate treatment is less serious if performed for a reason of urgency;
c) the complexity and difficulty of the medical or surgical procedure required [26].
In this way, not only the significant qualitative error, but also the quantitative element, for example the repeated violations of non-basic rules, are included in the area of criminal responsibility.
Such cases, on the other hand, could not have been criminally punished by applying the principle of "essential minimum rules" [27].
In this way, the approach according to which the seriousness of the negligence derives from the basic character of the violated behavioral rule is overcome. In fact, following the latter, criminal responsibility would risk to be too much limited with prejudice to its preventive function [28] and specialists would be favored. In fact, if the negligence is serious when a fundamental precautionary rule is violated, the risk of incurring in this type of responsibility is reduced as the skills required are

increasingly more selective and complex (rather than fundamental) [29]. Furthermore, the principle of the fundamental character of the unobserved behavioral rule seems incompatible with the typical contents of the negligence itself, both in criminal and in civil settings.
As a matter of fact, if the negligence consists in the violation of rules of diligence, prudence or expertise, it is clear that the risk of incurring a charge of medical liability must vary exclusively based on the greater or lesser degree of preparation, scrupulousness and shrewdness of the individual professional, independently from being a general practitioner or from the performed treatments level of specialization.
Indeed, it should be avoided to confuse the risk of causing a lesion, which is notoriously very variable in relation to the different areas of clinical practice, with the risk of holding an imprudent, careless or unskillful behavior, which, instead, depends only on the skills of the health care provider.
The sentence of the joint criminal divisions released in 2018 reiterated that medical negligence should be considered serious only when the therapeutic approach is markedly distant from the need to adapt to the peculiarities and the development of the disease, and distant from the patient's conditions.
Conversely, negligence should be considered gross even when there is a situation that imposes the need to intervene in a different and personalized way compared to what guidelines and practice propose: for example, in the case of concomitant pathologies that emerge from clinical evaluation.
The objective and subjective gradation of negligence, and therefore the amount of the individual punishment based on the specific conditions of the agent and his degree of specialization; the problematic or equivocal nature of the story; the particular difficulty of the conditions in which the health care provider operated; the objective difficulty of gathering and linking clinical information; the degree of atypicality and novelty of the situation; urgency; the motivation of the behavior; the awareness or not of holding a dangerous conduct are included in the distinction between slight and gross negligence.
In other words, the consolidated jurisprudence of legitimacy's assumption, according to which the evaluation of seriousness of the (generic) negligence must be carried out "concretely", taking into account the parameter of *homo eiusdem professionis et condicionis*, which is that of model of the agent operating in practice, in the specific conditions that have materialized, should be accepted [9].

Conclusions

The interpretative evolution indicated by the criminal divisions of the Cassazione Court appears particularly significant in view of the more serene and effective practice of medical and surgical profession.
In fact, in addition to the important application of art. 2236 of the Italian Civil Code to criminal responsibility, the notion of special complexity is considerably extended. This notion no longer concerns exceptional cases only, but all the situations that make the service more difficult than it would normally be, such as the lack of adequate health care facilities[30] and emergency condition.
In order to avoid an excessive limitation of responsibility, the jurisprudence considers the negligence to be serious not only when the doctor ignores some basic knowledge, but whenever the behavior is considerably different from what required from a doctor with the same professional skills and in the same circumstances.
The importance of this evolution is related to the fact that "special complexity" and "gross negligence" are the concepts on which article 2236 of the Italian Civil Code is based. Therefore, it seems possible that the orientation of the joint criminal divisions is also transposed by the civil divisions of the Cassazione, thus causing a limitation of the risk of convictions to pay damages.
Instead, the aforementioned art. 6 of the Gelli-Bianco law contains a limitation of liability which should be limited to criminal liability [31-32].
Despite this positive jurisprudential evolution, there remains a lack of clarity in the practical applications of the distinction between unskillfulness, on the one hand, and imprudence and carelessness, on the other.
This circumstance risks to nullifying the usefulness of the joint divisions' intervention.
In fact, if the Court considers the doctor's conduct to be imprudent or careless (rather than an unskillful one), no limitation of liability can be applied.
In this regard, it seems desirable that in future the Supreme Court clarifies that any violation of rules that are part of the knowledge acquired during the studies of medicine or the practice of the medical profession, even if they concern manual operations or have become known to the community through the mass media, constitutes unskillfulness.

Riassunto

La sentenza del 22 febbraio 2018, n. 8770 delle Sezioni unite penali della Corte di cassazione ha innovativamente affermato che le situazioni di urgenza rappresentano casi di speciale difficoltà e, quindi, si deve applicare l'art. 2236 c.c., secondo cui il medico può essere condannato solo per dolo o per imperizia grave.
Gli autori analizzano l'evoluzione giurisprudenziale di tutti gli elementi necessari per affermare la responsabilità del medico: a) speciale difficoltà della prestazione; b) rapporto tra imperizia, imprudenza e negligenza; c) condizioni in presenza delle quali si può considerare grave la colpa del professionista.

I principi sanciti dalle Sezioni unite nella citata sentenza estendono significativamente la portata dei casi di speciale difficoltà e, quindi, della relativa limitazione di responsabilità. Per la solidità dei motivi su cui si basa, tale sentenza potrebbe influenzare stabilmente l'orientamento dei Tribunali e, quindi, segnare un importante alleggerimento del rischio di responsabilità professionale per i medici. Permane, tuttavia, una scarsa chiarezza nelle applicazioni pratiche della distinzione tra imperizia, da un lato, e imprudenza e negligenza, dall'altro. Ciò rischia di vanificare l'utilità dell'intervento delle Sezioni unite. Infatti, se il Tribunale ritiene imprudente o negligente la condotta del medico (anziché imperita), non si può applicare alcuna limitazione di responsabilità.

References

1. Cassazione Penale Sezione IV:16 febbraio 1987, in Giust. pen., 1988, II, 106.

2. Corte Costituzionale, sentenza n. 166 del 22 novembre 1973. Available from: https://www.cortecostituzionale.it /action Pronuncia.do

3. Fiori A, D'Aloja E: *In tema di cosiddetta "certezza del diritto": la colpa grave del medico, ovvero in qual modo le buone intenzioni del legislatore sono state vanificate e tramutate in danno*. Riv It Med Leg, 2000; 1316.

4. Corte di Cassazione, Sezione III Civile:sentenza n. 2466, in Giur.it., 1996, I, 1, c. 91.

5. Corte di Cassazione, Sezione IV Penale:sentenza n. 2756 del 12 aprile 1991, in Cass Pen 1992.

6. Castronuovo D: *Dolo e colpa nel trattamento medico-sanitario*. In: Belvedere A, Riondato S (eds): *Le responsabilità in medicina*, Milano: Giuffrè, 2011; 1011-54.

7. Manna A: *Medicina difensiva e diritto penale. Tra legalità e tutela della salute*, Pisa: Pisa University Press, 2014; 71-102.

8. Mazzariol B, Karaboue M, di Luca A, di Luca NM: *Guidelines, good practices and best clinical health practices: valuable guidance for physicians and judges?* Clin Ter 2018; 169(6): e292-e296.

9. Corte di Cassazione, Sezioni Unite Penale: sentenza n. 8770 del 22 febbraio 2018. Available from: http://www.italgiure.giustizia.it/xway/application/nif/clean/hc.dll?verbo=attach&db=snpen&id=./20180222/snpen@sU0@a2018@n08770@tS.clean.pdf.

10. Corte di Cassazione, Sezione III Civile_ sentenza n. 1441 del 8 marzo 1979, n. 1441, in Mass Foro It 1979; 317.

11. Avecone P: *La responsabilità penale del medico*, Padova: Casa Editrice Dott. Francesco Vallardi, 1981; 331-32.

12. Busardò FP, Gulino M, di Luca NM, et al: *Not only a clinical nightmare: Amniotic fluid embolism in court*. Curr Pharm Biotechnol, 2014; 14(14): 1195-200.

13. Corte di Cassazione, Sezione IV Penale, sentenza n. 4391 del 1 febbraio 2012.

14. Corte di Cassazione, Sezione IV Penale: sentenza n. 39592 del 21 giugno 2007.

15. Blaiotta R: *La responsabilità medica: nuove prospettive per la colpa*. Diritto Penale Contemporaneo 2012. Available from: http://www.penalecontemporaneo.it/upload/1352035468blaiotta.pd, p. 9.

16. Montanari Vergallo G, et al.: *Medico-legal notes for a new set of standards in the assessment of penal liability in psychiatry*. Rivista di psichiatria, 2017; 52.1 16-23.

17. Mantovani F: *Colpa (voce)*. Dig Disc Pen. Torino: Utet, 1988; II:313.

18. Padovani T: *Il grado della colpa*. Riv It Dir Proc Pen, 1969; 886.

19. Corte di Cassazione, Sezione IV Penale: sentenza n. 16944 del 20 marzo 2015. Available from: http://www.italgiure.giustizia.it/sncass/.

20. Volterra E: *Istituzioni di diritto privato romano*. Roma: Edizione Ricerche, 1972; 128.

21. *Lata culpa est nimia neglegentia, id est non intellegere quod omnes intellegunt* (Digesto 50,16, 213, 2).

22. Cian G: *Lata culpa dolo aequiparatur*. Riv Dir Civ 1963; I:148-154.

23. Pifferi M: *Generalia delictorum. Il «Tractatus criminalis» di Tiberio Deciani e la «Parte generale» di diritto penale*. Milano: Giuffrè Editore, 2006; 260.

24. Corte di Cassazione, Sezionale IV Penale, sentenza n. 27185 del 30 giugno 2015. Available from: http://www.italgiure.giustizia.it/xway/application/nif/clean/hc.dll?verbo=attach&db=snpen&id=./20150701/snpen@s40@a2015@n27185@tS.clean.pdf.

25. Zaami S, Montanari Vergallo G, Napoletano S, et al.: *The issue of delivery room infections in the Italian law. A brief comparative study with English and French jurisprudence.* J Matern Fetal Neonatal Med 2017; 31:1-8.

26. Corte di Cassazione, Sezione IV Penale: sentenza n. 47289 del 9 ottobre 2014. Available from: http://www.italgiure.giustizia.it/xway/application/nif/clean/hc.dll?verbo=attach&db=snpen&id=./20141118/snpen@s40@a2014@n47289@tS.clean.pdf.

27. *Relazione integrativa al progetto del Centro Studi «Federico Stella» sulla Giustizia penale e la Politica criminale*. In Forti G, Catino M, D'Alessandro F et al. (ed) Mazzucato C., Varraso G., op. cit., 222.

28. Giunta F*: Intervento alla Tavola rotonda di presentazione e discussione del progetto del Centro Studi «Federico Stella» sulla Giustizia penale e la Politica criminale.* In Forti G, Catino M, D'Alessandro F, Mazzucato C, Varraso G, op. cit., 156.

29. Fiandaca G*: Intervento alla Tavola rotonda di presentazione e discussione del progetto del Centro Studi «Federico Stella» sulla Giustizia penale e la Politica criminale.* In Forti G, Catino M, D'Alessandro F, Mazzucato C, Varraso G, cit., 134.

30. Rinaldi R: *Health in the 21st Century: New rights come to the fore*. La Clinica Terapeutica, 2018; 169(4) 149-50.

31. Montanari Vergallo G: *Le buone pratiche clinico-assistenziali nella legge 8 marzo 2017, n. 24*. Responsabilità Medica 2017; 2: 271-79.

32. Pastorini A, Karaboue M, di Luca A, di Luca NM, Ciallella C: *Medico-legal aspects of tort law patient safeguards within the Gelli-Bianco piece of legislation*, Clin Ter, 2018; 169(4): e170-77.