Chapter 13
Medico-Legal Methods of Ascertainment and Criteria of Evaluation in Medical Responsibility and Liability

S. Davide Ferrara, Eric Baccino, Thomas Bajanowski, Rafael Boscolo-Berto, Maria Castellano Arroyo, Ricardo De Angel Yágüez, Alvydas Pauliukevičius, Pietrantonio Ricci, Peter Vanezis, Duarte Nuno Vieira, Guido Viel and Enrique Villanueva

The EALM Working-Group on Medical Malpractics

Abstract This chapter presents the European Guidelines on Medico-Legal Methods of Ascertainment and Criteria of Evaluation in cases of suspected subjective "Medical Responsibility and/or Liability" developed under the patronage

European Guidelines
Under the Patronage of the *European Academy of Legal Medicine*.

S. D. Ferrara (✉) · R. Boscolo-Berto · G. Viel
Department of Molecular Medicine, Institute of Legal Medicine,
University Hospital of Padova, Via Falloppio 50, 35121 Padova, Italy
e-mail: santodavide.ferrara@unipd.it

R. Boscolo-Berto
e-mail: rafael.boscoloberto@unipd.it

G. Viel
e-mail: guido.viel@unipd.it

E. Baccino
Service de Médecine Légale Hôpital Lapeyronie, University of Montpellier, 191 Avenue du Doyen Gaston Giraud 34295 Montpellier Cedex, France
e-mail: e-baccino@chu-montpellier.fr

T. Bajanowski
Institute of Legal Medicine, University of Duisburg-Essen Hufelandstr, 55 D-45122 Essen, Germany
e-mail: thomas.bajanowski@uk-essen.de

M. Castellano Arroyo · E. Villanueva
Department of Legal Medicine, Toxicology and Physical Anthropology,
University of Granada, Avda Madrid 11 ES-18071 Granada, Spain
e-mail: mcarroyo@ugr.es

E. Villanueva
e-mail: guadalfeo40@telefonica.net

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of the European Academy of Legal Medicine (EALM). It includes a step-by-step illustrated explanation of approved Flow Charts, articulated on 18 sequential steps, comprehensive of both Methods of Ascertainment and Evaluation Criteria. This document is adopted as European Guideline on the issue by the EALM.

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R. De Angel Yágüez
Department of Private Law, University of Deusto, Heros, 28 48007 Bilbao, Spain
e-mail: rdeangel@arrakis.es

A. Pauliukevičius
Department of Biolaw, Mykolas Romeris University, Ateities 20 LT-080303 Vilnius, Lithuania
e-mail: biok@mruni.eu

P. Vanezis
Department of Clinical Pharmacology, Cameron Forensic Medical Sciences, William Harvey Research Institute, Barts and the London, Queen Mary University of London, Charterhouse Square, London EC1M 6BQ, UK
e-mail: p.vanezis@qmul.ac.uk

D. N. Vieira
National Institute of Legal Medicine, University of Coimbra, da Sé Nova 3000-213 Coimbra, Portugal
e-mail: dnvieira@inml.mj.pt

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Medical responsibility and liability lawsuits have become a fact of life in every physician's modern practice, complicated by factors beyond the traditional realm of patient care, including novel technologies which involve economic pressures, loss of physician autonomy, and increasingly defensive medicine (Ferrara and Pfeiffer 2010; Brinkmann et al. 1994).

From the latter half of the 20th Century *Medicine* became a victim of its own success, and the populace, made aware of the huge advances in medical technology via media interest and wide publicity, is now led to expect the latest techniques and the best outcome with regard to eventual health problems. The surge of technology and the hyper-specialization in every field of medicine imply that each malpractice claim gives rise to a scientific challenge, requiring specific expertise in the analysis and evaluation of the clinical case in question.

The role of Legal Medicine has become increasingly specific, essential and ineluctable in the judicial setting, in order to prevent and avoid erroneous interpretations and hasty scientific verdicts. The multiplicity of regulatory frameworks and operative systems (Madea and Saukko 2008; Eurobarometer Series 2006), the literature on medical malpractice (Ferrara et al. 2011; Viel et al. 2011; Boscolo-Berto et al. 2012), as well as a recent exploratory supranational survey (Ferrara et al. 2010), prove the absence of international medico-legal guidelines and/or recommendations governing the ascertainment and evaluation process in cases of suspected medical liability.

This document, the result of a scientific initiative by the President-Representative of the *European Academy of Legal Medicine* (EALM), proposes *European Guidelines* on *Medico-Legal Methods of Ascertainment and Evaluation Criteria* in cases of suspected subjective "*Medical Responsibility and/or Liability*".

Before preparing the above-mentioned document a Board of Experts analysed the rules, regulations and operational procedures as currently used in Austria, Belgium, Bulgaria, Estonia, France, Germany, Great Britain, Italy, Latvia, Lithuania, Luxembourg, Portugal, Russia, Slovak Republic, Spain and Switzerland.

This examination and the consequent comparative evaluation involved a Questionnaire, prepared by the Coordinator of the EALM Working Group and

compiled by a Board of Experts, as well as sources of European regulations on the topic of Medical Malpractice.

The Jurists and medico-legal Experts who took part in this preliminary analysis, and/or prepared, revised and expressed a *Consensus* on the *European Guidelines* are listed below.

- Prof. ***S. Davide Ferrara***, Full Professor of Legal Medicine, University of Padova, President-Representative of the European Academy of Legal Medicine (EALM), *Scientific Coordinator of the EALM Working Group* (Italy).
- Prof. ***Eric Baccino***, Full Professor of Legal Medicine and Clinical Toxicology, University of Montpellier (France).
- Prof. ***Thomas Bajanowski***, Full Professor of Legal Medicine, University of Duisburg-Essen, Editor-in-Chief of the "International Journal of Legal Medicine" (Germany).
- Prof. ***Jean-Pol Beauthier***, Full Professor of Legal Medicine, University of Bruxelles (Belgium).
- Dr. ***Marc Bollmann***, Researcher in Legal Medicine, University of Lausanne, Centre Universitaire Romand de Médicine Légale (Switzerland).
- Dr. ***Rafael Boscolo-Berto***, Researcher in Legal Medicine, University of Padova (Italy).
- Dr. ***Marija Caplinskienė***, Full Professor of Legal Medicine, Mykolas Romeris University, Vilnius (Lithuania).
- Prof. ***Maria Castellano Arroyo***, Full Professor of Legal Medicine, University of Granada (Spain).
- Prof. ***Ricardo De Angel Yágüez***, Professor Emeritus of Civil Law, University of Deusto (Spain).
- Prof. ***William Victorov Dokov***, Full Professor of Legal Medicine, Bulgarian Institute of Forensic Medicine (Bulgaria).
- Dr. ***Tony Fracasso***, Director Unité de médecine forensique, Centre Universitaire Romand de Médicine Légale, University of Geneva (Switzerland).
- Prof. ***Paola Frati***, Full Professor of Legal Medicine, "Sapienza" University of Rome (Italy).
- Prof. ***Alvydas Pauliukevičius***, Full professor of Legal Medicine, Faculty of Law, Mykolas Romeris University, Vilnius (Lithuania).
- Prof. ***Walter Rabl***, Full Professor of Legal Medicine, University of Innsbruck (Austria).
- Prof. ***Vera Lúcia Raposo***, Lecturer at Coimbra Faculty of Law, University of Coimbra (Portugal).
- Dr. ***Romas Raudys***, Professor of Legal Medicine, Mykolas Romeris University, Vilnius (Lithuania).
- Prof. ***Pietrantonio Ricci***, Full Professor of Legal Medicine, University Magna Graecia of Catanzaro (Italy).
- Prof. ***Ojars Teteris***, Professor of Legal Medicine, Riga Stradin University (Latvia).

- Prof. ***Grigorijs Vabel***, Professor of Legal Medicine, Riga Stradin University (Latvia).
- Prof. ***Marika Väli***, Professor of Legal Medicine, University of Tartu (Estonia).
- Prof. ***Peter Vanezis***, Full Professor of Forensic Medical Sciences, Queen Mary University of London (United Kingdom).
- Prof. ***Duarte Nuno Vieira***, Full Professor of Legal Medicine, University of Coimbra. President of the International Academy of Legal Medicine (IALM), and European Council of Legal Medicine (ECLM) (Portugal).
- Dr. ***Guido Viel***, Researcher in Legal Medicine, University of Padova (Italy).
- Prof. ***Enrique Villanueva***, Professor Emeritus of Legal Medicine, University of Granada (Spain).

13.1 Itemisation of Guidelines

The guidelines were subdivided into the following *items*.

1. Expert definition and essential knowledge
2. Methods of ascertainment on living persons
    a. Collection and examination of clinical and documentary data
    b. Consultation with specialist
    c. Clinical examination
    d. Further instrumental diagnostic exams
    e. Clinical synthesis
3. Methods of ascertainment on cadavers
    a. Collection and examination of clinical and documentary data
    b. Consultation with specialist
    c. Pre-autopsy examinations
    d. Autopsy
    e. Choice and execution of further diagnostic procedures
4. Evaluation criteria
    a. Comparative evaluation of data
    b. Identification of pathological features
    c. Damage identification
    d. Reconstruction of physiopathological pathways and ideal medical conduct
    e. Reconstruction of the real medical conduct
    f. Reconstruction and verification of real conduct of medical and healthcare personnel
    g. Identification of error/non-observance
    h. Classification of error/non-observance
    i. Error evaluation—ex-ante. Possible causes of justification

j. Causal value and causal link between error and damage/event
k. Universal law, statistical law or criterion of rational credibility
l. Identification of the degree of probability of causal value and causal link
m. Damage estimation.

The Medico-Legal Methods of Ascertainment and Criteria of Evaluation regarding "Medical Responsibility and/or Liability" are adopted as *European Guidelines by the European Academy of Legal Medicine*.

13.2 Expert Definition and Essential Expertise

The present consensus document specifies that, in order to be appointed as an Expert and/or Consultant in a judicial or extra-judicial setting in cases of ascertainment of Medical Responsibility and/or Liability, the physician must be in possession of the minimum requirements, competences and expertise, as indicated below.

1. It is recommended that the appointed Expert is a Specialist in Legal Medicine and/or Forensic Pathology, or that the Expert has fully completed postgraduate training in legal medicine, preferably at university level and is recognised as a medicolegal expert by the supervising authority in his or her country and habitually practices that speciality.
2. The Expert should demonstrate adequate training (preferably at university level) in the following areas.

   a. Basic competence in criminal, civil and administrative law, with particular reference to those regulations in the field of medical health.
   b. Theoretical and practical experience of medico-legal semeiotics and of the medico-legal evaluation of psychophysical validity in the areas of civil law and private/public insurance.
   c. In the case of ascertainment on cadavers, 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.
   d. Theoretical notions and practical experience 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, subsuming the phenomena under scientific laws.

13.3 Methods of Ascertainment on Living Persons

Cases of medical liability lawsuits are quite varied and occur in all specialities, although with different frequencies and degrees of seriousness.

In order to present a lawsuit, it is necessary to have suffered some kind of injury or loss. In the case of a living person, that person is the one who sustains the injury. In normal conditions, that person files the claim, but when the person in question is a minor or one whose mental capacities are affected, family members will represent that person in the lawsuit.

Although the regulations in various European countries are extremely heterogeneous—as, indeed, are the operational procedures in the same countries—medico-legal experts are involved in the majority of cases of presumed Medical Responsibility and/or Liability on living persons.

Apart from the juridical framework (penal, civil) or extra-juridical in which the medico-legal professional works, and apart from the fact that person acts as a consultant for the judge, insurance company, injured party or other institution or figure, the method of ascertainment to be followed is the same, including analysis of clinical and documentary data and execution of clinical and medico-legal examination, described in the following sections and in the Flow Chart 1.

13.3.1 Step 1: Collection and Examination of Clinical and Documentary Data

The first operation which the medico-legal expert must carry out is collection of clinical and documentary data, retrieving all medical and healthcare information believed to be useful for a diagnostic framework, for later identification of the pathological features and damages, and examination of the conduct of medical and healthcare personnel (Fig. 13.1—Flow Chart 1).

In many countries, in the civil framework, it is not always possible (even with a judge's authorisation) to integrate medical and healthcare documentation presented by the parties (plaintiffs and defendants), and the medico-legal expert is obliged to limit examination to written documentation.

The documents of prime importance to be collected and examined are as follows.

- *Authorisation for Admission*. This consent from the patient is essential, and must have been signed by the patient's legal representative if the patient was not physically or psychologically able to do so.
- *Anamnesis and Physical Examination*. As this is essential for top-quality medical care and represents a prior step for diagnostic and therapeutic accuracy, its omission or insufficient completion indicates inadequate medical conduct.
- *Patient's Journal*. This document is generated for hospitalised patients. It records daily changes in the patient's condition, response to treatment, recommended tests and their results, and clinical evaluation of the patient's state until discharged.
- *Medical Orders Sheet*. The decisions made by doctors attending the patient, according to how the case develops, are noted on this sheet. Every decision

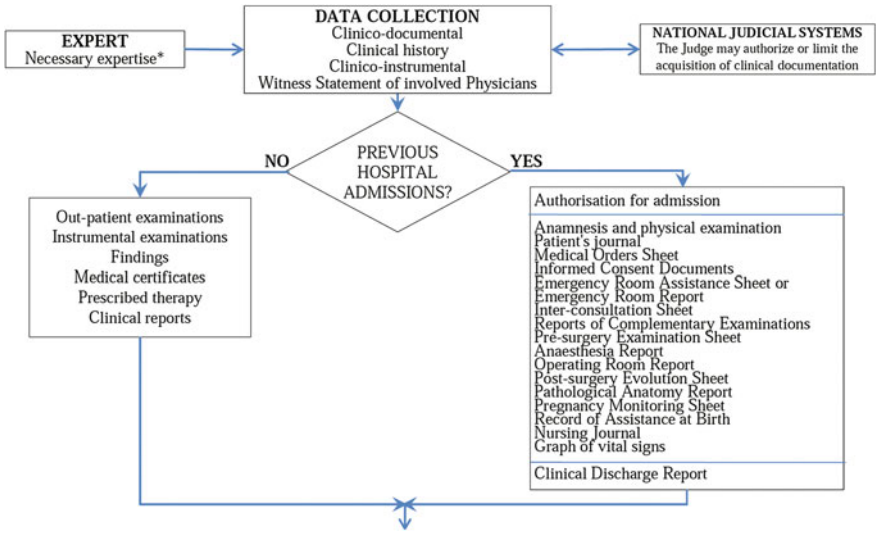


Fig. 13.1 Step 1

(medical order), request for tests, prescriptions, etc., must be recorded, and the professional who orders them must be identified.

- *Informed Consent Documents*. These documents are generally compulsory by law. Retrieving them is extremely important for subsequently assessing whether the patient was properly informed and whether the informed consent form was filled out. The aim of this document is for the patient to have all necessary and sufficient information in order to be able freely to choose or reject a treatment or a diagnostic test.
- *Emergency Room Assistance Sheet* or *Emergency Room Report*. This document is compiled when the patient has requested care in the Emergency Room: it includes the reason for consultations, the results of any examinations and tests requested, clinical opinion and diagnosis; as a result, the following decisions are made: to request inter-consultation or collaboration with a specialist (according to pathology), to start treatment and to send the patient home, or to indicate admission to the hospital. If the death of a patient occurs at home (generally in the case of acute pathologies such as myocardial infarction, cerebral haemorrhages, others), this Emergency Room Report is fundamental in checking whether it indicates the proper diagnostic tests, whether the results were interpreted correctly, and whether the medical decision was in keeping with the appropriate guidelines of good practice or protocols, where they exist.
- *Inter-Consultation Sheet*. This sheet records all actions by other specialists who may examine the patient at the request of the doctor responsible for that patient. It is compiled when the patient's state, other than that for which that patient was admitted to hospital, is documented by a specialist from another discipline. The

Inter-consultation Sheet is important because when medical-legal evaluation of the case is performed, all professional actions and their quality, degree of diligence, opportunity and effectiveness are all taken into account.

- *Reports of Complementary Examinations*. These refer to diagnostic tests, the results of which are interpreted and reported by the specialists who made them, e.g. imaging, neurophysiological, psychological tests, etc.
- *Pre-Surgery Examination Sheet*. This document is compiled when surgical intervention is necessary. Pre-surgery examinations are carried out by an anaesthetist, according to established procedures, and patients are classified with respect to their ASA index or risk level. This sheet is very important in view of the information which must be given to patients and of the risks which they knowingly accept.
- *Anaesthesia Report*. This report comprises all information on the physiopathological state of the patient during anaesthesia and surgery. It is very important in lawsuits for death during surgery or anaesthetic accidents.
- *Operating Room Report*. This report records the nature of the surgical intervention, all incidents related to the technique used, and specific patient findings. It is therefore a patient document which is usually illustrated with simple drawings showing what actions were taken in the surgical field, e.g., sutures, drains, etc. This sheet is essential for examining medical conduct if surgical or post-surgery complications arise.
- *Post-Surgery Evolution Sheet*. This sheet describes monitoring of the patient with respect to general conditions and the specific surgical operation performed. It is also very important when examining the quality of health care in this phase (early detection of complications, early and correct actions to avoid them, etc.).
- *Pathological Anatomy Report*. If such studies are requested by physicians.
- *Pregnancy Monitoring Sheet*. Very important in cases of pregnancy. In Spain, monitoring is carried out the family doctor and the midwife. The pregnant woman goes to the gynaecologist for initial examinations, in the 20th week and just before term. This sheet a very important document, as it indicates all examinations, records of vital signs, incidents occurring to the mother, development of the foetus (size, weight, heartbeat, etc.), results of screening for chromosomopathies and malformations, etc.
- *Record of Assistance at Birth*. When all details about the pregnancy are normal, assistance to the mother in hospital is provided by the midwife; when there are complications, the midwife is the person who informs the gynaecologist. This procedure may give rise to medico-legal problems since, when the doctor arrives, injury to the foetus may already have occurred, for which the doctor may subsequently be liable. A clearly compiled record of the phases of the birth will clarify problems, when they are detected, and at which moment each professional intervened.
- *Nursing Journal*. This sheet covers all incidents relating to vital signs, administration of medicines and medications, requests for care and any unusual decisions (including, for example, requests to doctors on duty made by nurses

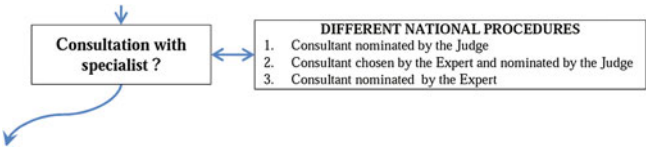


Fig. 13.2 Step 2

for extra medicines, especially analgesics, etc., outside usual working hours). Detailed notes which may be of interest are frequently found in nursing sheets.

- *Graph of vital signs*. This also corresponds to the nursing staff and is done with the frequency that the doctor indicates.
- *Clinical Discharge Report*. This is issued when the patient is discharged from the medical viewpoint and goes home or to another hospital. It summarises the period in which the patient was hospitalised and, although and specific, it should be a complete document which includes the cause of hospitalisation, with precise diagnoses, treatments administered, evolution, state of the patient at discharge and treatment(s) to be followed, with indications of any future examinations and whether the family doctor should carry out monitoring.

Witness Statement of Involved Physicians

According to national regulations, the expert might be authorized by the competent judicial authorities in the acquisition of testimonies/witness statements of physicians and paramedical staff regarding the facts under examination.

13.3.2 Step 2: Consultation with Specialist

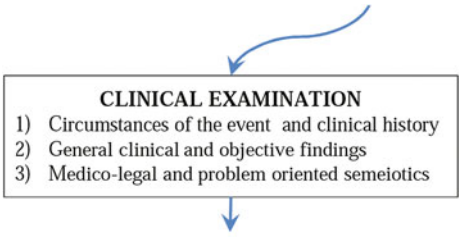
Preliminary evaluation of the clinical and healthcare documentation may reveal the need/suitability of requesting the advice of one or more medical specialists in the ascertainment phase, to ensure better definition of the case in question. This involvement should preferably take place before clinical ascertainment (Fig. 13.2—Flow Chart 1), as the specialist may profitably contribute to the clinical ascertainment phase and to the choice of any further examinations to be carried out.

Regarding the method used in appointing the Specialist there are important regulatory and operative differences between the European Countries considered, with three fundamental types of appointment of the Specialist Consultant:

1. appointment on the part of the judge's own spontaneous initiative;
2. appointment on the part of the judge via counsel/recommendation on the part of the medico-legal Expert;
3. direct Appointment on the part of the medico-legal Expert.

The present Consensus document recommends that the opinion of the medico-legal Expert is always taken into account prior to the appointment of the Specialist Consultant.

Fig. 13.3 Step 3



13.3.3 Step 3: Clinical Examination

This clinical step involves careful collection of anamnestic data and an objective clinical examination including internal medicine, neurological and clinic-objective tests aiming at specific problems (Fig. 13.3—Flow Chart 1).

In addition, in view of the possibility that the patient being examined may simulate non-existent injuries or accentuate the severity of injuries already present, proper medico-legal semeiotics must be applied in all clinic-objective examinations.

The essential data which must be collected and verified during ascertainment are:

- the clinical condition of the patient at the time of the examination;
- whether the clinical state corresponds to what is shown in the prior documentation, except for any developments occurring in the meantime;
- the relationship between the current state of health, claimed facts, events and medical actions; these will help the medico-legal expert to establish and sustain the causal value and link.

In the case of sequelae, the medico-legal expert must record them, describe their nature, location, importance, the limitations to which they may lead, of anatomical, functional and mechanical nature, etc. This point is important in proceeding to possible quantification of biological damage (see Sect. 13.5).

13.3.4 Step 4: Further Instrumental Diagnostic Exams

If after examination of medical and healthcare documentation and clinical objective signs, the available anatomo-functional data are not sufficient for a diagnostic picture, the possibility of further diagnostic tests, non-invasive and/or invasive, must be evaluated (Fig. 13.4—Flow Chart 1).

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 those procedures.

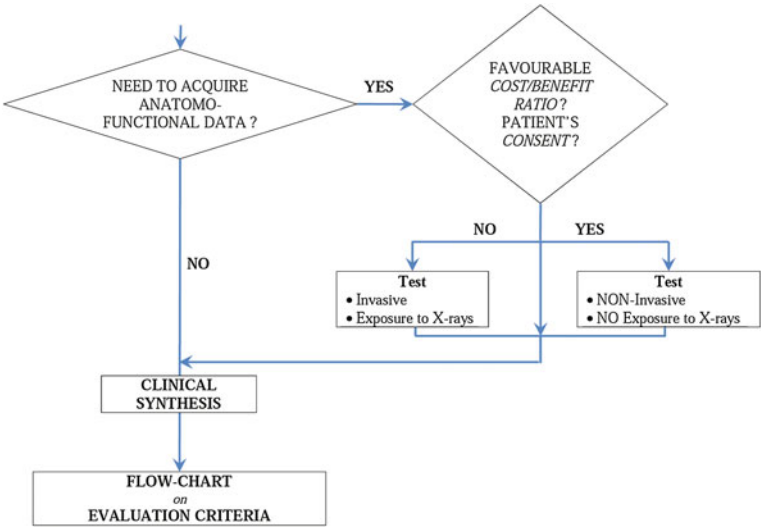


Fig. 13.4 Step 4 and 5

13.3.5 Step 5: Clinical Synthesis

Before the phase of analysis and evaluation (Fig. 13.4—Flow Chart 1), the clinical, documentary and objective data must be summarised.

13.4 Methods of Ascertainment on Cadavers

Although regulations and operational practices are heterogeneous in all the countries considered, the medico-legal Expert is involved in almost all cases of presumed Medical Responsibility and/or Liability on cadavers.

Apart from the juridical framework (penal, civil) or extra-juridical in which the medico-legal professional operates, and apart from the interested party/(judge, insurance company, plaintiffs or others), the method of ascertainment is the same, including examination of clinical and documentary data, execution of autopsy and possible further analyses (Flow Chart 2).

13.4.1 Step 1: Collection and Examination of Clinical and Documentary Data

For this operative phase, reference is made to Flow Chart 2 and to Step 1 of the "Methods of Ascertainment on Living Persons" (Fig. 13.5—Flow Chart 2).

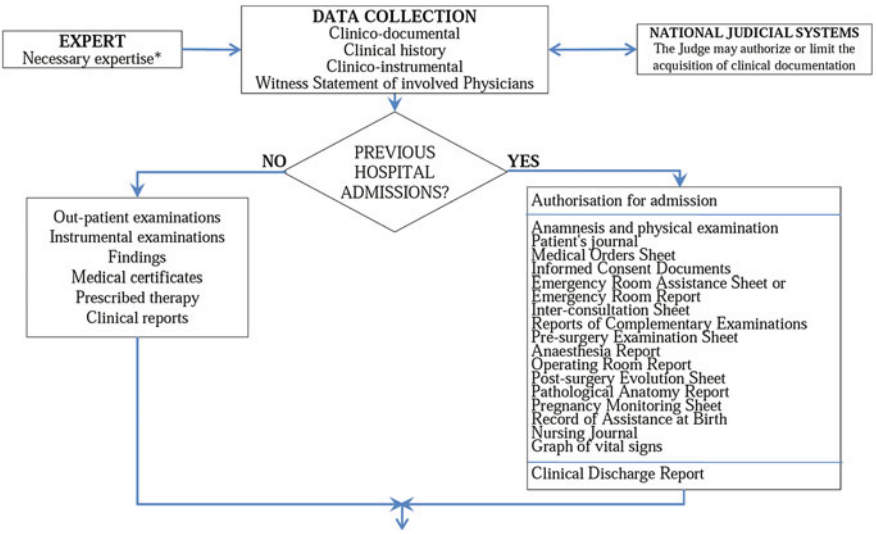


Fig. 13.5 Step 1

13.4.2 Step 2: Consultation with Specialist

Preliminary evaluation of the clinical and healthcare documentation may reveal the need/suitability of involving one or more medical specialists in the ascertainment phase, to ensure better definition of the case in question. This involvement should preferably take place before any pre-autopsy ascertainment and medico-legal autopsy (Fig. 13.6—Flow Chart 2), as the specialist may profitably contribute to the choice of pre-autopsy examinations, ascertainment and possible integrative examinations.

13.4.3 Step 3: Pre-Autopsy Examinations

Prior to autopsy, several types of radiological investigations may be performed (X-ray, Computed Tomography, Nuclear Magnetic Resonance). According to the case, it may be advantageous to take swabs for microbiological or genetic studies, prior to forensic autopsy (Fig. 13.7—Flow Chart 2).

13.4.4 Step 4: Autopsy

As indicated in "Recommendation no. R (99) 3 of the Committee of Ministers to Member States on the Harmonisation of Medico-Legal Autopsy Rules",

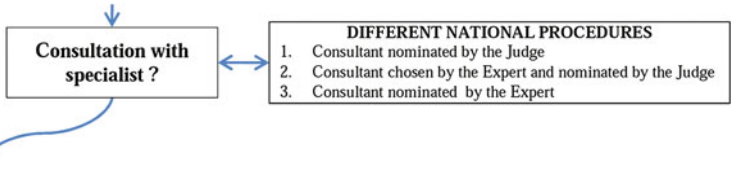


Fig. 13.6 Step 2

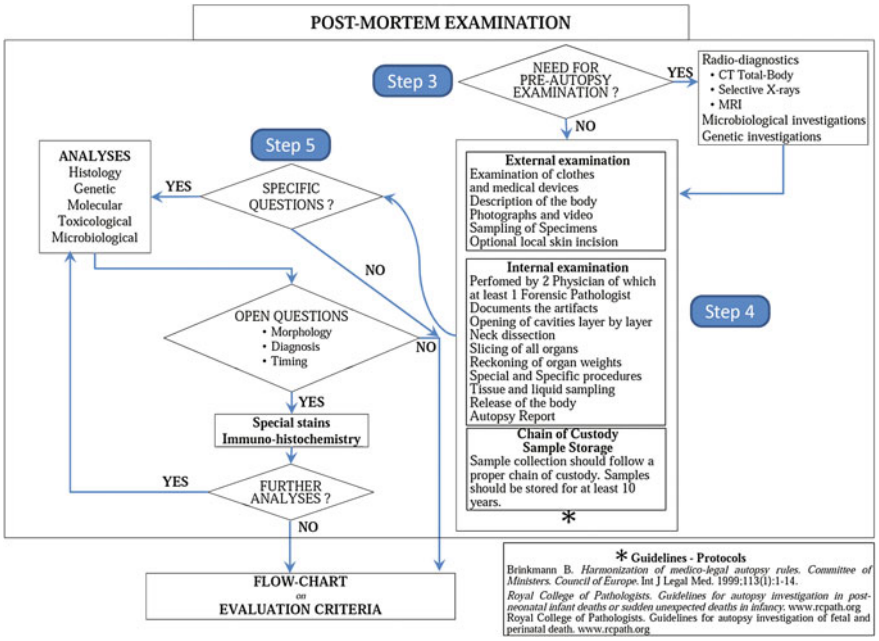


Fig. 13.7 Step 3 to 5

(Brinkmann 1999) autopsy is a moment of prime and essential importance in medico-legal ascertainments for Medical Responsibility and/or Liability on cadavers (Fig. 13.7—Flow Chart 2).

The present guidelines refer to the principles and operational procedures contained in the above-mentioned document, with particular reference to *Principle II* ("Autopsy physicians"), *Principle IV* ("General Considerations") and *Principle V* ("Autopsy procedures").

In particular, in cases of suspected Medical Responsibility and/or Liability, autopsies should be performed, whenever possible, by two physicians, of whom at least one should be qualified in forensic pathology or legal medicine.

A medico-legal Expert is a medical doctor who:

1) has fully completed a postgraduate training in legal medicine preferably at university level and is accredited as a medico-legal Expert by the supervising authority in his or her country and
2) who habitually practices that speciality.

Before starting a medico-legal autopsy, the Recommendation underlines the importance of *preserving the dignity of the deceased*, of safeguarding the interests of his or her relatives and of having regard to the proportionality principle.

The Recommendation deals in great details with the question of autopsy procedures and it indicates that they should normally be divided in two stages, i.e., external and internal examination. Moreover, the investigation, description, documentation and sampling during a medico-legal autopsy should primarily follow medical and scientific principles and simultaneously consider the judicial requirements and procedures.

13.4.4.1 External Examination

The Recommendation indicates all the elements that should be included in the description of the body following an external examination.

Of particular importance is the accurate examination of clothes and all of the medical devices present. In this regard it is fundamental that the Expert informs the hospital where the alleged case of professional responsibility took place so that the state of the corpse is not altered (i.e., removal of medical devices).

The Recommendation stresses that during the external examination, all injuries should be described by shape, exact measurement, direction, edges, angles and location relative to anatomical landmarks. In addition, signs of vital reaction around wounds, foreign particles inside wounds and in their surroundings and secondary reactions, such as discoloration, healing and infections should also be described. Moreover, where appropriate, specimens from wounds must be removed for further investigations, such as histology and histochemistry. The Recommendation points out that all signs of recent or old medical and surgical intervention and resuscitation must be described and that medical devices (such as endotracheal tubes, pacemakers, etc.) must not be removed from the body before the intervention of the medico-legal expert.

It is recommended that the external examination and the subsequent dissection of the cadaver are documented with photos and video recordings.

13.4.4.2 Internal examination

The Recommendation requires that all three body cavities, i.e., head, thorax and abdomen, be opened and examined and it also specifies that all organs be examined and sliced following established guidelines of pathological anatomy. Once the medico-legal autopsy procedure has terminated, the Recommendation underlines the need for the body to be released in a dignified condition.

In some specific cases of autopsy ascertainment, for example foetal or perinatal deaths or deaths in infancy, reference should be made to the guidelines of the *Royal College of Pathologists* and, in particular, to its Appendixes 6 and 7.

During the ascertainment, biological fluids and organ fragments must be collected as specified in the Recommendation "R (99) of the Committee of Ministers to Member States" for possible subsequent supplementary in-depth analysis (i.e. histology, toxicology, genetics, microbiology etc.) These samples must be properly conserved for at least 10 years, guaranteeing an adequate chain of custody.

13.4.5 Step 5: Choice and Execution of Further Diagnostic Procedures

The choice of analyses or examinations to carry out is made by the medico-legal expert (with or without the help of a clinical or surgical specialist) according to documentary data and the autopsy results. In most cases, even before autopsy, the expert is able to make a list of the analyses which should be carried out on collected samples (Fig. 13.7—Flow Chart 2).

However, according to preliminary results, further analyses 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.

13.5 Evaluation Criteria

Due and proper accomplishment of the phase(s) of ascertainment is followed by assessment, according to *Evaluation Criteria*, subdivided into the following logical Steps (Flow Charts 3 and 4).

13.5.1 Step 1: Comparative Evaluation of Data

The medico-legal expert gathers together all the data from the various ascertainment phases, conducts an initial synthesis according to conceptual area and reaches a comparative final evaluation (Fig. 13.8—Flow Chart 3).

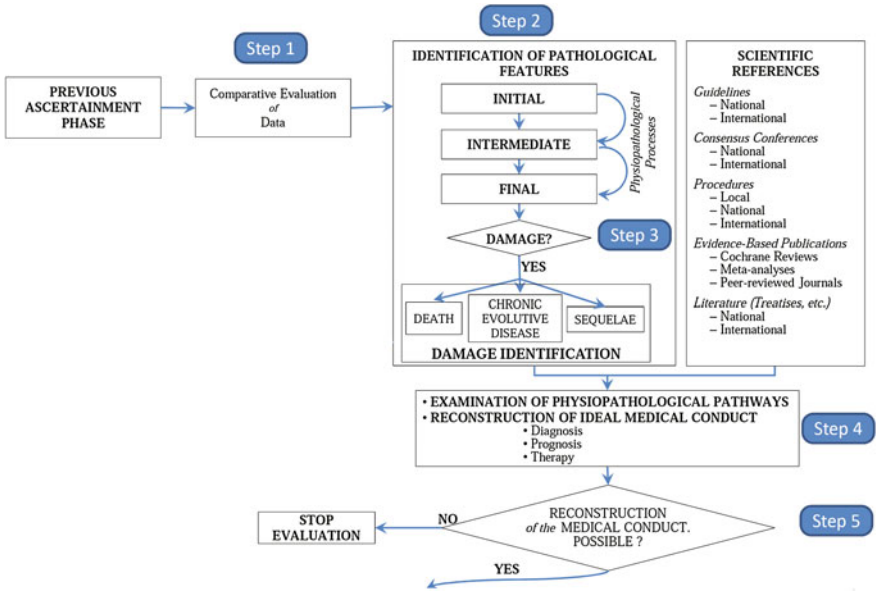


Fig. 13.8 Steps 1–5

13.5.2 Step 2: Identification of Pathological Features

Step 1 is followed by identification of *Pathological features*, subdivided into *initial*, *intermediate* and *final* clinical pictures resulting in restoration to health, death, chronic pathological state or permanent injury (Fig. 13.8—Flow Chart 3).

In this reconstruction, the physiopathological pathways revealing the chain of events must be identified and clearly described.

13.5.3 Step 3: Damage Identification

This covers possible damage or incapacity, either temporary or permanent (i.e. death, chronic evolutive disease, sequelae), as shown in Fig. 13.8 (Flow Chart 3).

13.5.4 Step 4: Reconstruction of Physiopathological Pathways and Ideal Medical Conduct

Identified *Pathological Features* are examined by analysing *scientific sources*, such as *Guidelines* (national and international), *Consensus Documents* (national

and international), *Operational Procedures* (local, national and international), *Evidence-Based Publications* (Cochrane Reviews, Meta-analyses etc.) and other *Literature* data, composed of treatises and articles published in peer-reviewed Journals (PubMed-Medline, Embase, Scopus, Ovid, ISI Web of Science etc.), preferably with *Impact Factor* (Fig. 13.8—Flow Chart 3).

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.

- Guidelines.
- Consensus Documents.
- Operational Procedures.
- Evidence Based Publications.
- National literature (Treatises, etc).

This examination aims at:

– identifying and reconstructing the physiopathological course composing the actual chain of events which took place, i.e. linking the initial pathological features with the intermediate and final ones;
– reconstructing the ideal conduct which a physician should have followed during diagnosis, prognosis and treatment.

13.5.5 Step 5: Reconstruction of the Real Medical Conduct

After examining the sources and the ideal medical conduct, as described above in Step 4, the medico-legal expert must establish 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 (Fig. 13.8—Flow Chart 3).

13.5.6 Step 6: Reconstruction and Verification of Real Conduct of Medical and Healthcare Personnel

The first phase consists of applying the *extrapolation method* to data, which are significant and useful for reconstructing and ascertaining the conduct of medical and healthcare personnel (Fig. 13.9—Flow Chart 3).

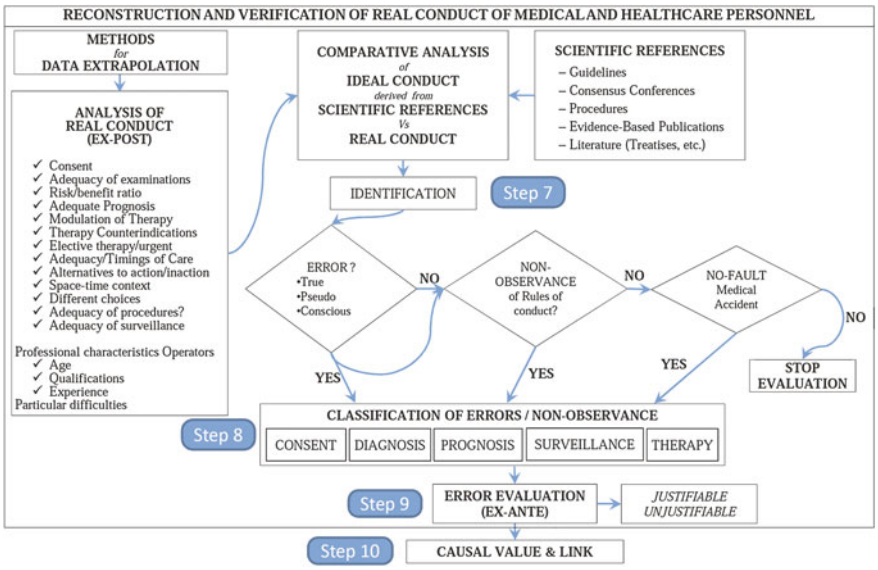


Fig. 13.9 Steps 6–9

The medico-legal expert must then reconstruct and analyse *ex-post* the *conduct of medical and healthcare personnel*, i.e. existence/validity of patient's consent, adequacy of diagnostic tests, correctness of prognosis, adequacy of treatment and care.

Evaluation of the correctness of the various diagnostic, *prognostic and therapeutic phases* is carried out by *comparing* ideal conduct, desumed from referenced scientific sources, such as *Guidelines* (national and international), *Consensus Documents* (national and international), *Operational Procedures* (local, national and international) and *Evidence-Based Publications*.

In some countries—for instance, the United Kingdom—guidelines are published not only by scientific associations, but also by the *Royal College of Physicians*,[1] established as a point of reference of prime importance in comparative evaluation between ideal conduct and conduct actually followed by medical and/or healthcare personnel. *However*, *failure to follow a guideline is not prima facie evidence of negligence*. The key step in medical negligence litigation is proving that the doctor did not meet the required standard of care, which may be inferred not only from guidelines, but also from detailed analysis of all available scientific sources.

[1] Several *Clinical Guidelines* can be downloaded from the official website of the *Royal College of Physicians*. http://www.rcplondon.ac.uk/resources.

13.5.7 Step 7: Identification of Error/Non-Observance

The process of analysis and comparative evaluation between ideal conduct and true conduct leads to the identification of possible error and/or non-observance of required rules of conduct, which must be characterised by type and qualified according to phase (patient's consent; diagnosis, prognosis, treatment) as shown in Fig. 13.9 (Flow Chart 3).

In order to identify possible error and/or non-observance of required rules of conduct, the present *Consensus Document* proposes the following definitions.

- *Error*. Violation of a rule shared by the national and/or international medical community as regards an aspect of professional practice, classified into the following types.
  - True/Real error
    This is a material error, of omission or commission, due to violation of a universal and/or epidemiological scientific law, or of consolidated rules of experience and competence.
  - Pseudo-error (apparent error)
    This is only an apparent error due to a general absence of scientific knowledge on a specific issue at the time of the event or, alternatively, related to an unpredictable and inevitable event (i.e. force majeure).
  - Conscious error
    This is an error made by a medical doctor or a member of the healthcare personnel in full conscience. Aware of having not identified the true (etiology of the) pathological state of the patient, the medical doctor applies diagnostic or therapeutic procedures with only an "ex adiuvantibus" aim (i.e., without true efficacy as regards diagnosis and/or treatment) causing damage to that patient.
- *Non-observance of required rules of professional medical conduct*. This concerns non-observance of rules of scientific medicine as taught in degree courses and in schools of specialisation, and permanently updated through the scientific literature, congresses and training courses. These rules are mainly orientative in nature and must be applied to each individual case, according to the diagnostic and therapeutic features of the clinical picture.

Some *examples of non-observance of required rules of conduct* are given below.

(1) Lack of information about the patient, (2) absence of patient's consent, (3) omission of normal attention and due caution, (4) superficiality or lack of interest shown towards basic rights (life, health, dignity), (5) inexcusable ignorance of the fundaments of the discipline, (6) non-observance of due prudence, (7) required cautionary measures not followed (8) inexcusable ignorance of consolidated literature, (9) inexcusable ignorance of regulations covering the medical profession,

(10) no check(s) made of the actions of others, (11) non-observance of administrative procedures and formalities, (12) violation of deontological rules.

- *No-Fault Medical Accident*
  This concerns all iatrogenic damages which are not causally related to a medical error but to a therapeutic risk.

13.5.8 Step 8: Classification of Error/Non-Observance

If the *comparative evaluation* between *ideal conduct* as desumed from scientific sources and *true conduct* reveals *evidence* of error(s) or non-observance of required rules of conduct, qualification-correlation of such error/non-observance (single or multiple) must be carried out, according to the specific area of expertise, as regards patient's consent and diagnostic, prognostic or therapeutic phase (Fig. 13.9—Flow Chart 3).

Consent. If consent to diagnostic tests and/or medical or surgical treatment is inadequate.

Diagnosis. If symptoms and/or clinical signs have been underestimated, with relative inadequacy and incorrectness of diagnosis. If a further diagnostic test has been omitted, i.e. evaluation of alternative diagnostic possibilities, of the risk/benefit related to the possible side-effects of diagnostic technique and/or method (i.e. adverse events due to allergic reactions, e.g. administration of radio-opaque contrast media etc.), compared with possible advantages in terms of interpretation in prescribing diagnostic tests and their timing.

Prognosis. If there is inadequacy in the prognostic evaluation correlated with a diagnostic error.

Surveillance. If there is inadequacy in the surveillance (i.e. monitoring) of the patient (particularly important in psychiatric patients).

Therapy. If there is inadequacy in the choice and type of treatment followed, to the exclusion of alternative treatments, in the case of actions taken during emergencies or in elective circumstances, or in the timing of treatment(s).

13.5.9 Step 9: Error Evaluation—Ex-Ante: Possible Causes of Justification

This evaluation involves the reasons for identified and classified error and/or non-observance. In particular, the medico-legal expert must establish whether the reasons for any such error and/or non-observance are True, or whether there is a Cause for Justification (Justifiable Error). This evaluation phase requires the medico-legal expert to enter a *state of ex-ante evaluation/judgement*, 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 (training, age, qualifications and professional experience) and the technical and instrumental equipment at their disposal (Fig. 13.9—Flow Chart 3). This evaluation is of prime importance in cases of surgical operations of *particular technical difficulty*. Ex-ante evaluation must consider all (and only) 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.

13.5.10 Step 10: Causal Value and Causal Link Between Error and Event

The causal value and the relationship of an actual causal link must be evaluated by means of a "criterion of scientific probability", such as universal law, statistical law or criterion of rational credibility. If this is not possible, due to the absence of "explanatory laws", evaluation must be interrupted (Fig. 13.10—Flow Chart 4).

13.5.11 Step 11: Universal Law, Statistical Law or Criterion of Rational Credibility

The causal value of error and the relationship of an actual causal link between error/non-observance and damage may 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 (Fig. 13.10—Flow Chart 4).

13.5.12 Step 12: Identification of the Degree of Probability of Causal Value and Causal Link

A later check of the causal value and causal link between error and injury must be made, by applying counterfactual reasoning and eventually additional criteria.

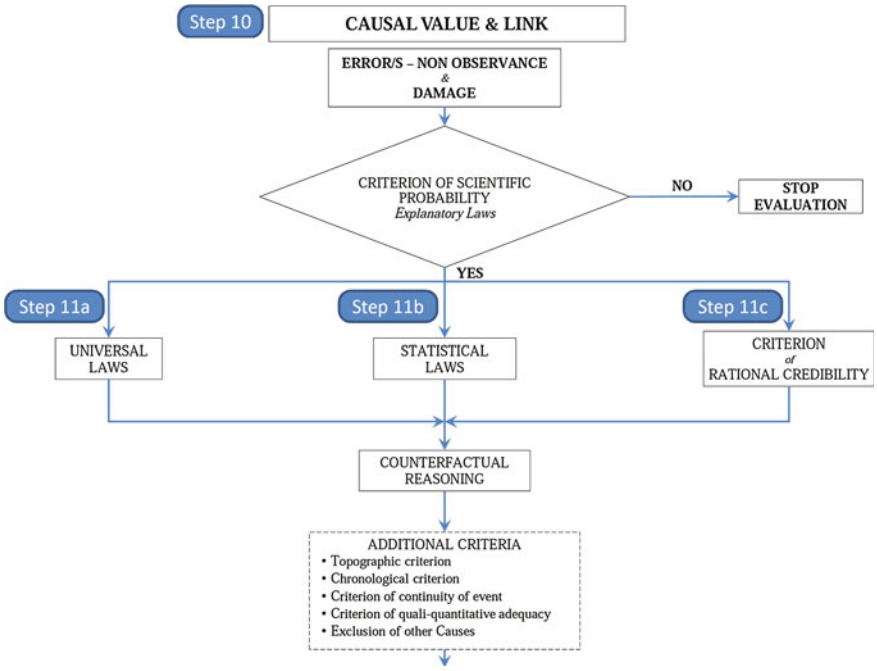


Fig. 13.10 Steps 10–11 (from a to c)

The conclusion must be expressed in terms of near certainty, probability (when possible estimating the percentage of probability) or exclusion of the causal value-causal link between error/non-observance and damage (Fig. 13.11—Flow Chart 4).

13.5.13 Step 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 injury causally correlated with error/non-observance (Fig. 13.12—Flow Chart 4).

As regards *temporary incapacity*, the following must 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:

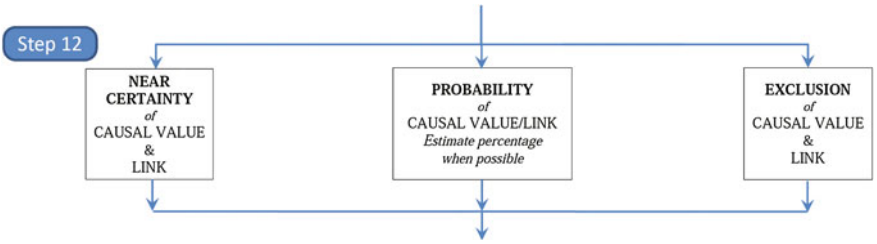
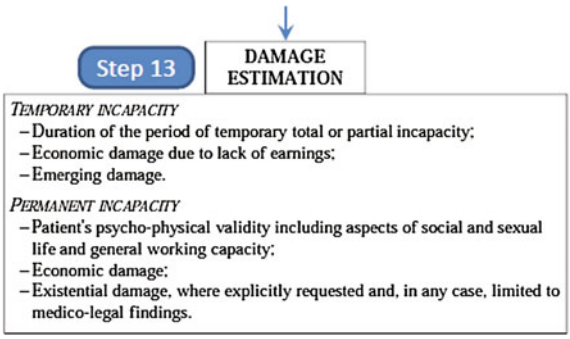


Fig. 13.11 Step 12

Fig. 13.12 Step 13



- 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.

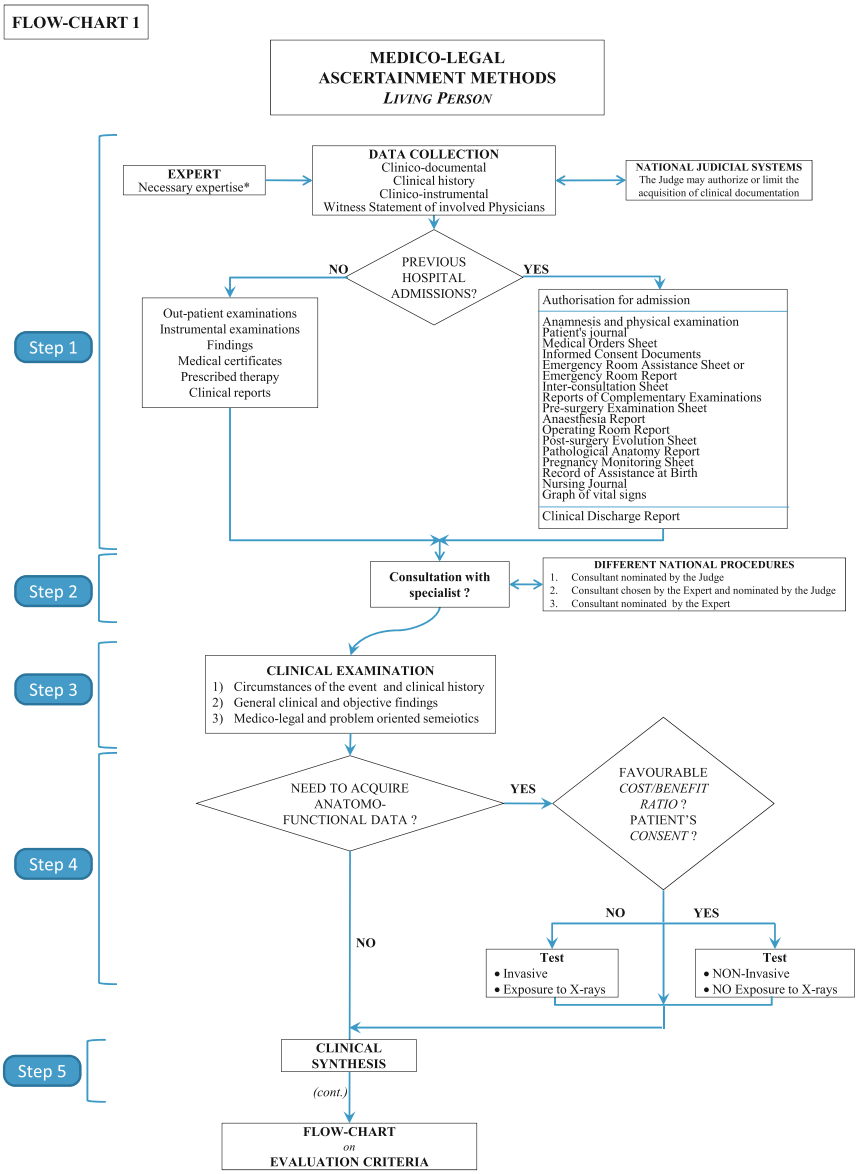
13.6 Conclusions

The present "Consensus Guidelines Document", elaborated by the EALM Working Group on Medical Malpractice, is the just first step towards the complex and multifaceted harmonization process of the legislative-juridical, operational and institutional practices of medical liability cases in the different European Countries.

This exemplary process of harmonization, triggered by the European Academy and Community of Legal Medicine, is certainly strengthened and enhanced by the contribution of other International Experts and Communities of various disciplines, as well as facilitated by a legislative reform, likely to be promoted by the European Council, which, in addition to the ascertainment methodology and criteria of evaluation, aims to standardize the structure of the juridical-legislative Medical Malpractice lawsuits in the various European States.

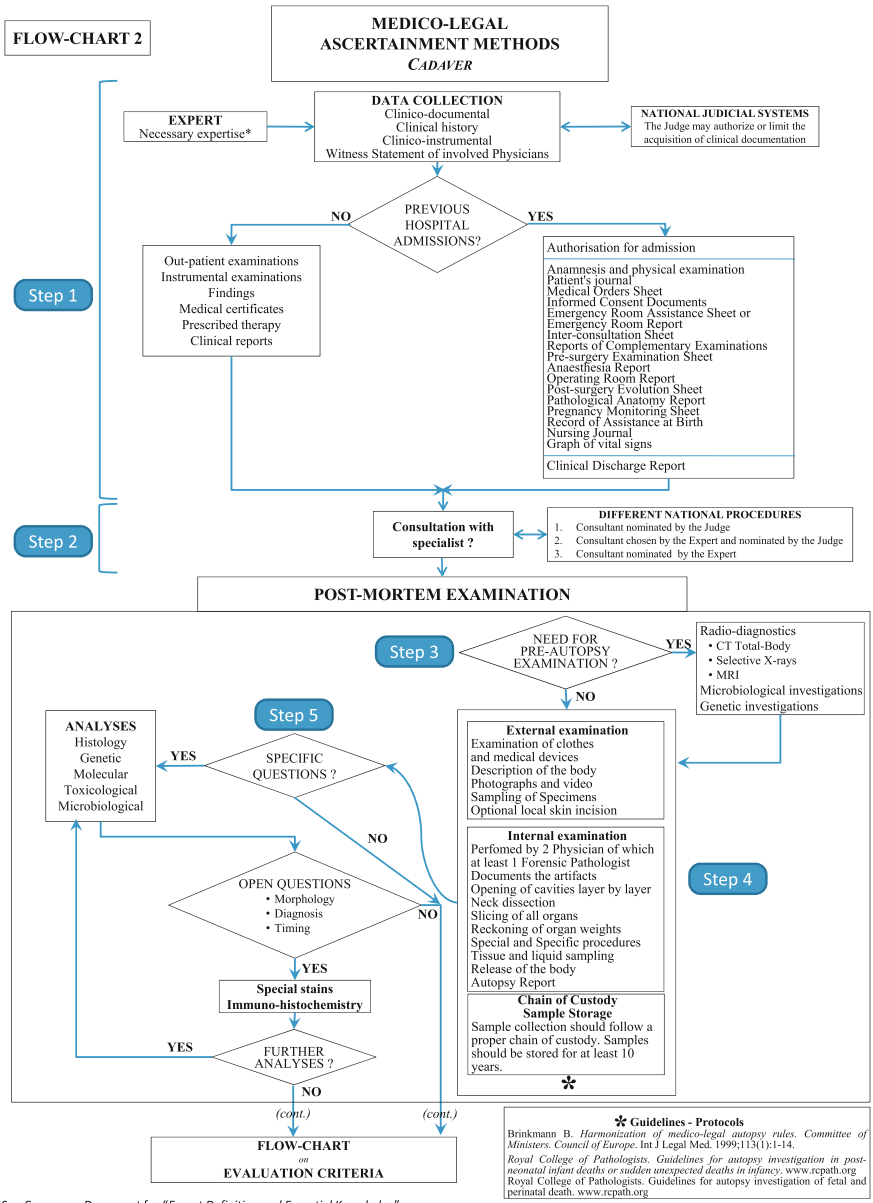
Appendixes: Flow Charts

Methods of Ascertainment on Living Persons



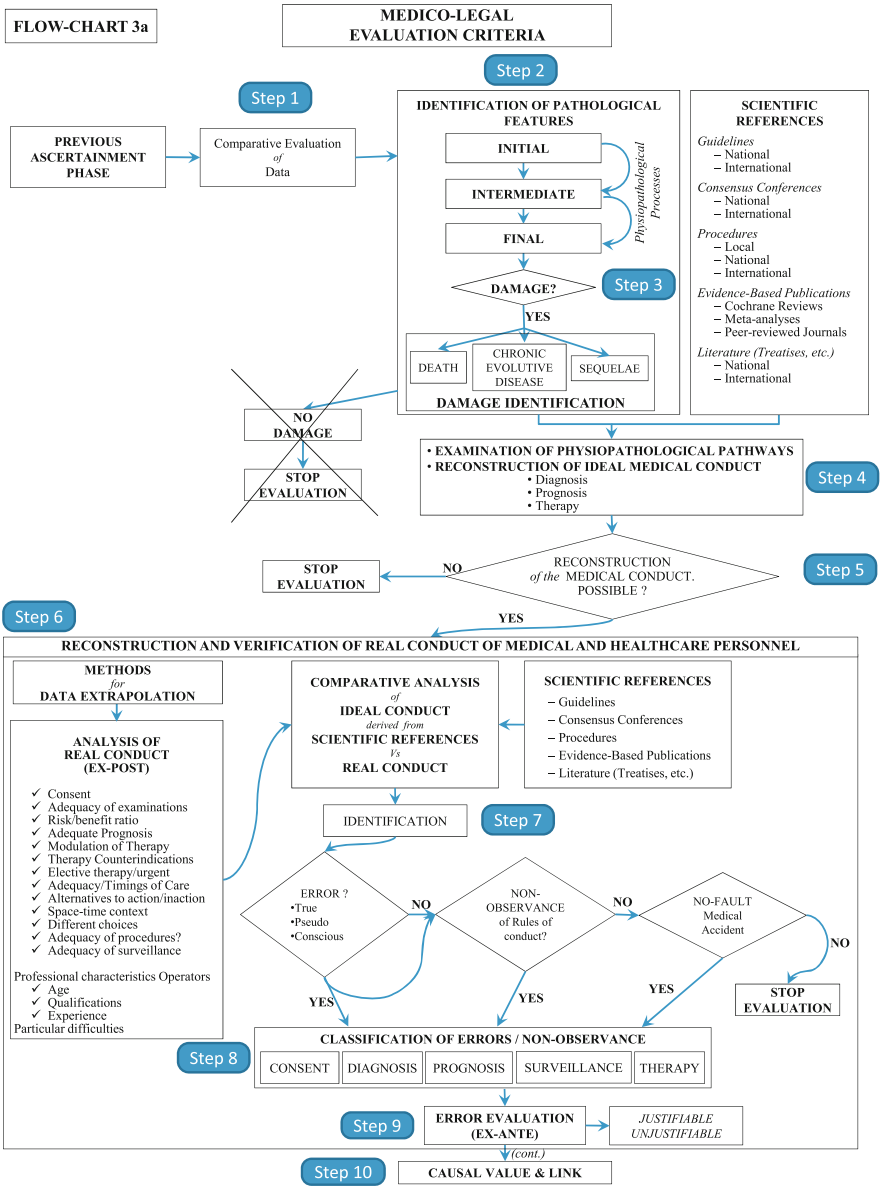
* See Consensus Document for "*Expert Definition and Essential Knowledge*"

Methods of Ascertainment on Cadavers

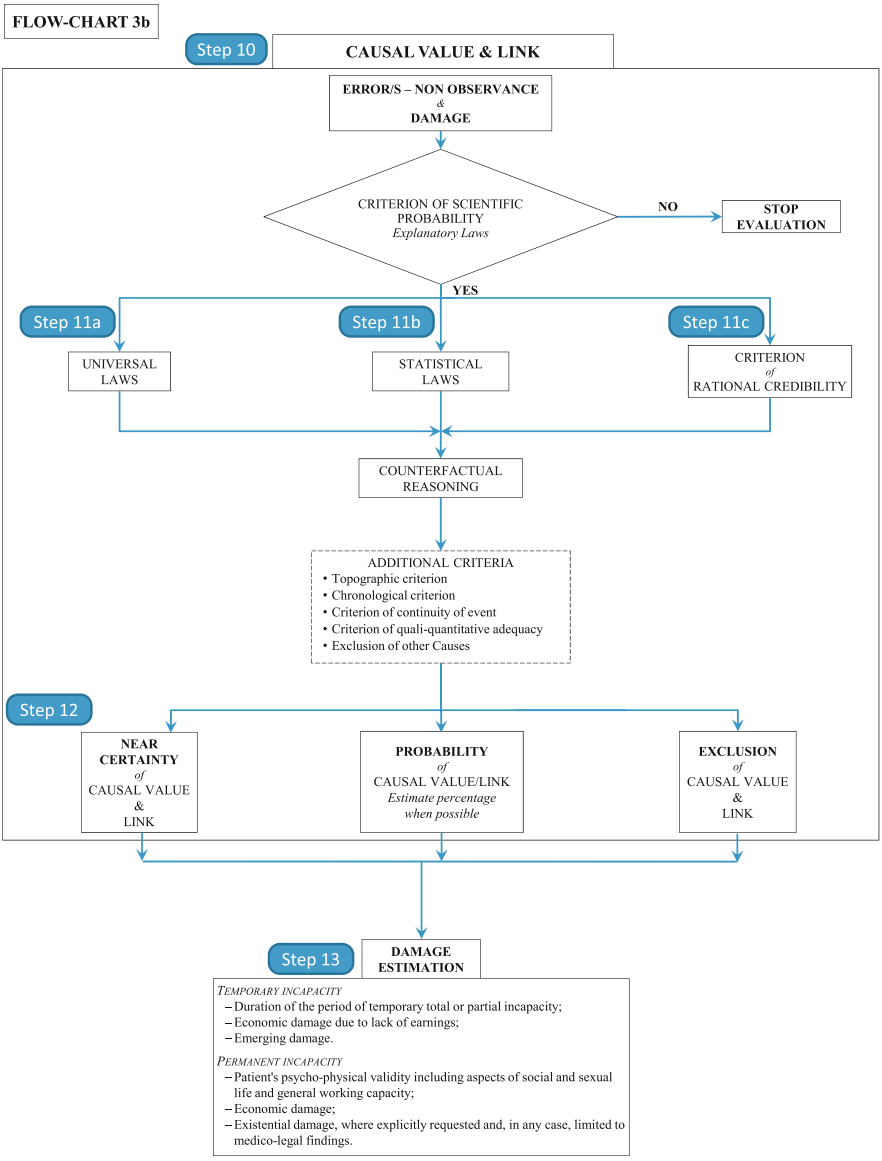


* See Consensus Document for "*Expert Definition and Essential Knowledge*"

Evaluation Criteria: Part a



Evaluation Criteria: Part b



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