Ann Ist Super Sanità 2025 | Vol. 61, No. 3: ?-?
DOI: 10.4415/ANN_25_03_0?

Needs for a shared operational methodology to draft guidelines and good practices in legal medicine

Patrizio Rossi and Andrea Mele

Sovrintendenza Sanitaria Centrale INAIL, Rome, Italy

Abstract

Introduction. Article 5 of Law n. 24/2017 established the obligation for medico-legal professionals to adhere to guidelines and good clinical-care practices, except in specific cases. However, the methodologies developed for clinical practice are not entirely applicable to the field of legal medicine, which presents unique characteristics in terms of regulatory context, objectives, and evaluative processes. Legal medicine does not primarily focus on diagnosis or treatment but on standardized assessment procedures, legal defensibility, and consistency of judgments.

Objectives. Starting from the experience of the Central Health Department (Sovrintendenza Sanitaria Centrale, SSC) of the Italian National Institute for Insurance against Accidents at Work (Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro, INAIL), the goal is to develop a dedicated manual outlining the appropriate methods for developing guidelines and best practices in legal medicine, proposing a methodological framework.

Methods. The authors conduct a review of the literature on the topic related to the methodology for developing guidelines and best practices in forensic medicine. They took inspiration from the methodological manual for the production of clinical practice guidelines by the Italian National Institute of Health (Istituto Superiore di Sanità, ISS).

Discussion. The authors highlight the lack of literature specifically addressing the development of guidelines and best practices in forensic medicine. *The methodological manual for the production of clinical practice guidelines* by the Italian National Institute of Health (ISS) requires some adaptations but certainly represents a highly useful tool for creating relevant recommendations for legal medicine. Therefore, the authors propose a specific methodology and a dedicated manual tailored to legal medicine. The manual should be adapted from the ISS methodologies used in clinical settings, revised to reflect the unique needs of medico-legal practice, and developed in close collaboration with the relevant scientific societies and institutions.

Conclusions. The method used for INAIL's SSC recommendations has proven effective in guiding internal medico-legal practices. Building on the ISS methodological manual, the authors propose a tailored approach for developing guidelines (LGML) and best practices (RBPML) in legal medicine. Given the unique challenges of the discipline – often not fully addressed by existing regulations or literature – standardized solutions are necessary to ensure consistent, high-quality medico-legal outcomes. Therefore, the establishment of a dedicated Working Group in collaboration with the ISS is essential to develop a structured methodology. INAIL's prior experience in this field provides a solid foundation for this initiative.

Key words

- medico-legal recommendations
- medico-legal guidelines,
- medico-legal good practices
- INAIL recommendations

INTRODUCTION

Article 5 of Law n. 24 of 8 March 2017 "Good clinical care practices and recommendations provided by the guidelines" [1] introduced a legal obligation for healthcare professionals performing services for medico-legal purposes to adhere – except in specific cases – to the recommendations set forth in officially recognized guidelines. These guidelines, pursuant to paragraph 3 of the same article, must be developed by public or private entities, scientific societies, and technical-scientific

Address for correspondence: Patrizio Rossi, Sovrintendenza Sanitaria Centrale, Direzione Generale INAIL, Piazzale Giulio Pastore 6, 00144 Rome, Italy. E-mail: sovrsancentrale@inail.it.

associations of health professionals, provided they are registered in a specific list established and regulated by the Ministerial Decree of 2 August 2017, and published in the Official Gazette n. 186 of 10 August 2017.

This provision significantly departs from earlier legislative drafts, which did not explicitly include healthcare services performed for medico-legal purposes, nor did they recognize technical-scientific associations and public or private institutions, alongside scientific societies, as bodies authorized to produce such guidelines.

In the past, there have been some reservations about the interpretation to be given to the formula used by the legislator [2]. Specifically, there was debate as to whether the law referred solely to clinicians whose work might carry medico-legal implications, or whether, as argued by other authors [3, 4], article 5 should also be understood to encompass the services provided directly by specialists in legal medicine.

The phrasing of the law, explicitly requiring healthcare professionals who perform activities for medico-legal purposes to comply with guidelines, or in their absence, with good clinical-care practices (except when the specific case justifies deviation), appears to support the latter interpretation. Accordingly, even medico-legal experts are now expected to follow recommendations found in validated guidelines and good practices, despite the current lack of such documents within the Italian National Guidelines System (Sistema Nazionale Linee Guida, SNLG).

This makes it evident that specific, tailored guidelines and good practices are necessary for legal medicine, particularly in those contexts where general clinical guidelines may not be applicable [5, 6].

In both legal commentaries and the available literature, the issue has predominantly been addressed with explicit and preferential reference to clinical guidelines. Medico-legal practitioners tend to rely on these clinical guidelines primarily when formulating expert opinions on cases of clinical medical professional negligence. However, they do not typically align their broader professional activities with guidelines specifically tailored to legal medicine.

In this context, the role of guidelines for legal medicine would be, for example, to support medico-legal decision-making processes [7-10]. Unlike clinical settings, where guidelines are mainly intended to assist healthcare professionals in choosing diagnostic or therapeutic interventions, in legal medicine they aim to ensure consistency, transparency, and defensibility in evaluative judgments. A concrete example is their use in expert assessments within judicial proceedings, where medico-legal experts are required to justify both their methods and conclusions. When the expert follows validated and contextually appropriate guidelines, it becomes more challenging for opposing consultants, such as the public prosecutor's expert or the court-appointed assessor, to claim that an alternative procedure should have been employed or that the professional unjustifiably diverged from accepted standards. In this sense, guidelines not only inform the decision-making process but also confer legal protection and methodological credibility in high-stakes or contentious evaluations.

Moreover, medico-legal protocols often derive directly from regulatory frameworks that mandate specific assessment criteria. For instance, permanent disability assessments for occupational injuries at Italian National Institute for Insurance against Accidents at Work (Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro, INAIL) follow the Legislative Decree of 23 February 2000 and Ministerial Decree of 12 July 2000; civil disability assessments refer to the Ministerial Decree of 5 February 1992; while compensation for civil liability, involving impairments between 1% and 9%, is governed by the Ministerial Decree of 3 July 2003. These documents function more as prescriptive protocols than traditional clinical guidelines. Nevertheless, certain medico-legal assessment criteria are not codified in legislation nor derived from case law. In such instances, practitioners often rely on analogical reasoning, particularly when the specific condition under evaluation does not correspond to a defined percentage in the available assessment tables.

Additionally, various phases of the medico-legal assessment process remain undefined by either statutory law or jurisprudence, thereby necessitating structured guidance to support medico-legal professionals in conducting consistent and defensible evaluations.

Medico-legal practitioners, however, should not engage with the issue merely as users of clinical guidelines, but also because their services must be anchored to the same principles of appropriateness that underlie the guidelines and good clinical-care practices followed by clinical healthcare professionals.

In essence, the quality of medico-legal services must be ensured and assessed according to predefined and discipline-specific standards. This point has already been emphasized by several authors [11, 12], who highlighted the need to complement outcome indicators, typically quantitative, such as service volumes or response times, with process indicators that reflect the quality of the medico-legal assessment across the various steps of the evaluative pathway, from input to output.

To this end, focused attention on guidelines and good practices specific to legal medicine is essential, as they can serve as a foundation for the identification and development of appropriate process indicators or proxies, through a methodology expressly designed for the peculiarities of the field.

OBJECTIVES: FROM THE RECOMMENDATIONS OF THE INAIL CENTRAL HEALTH DEPARTMENT TO GUIDELINES AND BEST PRACTICES IN LEGAL MEDICINE

The idea of providing useful tools to legal medicine operators to standardize practices, establish quality benchmarks for medico-legal services, and define relevant process indicators – prompted the Central Health Department (Sovrintendenza Sanitaria Centrale, SSC) of INAIL to initiate the development of recommendations.

While the grades of recommendation, assessment, development and evaluation Working Group (GRADE) methodology for guideline development and the appraisal of guidelines for research & evaluation (AGREE)

and AGREE II methods [13] for assessing guideline quality have proven robust in the clinical setting – and are appropriately cited in the methodological manual published by the Italian National Institute of Health (Istituto Superiore di Sanità, ISS) [14, 15], they present several limitations when applied to the context of legal medicine.

In line with the approach adopted by the Ministry of Health, INAIL recognized the opportunity to utilize the "recommendation" as a more suitable instrument. As a result, the INAIL SSC launched the production of medico-legal recommendations.

These recommendations are defined as "specific documents aimed at offering tools to prevent adverse events, promote accountability, and foster systemic change" (https://www.salute.gov.it/new/it/tema/governo-clinico-e-sicurezza-delle-cure/raccomandazioni-del-ministero/).

They are "leaner" tools, simpler to produce and with a more agile method of revision, compared to the guidelines, which, however, allows to provide appropriate and exhaustive indications aimed at standardizing behaviors and preventing errors in medico-legal activities.

From the "INAIL medico-legal recommendations" checklists and process indicators were extracted and used as reference standards for medico-legal audit [16].

Currently, the production of recommendations involves the development of a draft at the INAIL SSC level by an *ad hoc* multidisciplinary Working Group, which usually studies a critical issue reported or highlighted by the territory, institutional governance or other stakeholders. The draft is then shared with the regional and provincial health departments and/or other central agencies (INAIL Central Directorates and/or Consultancies), depending on the topic addressed and the competencies of the Departments, for the necessary bottom-up and/or top-down feedback. The distribution takes place in such a way that the draft is disseminated by the Departments throughout the territory to collect as many comments as possible. The outcome of the consultation is followed by the possible acceptance of the notes received and the drafting of the final version of the INAIL medical-legal recommendation. The recommendations issued by the SSC must be general and focus on virtuous behaviors based on scientific evidence, regulatory and doctrinal sources, and internal reference on the different issues addressed.

However, the recommendations may impact a local reality which, due to various factors (such as work organization, personnel, equipment, etc.), find it difficult to adhere to them. For this reason, similar to what happens for the diagnostic-therapeutic assistance pathways (percorso diagnostico terapeutico assistenziale, PDTA), the medical-legal assistance pathways (percorso medico-legale assistenziale, PMLA) have been introduced. These pathways consider the organizational aspects and aim to provide optimal assistance to individuals with work-related injuries or illnesses, ensuring the safety of performance and overcoming any difficulties in applying INAIL SSC recommendations [17].

It is easy to highlight how this tool appears unsuitable for guiding the behaviour of doctors who approach INAIL legal medicine from outside the Institute, as the INAIL medico-legal recommendations do not adhere to the methodology proposed for guidelines and good practices in the clinical field as published in the documents edited by the ISS.

It is desirable to generate shared documents published on the ISS website, in the SNLG, with the role of guidelines and best practices for evaluating the conduct and performance quality of medico-legal practitioners, pursuant to article 5 of Law n. 24/2017.

It is necessary to develop a dedicated manual outlining the appropriate methods for developing guidelines and best practices in legal medicine, proposing a methodological framework.

METHODS

A PubMed search for methodologies specifically designed for the development of guidelines and best practices in legal medicine yields no results. Nevertheless, various documents labeled as guidelines are currently in use by medico-legal professionals and widely referenced within the scientific community, although they do not follow standardized or structured development methods. For instance, in the textbook by Ferrara *et al.*, 2013 [18] and in the article by Basso *et al.*, 2017 [19] such documents are referred to as "guidelines" yet they are essentially literature reviews lacking the methodological tools required for formal guideline production. Similarly, most national and international publications in areas such as forensic pathology, toxicology, hematology, and legal genetics serve as reference texts, but they are not based on recognized or systematic method of development and evaluation, as required for creating guidelines.

For clinical matters, the effort of the ISS was to create a manual that drives healthcare professionals in drafting guidelines and good clinical-care practices.

The same operation for legal medicine may appear more complex and, in some cases, presents peculiar differences for several reasons:

- the methodology suggested for the guidelines in the clinical field is not applicable *tout court* to legal medicine;
- the international and national legal medicine guidelines seem do not follow a structured methodology, despite being recognized by the scientific community and used in medico-legal practice;
- the guidelines used in legal medicine are often overcome by the criteria indicated by specific regulations (for example, the application criteria of legal tables that outline specific behaviours to follow) or by jurisprudential conclusions.

DISCUSSION

The discipline has difficulty adhering to the indications provided by the manuals for the production of guidelines and good clinical-care practices edited by the ISS. It is, therefore, necessary to establish specific "rules" for legal medicine.

As the guidelines and good clinical-care practices support healthcare professionals in making the best choices to ensure the health and safety of the patient, in the same way the development of guidelines and

good practices for legal medicine, according to the requirements of article 5 of Law n. 24/2017, can support the activities and decisions of the medico-legal practitioners. Adherence to a shared methodology that guides the investigation and decision-making process, ensuring homogeneity and uniformity of medico-legal judgment, represents, in fact, essential elements for the medico-legal service safety.

The medico-legal discipline, in fact, is characterized by the presence of so-called performance risk, essentially related to benefits (of both economic and non-economic nature, even to the limitation on individual freedom), which arise from the legal context of reference in which the medico-legal activity is performed.

The so-called medico-legal risk is a "spurious" risk since, in the medico-legal activity, two different risk components coexist: a clinical one, when the service may cause damage to the health and safety of the patient, and a medico-legal one, related to the safety of the service [11]. While the diagnostic and/or therapeutic health service aims at the safety and health of the patient, the medico-legal service aims at the safety of the service.

The medico-legal service safety represents a new concept of the healthcare management system, which also concerns individuals who are not direct receivers of the service. The collective interest can be threatened by a medico-legal performance error, for example, in the inappropriate release of a driving licence, inadequate assessment of capacity or social dangerousness, or absolute or temporary disability, or ability for a specific job.

Therefore, the analysis and management of medico-legal health risk must consider this broader connotation compared to the one intended for all healthcare professionals performing diagnostic-therapeutic activities and, consequently, the impacts of medico-legal error on the safety of the service.

To ensure the safety of medico-legal services, it is essential to introduce, also for this discipline, tools for risk prevention: recommendations of the guidelines (linee guida in medicina legale, LGML) and good practices (buone pratiche in medicina legale, BPML) for legal medicine.

As mentioned, guidelines may not be necessary in cases where specific regulations have already been issued for the different areas of evaluation with a precise description of the application criteria; instead, they may find space in regulatory gaps or for debated and not yet regulated topics.

The recommendations contained in the LGML and BPML appear necessary to optimize and personalize medico-legal processes. They should be based on solid evidence, pursuing the same principle of multidisciplinarity and sharing between Institutes and scientific societies involved, as well as the guidelines and good clinical-care practices.

A comparison between professionals interested in researching best practices may also allow the identification of virtuous realities as reference models (benchmark) and induce a positive mechanism of competitiveness, which leads to an effective continuous improvement in the quality and safety of medico-legal services.

As far as INAIL Institutional status is concerned, this comparison has already been defined. Therefore, the Institute, which has exclusive competence in the field of social insurance according to the legislation in force, must always be consulted when guidelines are drawn up by scientific societies.

If the error in clinical practice results in damage to the health and safety of the patient, the error in legal medicine entails no less harmful effects, such as the failure to ensure the necessary protection of subjects in need of assistance, adequate compensation and/or compensation for the damage suffered, the failure to condemn subjects responsible for crimes or the conviction of non-responsible subjects, etc.

As in clinical practice, it is necessary to introduce a system of valid guidelines and good practices, according to art. 5 of Law n. 24/2017, to evaluate the behaviours of healthcare professionals working in legal medicine.

Assuming that the recommendations of the guidelines for legal medicine could be those included in the dedicated regulations, it is quite clear that the slowness of the production process found for clinical practice would be even more amplified. Consequently, even for legal medicine, where the regulatory review process is slow and fraught with obstacles, the recommendations of the BPML could be more easily used. These will provide a rapid systematic literature review and allow relatively short drafting times (around 6 months), providing equally valid support, as it is anchored to some key principles. Similar to the recommendations for good practice in clinical care (raccomandazioni per le buone pratiche clinico assistenziali, RBPCA), the recommendations for good medico-legal practice (raccomandazioni per le buone pratiche medico-legali, RBPML) would guide aspects relating to medico-legal practice and the organization of health services.

To be reliable, the RBPML, with almost identical characteristics – net of the inevitable differences between medico-legal practice and clinical care practice – to the RBPCA [20], must:

be based on a rapid systematic review of existing evidence;

- be developed by a competent, multidisciplinary and multi-professional group of experts representing the competent bodies, institutions and main scientific societies involved;
- take into consideration the problems identified based on the prevalence, the urgency, the rate of medical-legal litigation, and the expression of non-homogeneity of behaviour;
- take into consideration the needs of the protected population for access to particular benefits provided by law;
- be based on an explicit and transparent process that minimizes distortions, prejudices and conflicts of interest;
- provide a clear explanation of any alternative methodological options and their implications on the results;
- take into account the preferences and will of the citizen, inviting the medical examiner to base his assessment on the elements available to him at the time of the assessment, in the event of the subject's refusal to undergo treatment and/or diagnostic tests [21];

- be reconsidered and revised when important new evidence justifies the change.

Referring to the methodological guidelines for drafting recommendations for good clinical care practices published by the ISS, "minimum" methodological requirements can also be referred to for legal medicine.

However, for legal medicine, minimum requirements n. 3 and n. 7 do not appear applicable. As for requirement n. 3, the evaluation of the "certainty of evidence" reported in the methodological indications of the RBPCA in the forensic and medico-legal fields takes on a different meaning and should be reserved for those areas in which the evidence must overcome even reasonable doubt and be endowed with high logical probability [22]. Requirement n. 7 does not concern the strength of the recommendation but the evidence to which the recommendation refers; such evidence is part of the selection process, based on the authoritativeness and concordance of the sources.

The minimum methodological requirements are shown in the following *Table 1*.

As with RBPCA, the production method can be based on the four elements summarized by the acronym PICO:

- P, problem/population: indicates the subject or population of reference for the question (e.g., the problem of "telemedicine applied to legal medicine" [23], or citizens with civilian invalidity or work-related disability, etc.);
- I, interventions: indicates the main intervention taken into consideration;
- C, comparison/control: indicates the main alternative with which the intervention (I) is compared, capable of relating to the outcome (O);
- O, outcome: this is what is hoped to be achieved, the result or purpose of the recommendation.

Regarding topic selection, unlike RBPCA, it is not necessary to identify an additional expert panel, as the group addressing the topic already comprises qualified professionals. Integration of further experts may be considered only if the proposal originates from entities other than the designated Working Group. The Working Group should be structured around a multidisciplinary and inter-institutional core, with the possibility of including field-specific experts as needed.

To gather expert consensus within the Working Group, the RAND/UCLA appropriateness method can be employed. Although traditionally positioned at the final tier of the evidence pyramid as a tool for eliciting expert opinion, this methodology proves particularly valuable in the field of legal medicine, especially in areas where no clear guidance exists through legislation, jurisprudence, or well-established literature [24]. It should be highlighted that medico-legal expertise today is increasingly hyper-specialized in a scientific world in constant evolution.

The Working Group should consist of an odd number of members to ensure that any proposals can be voted on with a clear majority, allowing for the prioritization of actions. From a risk management perspective, if multiple proposals are presented simultaneously, intervention priorities may be established using the priority index (e.g., frequency × severity, or frequency × severity × detectability). These proposals may originate from stakeholders or specific population groups (e.g., individuals with disabilities, injured workers, privately insured parties, victims of duty), who may address the Working Group directly.

The same majority-based decision-making approach may be applied to the formal approval of the recommendation. A methodology that has proven effective within INAIL involves broad consultation with regional branches during the development of centrally drafted recommendations. This collaborative process may also be adopted for RBPML, enabling Working Group members to submit the draft to a selected group of institutional, academic, or scientific society collaborators for feedback and contributions.

The final draft, according to what happens for the RBPCA, can be submitted "to external review by two independent referees, selected by the Working Group,

Table 1
Minimum methodological requirements

1. Identification of regulatory, legal and bibliographic sources related to the topic, describing the process of selecting evidence, also concerning keywords and any filters used. This will also be useful to make the search "repeatable". Evaluation of the authoritativeness and concordance of the available evidence. Certainty (or high logical probability) is necessary if the scope of the recommendations for good medico-legal practice (RBPML) is a criminal process, the greatest probability, instead, if the scope is a civil process, social security, etc. It has to be evaluated the majority of literature, but also only the most authoritative part, the strongest evidence, and the one with the greatest value. Even if the sources are numerically lower than the total evidence available, they are relevant for medico-legal purposes if they are among the most authoritative and concordant. As for clinical scientific evidence, the reference selection must consider the quality of the evidence and the strength and weight of the recommendations [23].
2. The authority and concordance of the references must be evaluated in each phase of the medico-legal process since it is considered important or critical to issue the final judgment.
4. The minimum requirement for the presentation of the summary of evidence is a clear description of the sources and the method used to identify them and assess their degree of authoritativeness and consistency. Synoptic tables can be used to report the domains indicated (e.g., legislation, jurisprudence, scientific literature, and related authoritativeness and concordance).
5. Explicit criteria should provide the basis for making recommendations or decisions. Explicit judgments should be made for each criterion chosen, including those that might be added, and evidence used to support those judgments should be provided. Additional considerations affecting the recommendation or decision should also be documented and accessible.
6. Those who develop RBPML should describe the expected outcomes and, where possible, monitor them through medico-legal audits.

based on requirements of authoritativeness and competence in the area covered. The referees will express observations and comments on the document contents, with particular reference to the consistency between evidence and recommendations and the formulation and applicability of the latter. The report from the external review will be examined by the Working Group, before finalising the document" [20].

Similar to the structure required for RBPCA, the RBPML must include:

1. a detailed description of the Working Group, specifying the roles of involved bodies, institutions, and scientific societies;
2. explicit description of the process and method used to draft the document, reviewing and documenting all stages: topic selection, evidence search strategy, and consensus process for each recommendation;
3. summary of evidence and recommendations;
4. summary of the external audit findings;
5. conflict of interest declaration forms, filled and signed by all RBPML development participants;
6. declaration of commitment not to publish or disclose the RBPML, in whole or in part, before completion of the assessment process.

In March 2025, a document titled "Procedures for the submission and evaluation of recommendations for good clinical care practices" was published. Annex 3 of the document outlines the criteria used to assess the methodological quality of these recommendations. Specifically, recommendations must address the following items:

1. the composition of the development group;
2. the methodology used in the development of the recommendation;
3. the management of conflicts of interest.

However, the development methodology cited refers to the application of the GRADE approach, which was originally designed for clinical care contexts. For the reasons outlined above, this method cannot be applied to medico-legal best practices, which differ in both content and purpose, and are governed by regulatory, contractual, or statutory provisions rather than clinical objectives.

Recently, the SNLG website published a good practice applied to legal medicine [25]. This represents a significant milestone and may serve as a valuable starting point for fostering collaboration among the various institutions involved in the field. It could help identify a shared methodology for the development of good practices, ultimately leading to the much-needed publication of a dedicated manual outlining the appropriate procedures for their formulation.

CONCLUSIONS

The methods tested in the development of recommendations by the Central Health Department of INAIL, responsible for the governance of institutional health activities, have proven effective in guiding medico-legal practices within the institution. However, these documents lack the formal status and recognition afforded to guidelines and good practices validated by the ISS for clinical-care contexts.

Despite the inapplicability of tools designed for clinical medicine, we assert that legal medicine must also be grounded in evidence-based principles. Building upon the methodological framework outlined in the "ISS methodological manual for the production of clinical practice guidelines", we propose a method for the production of recommendations in the form of guidelines (LGML) or best practices (RBPML) dedicated to legal medicine.

The subject's specificities demand resolving problems (P of PICO) that have not been fully or only partially resolved through regulatory intervention, from sources within National institutes focusing on legal medicine, or from relevant literature. Then, there are phases of the medical-legal processes that require a univocal reading and framing to homogenize the behaviours and guarantee quality, uniformity and safety of the medico-legal service outcomes.

Therefore, the establishment of a dedicated Working Group in collaboration with the ISS is essential to develop a structured methodology for producing recommendations in legal medicine. These recommendations should serve as a reference standard for practitioners, with exceptions allowed only in well-justified cases. In this evolving landscape, the experience gained through the drafting and dissemination of recommendations by INAIL's Central Health Department can serve as a valuable foundation.

Conflict of interest statement

The Authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Received on 14 March 2025.
Accepted on 26 May 2025.

REFERENCES

1. Italia. Legge 8 Marzo 2017 n. 24. Disposizioni in materia di sicurezza delle cure e della persona assistita, nonché in materia di responsabilità professionale degli esercenti le professioni sanitarie. Gazzetta Ufficiale – Serie Generale n. 64, 17 marzo 2017. Available from: https://www.gazzettaufficiale.it/eli/id/2017/03/17/17G00041/s.
2. Mele A, Gallo M. L'art. 5 della Legge 8 Marzo 2017, n. 24: le linee guida in medicina legale. Riv Infort Mal Prof. 2016;3:491.
3. Del Sordo S, Genovese U. Articolo 5. Buone pratiche clinico-assistenziali e raccomandazioni previste dalle Linee Guida. Genovese U, Martini F (Eds). La nuova

responsabilità professionale in Sanità. Santarcangelo di Romagna (RN): Maggioli; 2017. p. 41.
4. Frati P, La Russa R, Campolongo AA, Viola RV, Romano S, Volonnino G, Fineschi V. Le innovazioni procedurali della novella Gelli e le reali prospettive di arginare il fenomeno del contenzioso sanitario. Responsabilità Civile e Previdenza. 2019;3:1056-1072.
5. Mele A, Rossi P. L'audit, la root cause analysis e il safety walk round in medicina legale. In: Atti del Convegno nazionale di medicina e sanità INAIL salute, benessere e sicurezza del lavoratore al centro della sanità. Roma: 26-29 giugno 2023. p. 975.
6. Rossi P, Mele A. Il ruolo medico-legale e l'approccio evidence based in ambito assicurativo sociale. Riv Infort Mal Prof. 2023;1:2.
7. Caputo M, Centonze F. La risposta penale alla malpractice: il dedalo di interpretazioni disegnato dalla riforma Gelli-Bianco. Riv Ital Med Leg Dirit Campo Sanit. 2017;4:1361.
8. Buccelli C, Abignente, I, Niola M, Paternoster M, Graziano V, Di Lorenzo P. La rilevanza delle linee guida nella determinazione della responsabilità medica. Le novità introdotte dalla cd. Legge Balduzzi, le problematiche connesse, i tentativi di risoluzione. Riv Ital Med Leg. 2016;2:663.
9. Conti A. Il significato delle linee guida prima delle recenti norme. Riv Ital Med Leg Dirit Campo Sanit. 2019;2:635.
10. Ricciardi GW, Iannone P, Trojano V, Cirese V, Mariotti, P, Caminiti R. Linee guida e buone pratiche clinico-assistenziali. In: Gelli F, Hazan M, Zorzit D (Eds). La nuova responsabilità sanitaria e la sua assicurazione. Milano: Giuffrè; 2017. p. 151.
11. Rossi P, Comacchio A, Mele A. La gestione del rischio sanitario medico-legale. Dalla clinical governance ai processi medico legali. Milano: Giuffrè; 2014.
12. Comacchio A, Goggiamani A, Mele A, Rossi P. Dagli esiti alla prevenzione: indicatori di processo versus indicatori di esito in medicina legale. Riv Ital Med Leg. 2015;4:1675.
13. Agree Next Step Consortium. AGREE II. Checklist per valutare la qualità delle linee guida. Bologna: Fondazione Gimbe; 2019. Available from: https://www.gimbe.org/pubblicazioni/traduzioni/AGREE_IT.pdf.
14. Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure. Manuale metodologico per la produzione di Linee Guida di Pratica Clinica. Versione 1.3.1. Roma: Istituto Superiore di Sanità; 2019.
15. Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure. Manuale metodologico per la produzione di Linee Guida di Pratica Clinica. Versione 1.3.3. Roma: Istituto Superiore di Sanità; 2023.
16. Mele A, Rossi, P, Gallo M. La legge n. 24/2017: linee guida, buone prassi e audit come strumenti di miglioramento della qualità in medicina legale assicurativa previdenziale. In: XII Convegno nazionale di medicina legale previdenziale "Nuove frontiere della medicina legale previdenziale". Bologna, 28-30 novembre 2018.
17. Rossi P, Mele A. Dalle raccomandazioni medico-legali ai percorsi medico-legali assistenziali (PMLA) in ambito INAIL. Riv Infort Mal Prof. 2023;3:227.
18. Ferrara SD, Baccino E, Bajanowski T, Boscolo-berto R. Malpractice and medical liability. European guidelines on methods of ascertainment and criteria of evaluation. Int J Legal Med. 2013;545-57.
19. Basso C, Aguilera B, Banner J, Cohle S, Amati G. Guidelines for autopsy investigation of sudden cardiac death: 2017 update from the association for European cardiovascular pathology. Virchows Arch. 2017;691-705.
20. Istituto Superiore di Sanità. Indicazioni metodologiche per la stesura di raccomandazioni per le buone pratiche clinico assistenziali. Versione 1.0. Roma: ISS; 2024.
21. Mele A, Lauro A. L'importanza della cartella clinica nell'accertamento medico legale. La cartella clinica elettronica nel contesto della sanità italiana: potenzialità, prospettive e sinergie. Napoli: Direzione Regionale Campania-INAIL; 2019.
22. Istituto Nazionale Assicurazione contro gli Infortuni sul Lavoro – Sovrintendenza sanitaria centrale. Raccomandazione SSC n. 4/2023. Approccio evidence based per la tutela delle patologie da lavoro; Roma: INAIL; 2023.
23. Rossi P, Bramante L, Broccoli L, Mele A, Vantaggiato DR, Iera S. La telemedicina nella medicina legale in ambito assicurativo sociale. Riv Infort Mal Prof. 2022;3:311.
24. Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR, Lazaro P, van het Loo M, McDonnell J, Vader J, Kahan JP. Rand/Ucla appropriateness method user's manual. Santa Monica (CA): RAND Corporation; 2000.
25. Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure. Buone pratiche cliniche di valutazione medico legale delle menomazioni alla integrità psicofisica comprese tra 10 e 100 punti di invalidità permanente. Roma: Istituto Superiore di Sanità; 2025.