Chapter 14
Requirements and Final Recommendations

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Abstract This chapter sets out in summarised form the requirements and the final recommendations regarding the assessment and evaluation of medical professional liability in Europe as defined by the "Consensus Conference", held in Rome on the 14th and 15th of June 2011, under the patronage of the *European Academy of Legal Medicine* (*EALM*), which was attended by renowned forensic experts and lawyers from various European countries. The recommendations, which are listed in numerical order, pertain to the cultural background and minimum level of expertise and competence that the medico-legal Expert and his/her co-advisors must possess, and the logical and procedural steps indispensable for the establishment and evaluation of potential medical errors and/or the inobservance of important rules of conduct.

Contents

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14.1 Recommendation 1: Essential Expertise and Competence of the Medico-Legal Expert

The expert who deals with cases of Medical Responsibility and/or Liability should be a Specialist in Legal Medicine and/or Forensic Pathology, or have fully completed postgraduate training in legal medicine, preferably at the university level being accredited as a medico-legal expert by the supervising authority in his or her country and habitually practicing that speciality.

The expert will have to demonstrate adequate training in the following areas:

1. criminal, civil and administrative law, with particular reference to those regulations in the field of medical health;
2. theoretical and practical knowledge of medico-legal semeiotics and of the medico-legal evaluation of psychophysical validity in the areas of civil law and private/public insurance;
3. theoretical and practical notions of forensic pathology with a thorough first-hand and in-depth experience of many years as well as considerable expertise in forensic autopsies;
4. theoretical notions on the subject of the causal value/link, with particular reference to the demonstration of the causal link between a medical error and the damage.

14.2 Recommendation 2: Essential Expertise and Competence of the Consultant

The expert clinician or surgeon who assists the medical-legal consultant in cases of Medical Responsibility and/or Liability must possess the title of Specialist in their particular field of study, obtained at the university level.

He/She is required to demonstrate particular theoretical and practical competence in the specialist sub-discipline which is the object of the case under examination.

Due to the difficulty in obtaining specialist figures with proven experience and documented preparation, and given the heterogeneity of regulations and procedures governing the selection of experts in the different European countries, it is recommended that the medico-legal expert suggests to the Judicial Authority a list of potential Advisors to be appointed.

14.3 Recommendation 3: Collection and Examination of Clinical Data

It is recommended that the medico-legal expert and his/her possible co-advisor collect and examine all the medical-healthcare documentation available in order to identify the pathological features and damages, and reconstruct the medical conduct.

The documents of prime importance to be collected and examined, which are described in detail in the Consensus Guideline (i.e. authorisation for admission; anamnesis and physical examination; patient's journal; medical orders sheet; consent documents; emergency room assistance sheet or emergency room report; inter-consultation sheet; reports of complementary examinations; pre-surgery examination sheet; anaesthesia report; operating room report; post-surgery evolution sheet; pathological anatomy report; nursing journal; graph of vital signs; clinical discharge report).

In addition to examining the printed documentation above mentioned, it is recommended in some specific cases that the medico-legal expert and his co-advisor obtain permission from the judge to collect witness statements from physicians regarding the facts under examination.

14.4 Recommendation 4: Clinical Examination of the Living

It is recommended that the clinical examination involves careful collection of anamnestic data and an objective clinical examination including internal medicine, neurological and clinic objective tests aiming at specific problems and utilising proper medico-legal semeiotics in order to identify any simulation or dissimulation actions.

The following data should always be collected:

- clinical condition of the patient at the time of the examination;
- correspondence of the clinical state with the examined documentation;
- relationship between the current state of health, the claimed facts and the medical actions;
- the nature, location and importance of the sequelae along with their anatomical and functional limitations.

14.5 Recommendation 5: Instrumental Diagnostic Exams in the Living

If after examining the medical documentation and collecting the clinical objective signs, the available anatomo-functional data are not sufficient for constructing the diagnostic picture, it is recommended to execute further non-invasive or invasive medical procedures.

If the need for unavoidable invasive tests arises, the medico-legal expert must carefully evaluate the cost/benefit ratio, in view of the diagnostic result and, in any case, receive patients' consent, after properly informing them on the risks connected with that procedure.

14.6 Recommendation 6: Ascertainment on Cadavers

It is recommended that prior to autopsy the possibility of carrying out different typologies of radiological investigations (X-ray, Computed Tomography, Nuclear Magnetic Resonance) is evaluated. According to the case, it may be advantageous to take swabs for microbiological or genetic studies, prior to forensic autopsy.

Forensic autopsy must be performed according to the "Recommendation no. R (99) 3 of the Committee of Ministers to Member States on the Harmonisation of Medico-Legal Autopsy Rules".

According to preliminary results, further post-autopsy examinations may be deemed necessary, to clarify, confirm or extend the initial analytical data.

Therefore, critical reflection of histopathological, toxicological, microbiological and biomolecular analyses may be extended in the most complex cases to the period after internal examination. It is precisely the role of the medico-legal expert to make a critical integration of results arriving from several laboratories. According to this critical integration, the expert can identify and then request further, more in-depth analyses.

14.7 Recommendation 7: Identification of Pathological Features

The first step in the evaluation phase must be the identification of the *pathological features,* subdivided into *initial, intermediate* and *final* clinical pictures, resulting in restoration to health, death, chronic pathological state or permanent injury.

In this reconstruction, it is recommended that the physiopathological pathways revealing the chain of events are properly identified and clearly described.

14.8 Recommendation 8: Reconstruction of the Ideal Medical Conduct

It is recommended that the identified pathological features are examined by analysing scientific sources, such as Guidelines, Consensus Documents, Operational Procedures, Evidence-Based Publications and other Literature data, composed of treatises and articles published in peer-reviewed Journals, preferably with Impact Factor.

It is essential to consult *only* scientific *sources*, which predate or are *contemporary with the facts*, accredited by the referenced scientific associations or institutions of the competent disciplines.

These scientific sources of non-equivalent importance must also be graduated according to the source hierarchy shown below.

1. Guidelines.
2. Consensus Documents.
3. Operational Procedures.
4. Evidence-Based Publications.
5. National Literature (Treatises, etc.).

The examination aims at identifying and reconstructing the physiopathological course composing the actual chain of events which took place and reconstructing the ideal conduct which a physician should have followed during diagnosis, prognosis and treatment.

14.9 Recommendation 9: Reconstruction of the Medical Conduct

It is recommended that after examining the sources and ideal medical conduct, the medico-legal expert establishes whether there are sufficient data to proceed to the reconstruction and ascertainment of the conduct of medical and healthcare personnel. If this is not possible (i.e., salient data missing, incomplete documentation, lack of physiopathological links of pathological features, etc.), further ascertainment of possible Medical Responsibility and/or Liability ceases.

On the contrary, if sufficient data are present, the medico-legal expert must compare the ideal conduct desumed from the reference scientific sources with the real conduct establishing the existence/validity of the patient's consent, the adequacy of the diagnostic tests, the correctness of the prognosis and the adequacy of the treatment and care.

14.10 Recommendation 10: Identification and Classification of Error/Non-Observance

The process of analysis and comparative evaluation between ideal conduct and true conduct leads to the identification of possible errors and/or non-observances of required rules of conduct (see for details Sect. 13.5.7) which have to be qualified and classified according to the phase (i.e. patient's consent; diagnosis, prognosis, treatment).

14.11 Recommendation 11: Evaluation of the Error/Non-Observance

Once an error or non-observance has been identified, it is recommended that the medico-legal expert establishes whether the reasons for any such error and/or non-observance are TRUE, or whether there is a CAUSE FOR JUSTIFICATION.

This evaluation phase requires the medico-legal expert to enter a state of *EX-ANTE EVALUATION/JUDGMENT* (i.e., to imagine being in the same space–time circumstances in which the facts under examination took place, bearing in mind the characteristics of the medical and/or healthcare personnel involved, such as training, age, qualifications and professional experience) and the technical and instrumental equipment at their disposal. This evaluation is of prime importance in cases of surgical operations of *particular technical difficulty.* Ex-ante evaluation must consider all the *diagnostic, prognostic and therapeutic hypotheses which could be formulated* a priori with respect to knowledge of the *true pathological state/condition, desumed ex-post* from the data collected after the event in question, since only such an evaluation can reflect the aspects of evaluation and decision-making existing in the space–time conditions in which the medical and healthcare personnel were working, and their conduct as examined in those conditions. The medico-legal expert must supply technical reasons for cases of justifiable error, since a final decision will be made by the judge of the court.

14.12 Recommendation 12: Evaluation of the Causal Value of the Error

The causal value of error and the relationship of an actual causal link between error/non-observance and damage must be evaluated according to: (a) *Universal Laws*, by means of deduction; (b) *Statistical Laws*, by means of inference; or, in the absence of such laws, according to (c) a *Criterion of Rational Credibility*, i.e. referring only to the average experience and expertise of the medical category or class in question.

It is recommended that the causal value and causal link between error and injury is made by also applying counterfactual reasoning and possible additional criteria (topographic criterion, chronological criterion, criterion of continuity of event, exclusion of other causes).

Finally, it is recommended to estimate, when possible, the degree of probability in percentage.

14.13 Recommendation 13: Damage Estimation

At the end of medico-legal evaluation, whether within the juridical ambit or outside it, the medico-legal expert must quantify the temporary or permanent biological damage causally correlated with error/non-observance.

As regards *temporary incapacity,* the following should be quantified:

- the duration of the period of temporary total or partial incapacity;
- economic damage due to lack of earnings;
- emerging damage, i.e. due to expenses for medical treatment.

As regards *permanent incapacity,* the following must be quantified:

- basic permanent incapacity, i.e. reduction of the patient's psycho-physical validity (including aspects of social and sexual life and general working capacity);
- economic damage (current or future lack of earnings);
- existential damage, where explicitly requested and, in any case, limited to medico-legal findings.