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Malpractice and Medical Liability

European State of the Art and Guidelines

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Foreword

Paolo Zacchia (1584–1659), who is often called "the father of forensic medicine", published a 9-volume work entitled "Quaestiones Medico-Legales", in which he already dealt with medical malpractice liable to prosecution under the heading "De medicorum erroribus a lege punibilibus". On June 14 and 15, 2011, jurists and medico-legal experts from several European countries attended a consensus conference in Rome where Paolo Zacchia had worked as one of the outstanding founders of legal medicine. The topic of the conference, which took place under the patronage of the European Academy of Legal Medicine, was medical responsibility and liability, and the results of this meeting constitute an essential part of this monograph.

The Constitutio Criminalis Carolina is regarded as the first body of German criminal law (ratified in 1532 at the Diet in Regensburg) and as an early attempt to unify the legal system of the Holy Roman Empire. It already included a special provision concerning medical malpractice.

In the nineteenth century, forensic medicine became a special discipline at European Universities. Since then, medical responsibility and liability have been an integral part of medico-legal teaching and research. In practical forensic work, the assessment of real and alleged malpractice cases is one of the most challenging tasks of medico-legal experts.

Medical malpractice is defined as professional negligence of a health care provider who by act or omission causes injury or death due to an offence against accepted standards of treatment. Both these standards and the regulations concerning professional responsibility and compensations for harmed patients vary by country and jurisdiction.

Accountability for medical error can be assigned to individual physicians but also to a group of professionals cooperating in a complex health care system. In every malpractice claim, it has to be proved that the provider failed to observe the relevant standard of care resulting in an injury with consecutive damage in pecuniary or emotional respect. To be qualified as an expert in a medical malpractice case, the assessing person must have sufficient knowledge and experience regarding the specific issue. In many European countries, ascertainment and

medical evaluation of suspected malpractice is primarily done by forensic experts working at institutes of legal medicine.

In their monograph, the authors advanced towards new frontiers by dealing with the topic on a European level using an interdisciplinary approach. In his capacity as President of the European Academy of Legal Medicine, Professor Ferrara is particularly qualified for this transnational perspective.

For a better understanding of the current situation in the field of medical responsibility and liability it is helpful that the introductory chapters of the monograph give an overview of the historical background. The same is true for the legislative and judicial aspects including the rules of causality to be applied.

The systematic presentation of the national specifics by reputed scientists from various regions (German-speaking countries, UK, France, Spain, Portugal, Italy, and Baltic States) deserves special mention. On this broad basis, a panel of renowned jurists and medico-legal experts worked out a document in a consensus process with the objective to introduce uniform standards for the medico-legal assessment in cases of suspected malpractice. The ultimate goal of this proposal for European guidelines is a harmonization of methods and evaluation criteria similar to the already existing Recommendation on the Harmonization of Medico-Legal Autopsy Rules.

It is to be hoped that the guidelines proposed by the authors will help to bring about common principles of medical assessment in the context of malpractice claims. From this point of view, the editors and authors deserve the special thanks of the entire scientific community. The affected patients will certainly benefit from a uniformly high standard of evaluation.

Stefan Pollak
President of the German Society of Legal Medicine

Preface

As has often happened in other scientific and disciplinary contexts, *the medico-legal community has provided the first example*, by posing an *initial remedy* to the heterogeneous detriment of the patient's rights, through the triggering of a positive process aimed at European consensus on ascertainment methodology and the criteria for assessing damage from medical malpractice, on living and deceased persons.

To this end, the writer, in his capacity as President of the *European Academy of Legal Medicine* (*EALM*) in the years 2009–2012, has preselected and coordinated a *Working Group* of European Experts who have contributed to the realization of the present monograph and the European Guidelines set out in Part V of the text, the result of a Consensus Conference that took place in Rome from the 14th to the 16th of June in 2011.

This is the final outcome of a three-year evolutionary process of an EALM scientific project, created on the basis of a specific and coherent rationale (Ferrara and Pfeiffer 2010), aimed at acquiring knowledge of the "state-of-the-art" of the European medicolegal scientific culture and directed towards the harmonization of the scientific research, skills, and professional practice of the European biomedico-legal sciences. With the prospect, now actually forthcoming, of a recording in the Official Journal of the European Union of the specialization of "Legal and Forensic Medicine", for the time being already recognized in October 2012 by the European Union of Medical Specialists, such as the "Thematic Federation" of interdisciplinary interest.

The state of the art, acquired on the subject of professional practice (Ferrara et al. 2010) and associated guidelines of ascertainment and evaluation, as well as of scientific research (Ferrara et al. 2011), of innovatory productive capability (Viel et al. 2011), and of the role of impact of disciplinary Journals (Boscolo-Berto et al. 2012), has permitted the identification of those areas in need of present and future intervention. In the category of those pertaining to professional practice, "Medical Responsibility and Liability" and "Medical malpractice" were found to be the most in need of immediate interest and a marked necessity of early intervention, for the broad and diversified reasons expressed in Chap. 1 concerning the "present and future perspectives" of medical malpractice and responsibility.

In order to acquire cognitive data for a better and more effective development of the "Guidelines", a structured Questionnaire including dozens of "items" was utilized, whose comparative assessment proposed to the responsible Authors, members of the Working Group, the reasoned drafting of Reports on the situation of Malpractice, institutional and medico-legal roles, possible shared "ascertainment methodologies" and "evaluative criteria" in the respective countries, as well as, finally, the evaluation and correction in several successive stages of the "European Medico-Legal Guidelines" prepared, in the preliminary and first draft, by the Editor and Co-Editors, up until the definitive sharing that took place in the above-mentioned collegial Consensus Conference in Rome.

Chapters 6–12 of Part IV of the monograph, expository of the "national reports" and the "Guidelines" set out in Chap. 13, Part V, are accompanied by "historical contributions" of a "medical imprint" (Chap. 2) and a "juridical imprint" (Chap. 3), as well as of a "comparative supranational European legal structure" (Chap. 4), an in-depth study of principles and concepts concerning "causal value and nexus of material causality" (Chap. 5), and, finally, by a "glossary, final statements" and "historical iconography", designed to supplement the work in Part VI and furnish the proof of the ancestry and the terminology that characterize the remoteness and relevance of malpractice, medical responsibility and liability in the evolution of civilization. An ancestry and complexity that bring to mind the difficulty of scientific and juridical harmonization, in the course of attenuation on the basis of national, legislative, state, and legal-procedural models, gradually more and more similar and today summarized in the Anglo-German, French, Mediterranean, and Scandinavian models, and, in the near future, in a *European legislative-juridical model*, including the unique assimilation of the systems of *assessment of damage to the person and of related temporary and permanent impairment.*

Consistent with the rationale of the work's design and execution, as well as from the compendium of the operations put in place through this project, we hope to derive *tangible benefits for patients and their families*, for *physicians* and *healthcare institutions*, *for jurists and medico-legal experts,* for national economic macro-systems where the effect of the costs of malpractice absorbs substantial resources. More specifically, the uniformity of medico-legal assessment in every European Member State, based solely on rigorous and shared methodology and criteriology, will be focused on the objectivity of scientific data inferable from Treatises and from Publications of "Evidence Based Medicine".

The Patient and the Doctor will see applied throughout Europe the principles of systematic objectification and evidence of data, with the consequent result that the damage of each European patient-user will be able to be ascertained and evaluated in the same way, regardless of the country where he/she has received healthcare assistance.

The Healthcare System, benefiting from the clear references of a route of codified verification, will agree on a more rapid convergence of conflicting positions. And even more than that, the system will be better able to contribute to the

refinement of prevention and the clinical risk management of adverse events and malfunctions which generate medical malpractice.

Additional and desirable developments of the scientific initiative for consensus will consist in sensitizing the Council of Europe in the creation of an Institutional Organ with the role of a "Reporting System", on which to confer the role of proposing specific directives to the European Union, aimed at rationalizing and standardizing operating systems, budgets and the evaluation of Medical Malpractice and Liability in all European countries.

To the Reader and possible user of the Guidelines, which has also been prepared as a digital version in order to facilitate an easier professional use, is addressed the wish that any observations, comments, and above all, criticisms concerning improvement to the work be communicated to the Editor.

To the Co-Editors, R. Boscolo-Berto and G. Viel, the Authors of the chapters, and the Guidelines,

> Arbarello P, Ausania F, Baccino E, Bajanowski T, Cacciavillani I, Caplinskienė M, Castellano Arroyo M, De Angel Yágüez R, Fracasso T, Frati P, Gulino M, Pauliukevičius A, Rabl W, Raposo VL, Raudys R, Ricci P, Rippa Bonati M, Teteris O, Vabel G, Väli M, Vanezis P, Vieira DN, Villanueva E, Zampieri F, as well as the *Publisher*,

the most cordial thanks and appreciation for the distinguished individual and collegial contributions offered towards the realization of the monograph.

S. Davide Ferrara

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Part V Consensus Document: European Guidelines

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Part I
Overview

Herman Boerhaave—Hermanni Boerhaave ... Methodus studii medici, emaculata, & accessionibus loclupetata ab Alberto ab Haller ... Venetiis: ex Typographia Remondiniana, 1753. Courtesy of Historical "Vincenzo Pinali" Medical Library, University of Padova

Chapter 1
Present and Future Perspectives for Medical Malpractice, Responsibility, and Liability

S. Davide Ferrara, Guido Viel and Rafael Boscolo-Berto

Abstract This chapter examines the epidemiology of malpractice in Europe outlining the causes of the huge increase of this phenomenon, which has passed the stage and the connotation of mere *Epidemic*. Although the European Council has promoted actions to identify good practice in medical liability in 47 Member States, to allow a more uniform approach to the issue, the legal systems, operative roles, and institutions that handle medical responsibility in Europe remain heterogeneous and raise the need for an extensive harmonization process. The following chapters of the monograph and the medico-legal consensus guidelines developed under the patronage of the European Academy of Legal Medicine constitute a first step in this process of harmonization.

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The phenomenon of *Malpractice* or *Bad Healthcare* has long passed the stage and the connotation of mere *Epidemic*.

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Developed in the early 1980s in North America as a result of a series of significant cultural, social, structural, and economic factors relating to post-modern western society, today the phenomenon has definitively assumed the dimensions and the severity of a *Pandemic*, whose transversal invasiveness does not spare nations, structures, politico-institutional regimes, social classes, professional contexts, or cultural and ideological orientations. All are united and nourished by the propellant of the claim for *compensation of damage*, allegedly unjust, insofar as endured for the more or less serious subjective and/or objective fault-based liability of physicians, institutions or health professionals (Ferrara et al. 2010).

This concerns the fulfillment of the centuries-old path of emancipation that sees the decline of the trust of the "patient-child" in relation to the "Doctor-Father", once the exclusive protagonist of acts as a matter of priority driven by the principle of "first do no harm" (Kennedy 2003). It therefore concerns the definitive affirmation of the "Sick-Man", the new and unique protagonist of the "confrontation-conflict" with the physician and the institution. Both of these are technocrats, called upon to guarantee not only the means, but also the results of the healthcare process. Technocrats who provide healing, even at the advanced stages of illness, for virtually all diseases. In fact, they dispense constant physical and mental well-being, guaranteeable by reason of the pluripotency of Science that has become, in the collective imagination, a media-constructed myth of the infallibility and supremacy of man over nature and the dominion of reason over the mystery of life (Blendon et al. 2002). In truth, in the current and most advanced post-genomic era of "Systems Biology", science is only the cognition and vehicle of probability (rather than certainty) and, often, of the limited possibility of healing or partial therapy. The specialistic multi-fragmentation of knowledge and the know-how of each discipline are exhausted in the endless comparison between two kinds of truth (i.e., reason and fact), which belong to the current global society of risk, both environmental and behavioral, in which clinical and therapeutic medicine are an art of scientific "mimesis". That is, still "art", although with a scientific foundation and increasingly technological content. An art in which the primary responsibility resides in the respect of the Hippocratic oath of the 3rd millennium, of *knowledge*, *know-how* and again the *search for the truth*, through the identification and self-report to the medical community of errors committed during the performance of one's work and assistance (Ferrara and Pfeiffer 2010).

Over the past decade, the *phenomenon of denunciations* and/or *litigation*, judicial and extrajudicial, for cases of presumed "malpractice or bad healthcare" *has recorded an increase ranging from a minimum value of double-digit percentage* (>50 %) in Great Britain, the Baltic States, and Eastern Europe, to a maximum three-digit percentage (>200–500 %) in Germany, Italy, the Iberian countries and the Mediterranean area. The sole exceptions are France and the Scandinavian countries, where the growth of the phenomenon has been reversed as a result of exemplary innovations and simplifications of the system as set out below.

According to the latest epidemiological survey of the European Community, the Special Eurobarometer on Medical Errors in 2006, approximately 80 % of EU

citizens perceive medical errors as a major issue and about 50 % believe they will be personally involved in a case of Medical Malpractice (Eurobarometer Special 2006). This statistical analysis shows that public opinion has become aware of the fact that there are ways to pursue claims for compensation against healthcare professionals and Institutions that are not predestined to fail.

The percentage of acceptance for compensatory claims between 2005 and 2010 reached its peak in Sweden and Denmark (40 %), being smaller in Central and Southern Europe, with an average settlement of around € 30,000 per case in all of the EU Countries.

The exponential growth of the phenomenon has been accompanied by a proportional *increase in the cost of the coverage of claims*, estimated in excess of 200 % by the *European Hospital and Healthcare Federation* (HOPE) Standing Committee. These costs, distributed across the population, fluctuate between 9 and 15 euro per capita, with the highest figures recorded in Britain (Eurobarometer Special 2006).

Increases in the cost of coverage involve increasing difficulty in procuring insurance companies, especially for the most high risk surgical disciplines (gynecology, orthopedics, etc.), as well as for the largest hospitals, at times forced to resort to self-protection by budgetary adjustments, which are certainly not conducive to the ameliorative development of the quality and plurality of health services on offer.

Faced with this dramatic evolution, the *European Union* has thus far remained virtually *inert*, both on the legislative plane and that of proposals of operative systems, aimed at developing knowledge and solving the problems posed.

Since 1997, the year in which the "Convention on the dignity of human beings and biomedicine" was adopted (also called the "Oviedo Convention"), which in article four considers that the patient has a fundamental right to obtain compensation for unjustified damage (harm) suffered as a result of a medical intervention and in article 24 provides that any intervention in the healthcare sector should be carried out in compliance with norms and professional obligations, there has not been any normative action intended to harmonize the regulations regarding medical professional liability in Europe.

In May 2008 the Council of Europe organized a conference aimed at identifying good practice in medical liability in the 47 Member States, as well as alternative methods for resolving disputes.

The four sessions, into which the aforementioned Conference was divided, were devoted to giving an overview of medical liability in Europe, to the discussion and proposal of alternative methods that are more streamlined than the ordinary legal avenues for the resolution of cases of Medical Malpractice, as well as to the redefinition of the role of the public and private sectors in financing compensation (Heiderhoff 2009).

The Conference highlighted that benefits, with the very advantage of speed and cost-effectiveness for both patients and practitioners, were observed in European Countries in which alternatives to ordinary court-based channels had been introduced. The necessity of taking steps in order to strengthen trust between healthcare

professionals and patients was stressed, in particular with regard to new patient-safety policies, European training programmes for those concerned in healthcare, and appropriate ethical rules for professionals and responsible stakeholders.

Unfortunately, this useful moment for comparison and exchange, as well as for a statement of principles with a harmonizing value, was not followed by concrete initiatives with practical implications.

Dedicated *Reporting Systems*, capable of monitoring the phenomenon, are still lacking at the European level and at the level of individual nations. There are also no regulations, guidelines, recommendations, and EU guidelines to prevent, or at least reduce, the multiplicity of regulatory frameworks and national operative systems. Today one see the coexistence of systems anchored in the common law juridical models or, more directly, traceable to Roman law, such as, respectively, the Nordic countries and Great Britain, the Mediterranean countries and Central and Eastern Europe.

There exist dissimilar legislative-juridical models, from which arise diverse operating systems of dispute resolution, on the judicial, criminal, civil and/or administrative, or, mostly, extrajudicial basis.

In Belgium, Germany, Great Britain, Spain, and The Netherlands, the citizen can start either criminal or civil proceedings and there are few differences, if any, between these two routes to compensation.

In the remaining European countries, the criminal, civil, and administrative systems differ significantly from each other, in terms of the requirements used to ascertain possible medical liability, in the burden of proof, as well as in the assessment of the causal link between medical error and damage, and in the assessment of the compensable losses.

In the group of European countries that encourage judicial solutions, such as Austria, France, Germany, Great Britain, Portugal, and Sweden, systems exist based on national central institutions, divided into an interactive network with peripheral offices, to which are entrusted the tasks of settling disputes, establishing or denying the responsibility of the doctor and/or institutions and quantifying the damages suffered by the patient, whose compensation is entrusted to insurance companies or preestablished state compensatory funds. There are institutions such as the General Medical Council in the UK, the National and Regional sections Order of Doctors in Austria and Germany, the Institute and the National Council of Legal Medicine in Portugal or the Panel of Experts recognized in national registers, as in France and the Scandinavian countries.

In the German model, in force in Austria, Germany and the German-speaking area of Switzerland, albeit with minor inter-state differences, extrajudicial disputes are managed by specific Boards of Experts set up at the regional sections of the Order of doctors, in accordance with a statute approved by the individual Health Ministries (Heiderhoff 2009). These Boards, made up of doctors from various disciplines, provide their services free to patients who request it, according to the principle of voluntary participation of the parties involved in the case under examination, performed solely on the basis of written documentation and medical care, without any witnesses or circumstantial evidence. The opinion issued by the

Panel is not binding and the aggrieved party, if the outcome is unsatisfactory for him, may bring an action in the second instance by way of ordinary justice.

In the Portuguese model, still mainly focused on the solution of disputes through the judicial avenue, the fulcrum of medico-legal assessment is represented by the National Institute of Legal Medicine, organized over three main locations (Lisbon, Coimbra, and Porto). There is a National Medico-Legal Council, formed of regional representatives of the Orders of doctors, university professors of Law and Medicine, renowned specialists and representatives of the sections of the National Institute of Legal Medicine. This body may be consulted solely by the Ministry of Justice, the Supreme Council of the Judiciary, the Attorney General, and the President of the National Institute of Legal Medicine.

The Swedish model is interesting and peculiar, having provided since 1975 the Patient Claims Panel, a Board of Experts formed of nine Members, among whom there is the Chairman that presides over it (a regular Judge or a retired Judge), three Members who represent the interests of the patient, including one medical expert, a family member and one member who has special knowledge of health-care activities, and the other five Members representing the Insurance Company, the Hospital and the doctors involved. This Panel is an advisory body which provides recommendations. The patient benefits from the opinion of the Expert Body free of charge and is in any case free to make recourse to ordinary legal avenues if dissatisfied with the response, an eventuality that has proved quite remote, amounting to less than 2 % of all cases of suspected medical liability in Sweden.

Even more innovative and interesting is the French model introduced by the Law of the 4th of March 2002 ("Loi Kouchner"), which established the ≪ *Office National d'Indemnisation des accidents médicaux, des affections iatrogènes et des infections nosocomiales* ≫, usually called ONIAM.

The ONIAM, funded by a National Solidarity Fund, ≪ *dotation globale* ≫, intervenes in cases of medical accidents and iatrogenic injuries, when these are directly imputable to preventive actions, diagnosis or treatment with abnormal consequences for the patient in relation to his/her current or prospective state of health.

The claim, if the iatrogenic damage involves a permanent partial incapacity in excess of 25 % and/or a temporary incapacity to work for at least six months, is filed by the ≪ *Commission Régionale de Conciliation et d'Indemnisation* ≫ that designates an Expert or a Board of Experts selected from a national list, which provide a reasoned technical opinion within the maximum time of six months. The costs of that ascertainment are borne by the ONIAM.

From the above description, it can be seen that there exists a significant heterogeneity of legislative-juridical models, systems and operative practices, such heterogeneity being further reflected in the significant divergence of medicolegal assessment criteriology adopted in the various national contexts. This is so even within the category of the same nation, as in Italy and Spain, where there coexist diversified evaluative criteria as a result of the diverse guidelines and competence levels of the responsible Consultant, with the (so far) unavoided *consequence of*

assessing one and the same case of hypothetical medical malpractice and medical and/or institutional correlated liability *in a different manner*, depending on whether the patient has had the good or bad luck to come to harm from treatment provided in France rather than in Austria, Great Britain, Germany, Spain, or Italy.

The information owed to the patient, the consent to the medical act and the requirements necessary for the demonstration of the fact that the information has been provided and consent acquired are all understood in a different way. In Austria, Germany, France, Switzerland, and the Netherlands, the attending physician must demonstrate that he/she has adequately informed the patient of improbable, but serious, risks. Possible defects in information assume a decisive role in the criminal and civil trial for the ascertainment of possible professional liability. The legislation is not as stringent in other countries of Central, South, and East Europe.

Important differences are also detectable in the methodology used by the Technical Consultants and Surveyors of the various European countries in identifying diagnostic, prognostic and therapeutic errors and/or any possible failure to comply with important rules of conduct. Given the fact that, except in rare and specific exceptions, the doctor must answer not for the negative outcome of the diagnostic-therapeutic performance (obligation of result), but only the execution of that performance in accordance with appropriate standards of care (obligation of means or "*obligation de moyens*" in the French tradition), the problem lies in the lack of uniformity of these aforementioned minimum quality requirements of conduct, or a unique model of ideal reference that defines the standard of diligent conduct, understood as a set of duties incumbent on the physician and the other health professionals involved. One must of course differentiate the *standard of care* from the *duty of care* relating to each specific specialized medical sector, which are essential for the identification and grading of professional misconduct.

Professional standards for healthcare personnel are most commonly defined in general and vague terms in the majority of the legal systems of the various European countries. The operational details and procedures of a specific diagnostic and/or therapeutic act are typically derived from guidelines and recommendations developed within the medical profession; these documents are, however, only a guide to the medicolegal Expert called upon to assess the case and reconstruct the legal standard of care on the basis of available evidence (Cohen 2002).

Although the principle of taking medical knowledge as a reference, and in particular the evidence-based good practice, existing at the time of occurrence of the facts, is shared in almost all countries, the meaning to be given to the words "*duty of care*" is not equally harmonized. In some states, in fact, reference is made to "*lex artis*", intended as the best possible science at the relevant time (and thus the best treatment possible), while in others the possible liability of the practitioner or specialist physician is identified based on the comparison with the knowledge and technical-operational level of the average professional of that particular specialist field.

With regard to the concept of identification and grading of professional misconduct the example of Germany is emblematic, where the identification of a

serious therapeutic error ("*Grosse Behandlungsfehler*") involves shifting the burden of proof; the patient, in such a case, having only to report the circumstances of fact from which the serious error emerges, in violation of the rules of medical experience or basic knowledge of medicine (Heiderhoff 2009; Koziol 2011).

Even the evaluation of a material causal nexus between medical error and/or failure to comply with an important rule of conduct and the damage suffered by the patient is not homogeneous in the different European countries. Although in almost all Countries the theory of the "*conditio sine qua non*", supported by the model of subsumption under scientific laws of universal or statistical coverage, constitutes the minimum element that is essential for the causal imputation of the event, the interpretation of the concept of probability and therefore the degree of probability-certainty necessary to support the causal correlation between conduct and event varies, being sometimes frequentialist and at other times epistemological-logicist.

Even more heterogeneous is the assessment of the damage deriving from medical error, which in some countries, such as Germany, Austria, and Switzerland assumes the connotation of "*pretium doloris*", comprised of a plurality of immaterial damages and calculated on the basis of previous settlements in similar cases, while in Mediterranean countries such as Spain, Italy, and Portugal it is focused on the quantification and economic valuation of biological damage, distinct from existential loss, which is another form of extrapecuniary loss.

In Belgium, France, Italy, and Spain the damage from loss of *chances* is provided for, where chance is the possibility/right to be treated in an adequate manner and not to suffer any injury or harm from medical treatment. It concerns an extrapecuniary loss, clearly distinct from biological damage, quantifiable as a percentage of the loss corresponding to the likelihood of the chance, the rational assumption of which remains, however, somewhat doubtful due to the fact that the lost chance is not a real protected interest and, furthermore, it will always remain uncertain whether the physician has really caused the deterioration of the patient's health condition.

From the above-mentioned differences, the necessity of a future European harmonization of the legislative-juridical, operational, and institutional practices, and of the methodology of the medico-legal ascertainment clearly arises.

The following chapters and the drafting of the medico-legal guidelines constitute a first step in this process of harmonization.

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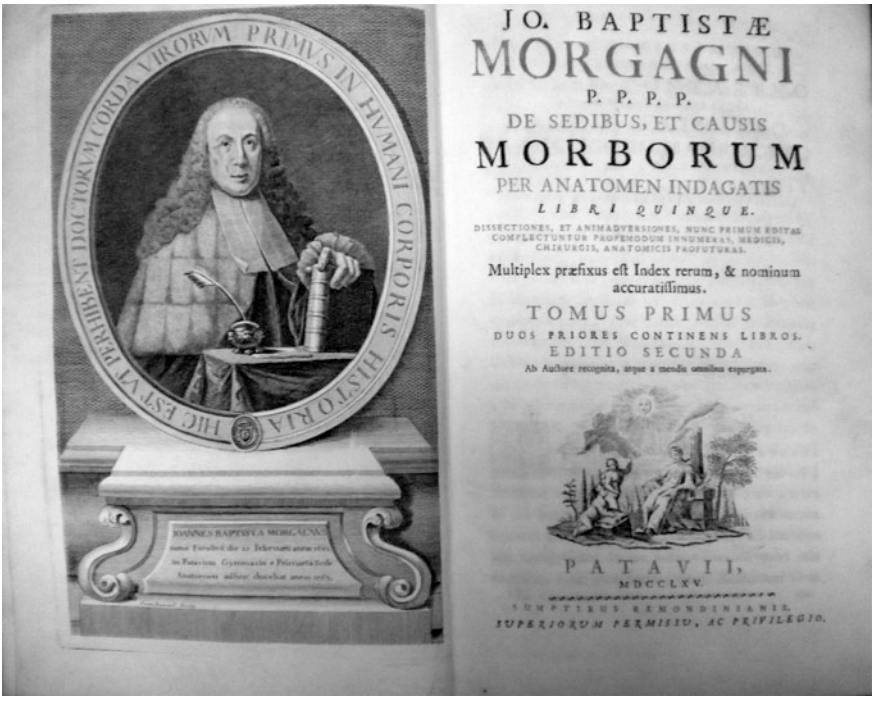
Part II
Historical Background



Giovanni Battista Morgagni—Jo. Baptistae Morgagni ... De sedibus et causis per anatomen indagatis ...Tomus primus …Editio secunda …Patavii: sumptibus remondinianii, 1765. Courtesy of historical "Vincenzo Pinali" Medical Library, University of Padova

Chapter 2
Historical Overview of Medical Liability

Maurizio Rippa Bonati and Fabio Zampieri

Abstract This chapter looks at the nature of medical responsibility through the examination of four emblematic "case studies" involving the experiences of the renowned Padovan physicians Gabriele Zerbi, Melchiorre Guilandino, Girolamo Mercuriale, Alessandro Knips Macoppe, and Gilberto Forti. The chapter's introduction provides a brief overview of the nature of the physician's role and responsibility from a historical point of view, especially with regard to the experience of Padova's first hospital and the development of the idea of medical responsibility through the works of the aforementioned physicians. Case I discusses the nature of the doctor–patient relationship as elaborated by Gabriele Zerbi in his *De cautelis medicorum*, one of the first works on medical deontology, as well as Zerbi's experience as physician to the Turkish Sultan. Case II concerns both the life of the physician Melchiorre Guilandino and the examination of his attempt, on behalf of the Venetian Council, to poison the Ambassador to the Turkish Sultan, thereby bringing into focus the difficulties concerning the role of the doctor in a specific political and diplomatic milieu. Case III focuses on the nature of political pressure on the physician and the issue of error in medical practice, through the examination of the events surrounding the outbreak of the plague of Venice in 1576 and Girolamo Mercuriale's role as medical advisor on the health care commission during that time. Case IV explores the aphorisms of Alessandro Knips Macoppe and the ideas of Gilberto Forti, highlighting the ambivalence of the physician who must care for and, in reputational terms, protect himself from his own patient. The conclusion of the chapter discusses the

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development of medical responsibility in the modern era and the difficulty of defining and monitoring the nature of medical responsibility as a branch of ethics.

Contents

2.1 Introduction

Medicine, whose noble task is men's health, has always been considered a superior—in some way sacred—activity, and thus often protected by a genuine immunity and, above all, impenetrability with regard to the judgment of the "non-medical".

Ladislao Münster, in an essay on the *De cautelis medicorum* of Gabriele Zerbi (1445–1505), which will be dealt with further on, wrote:

> [...] in the remotest times of Greek Medicine, the person of the physician, more than a common human being, is an infallible priest who interprets the will of a determined deity, and is far from being susceptible to the errors of a common mortal (Münster 1956, p. 60).

Even when, previously with Hippocrates, medicine had freed itself from religion in order to become a (secular) science, it maintained a certain aura of sacredness.

It is clear the doctors have always constituted a guild which pays close attention to its own preservation and self-defense, which is also—but not only—due to the delicacy of the profession, which is concerned with human lives, and its errors can have direct and dramatic repercussions on the life of men. Medicine has thus always been protected, explicitly or implicitly, from judgment regarding its work on the part of patients and society as whole. It is not by chance that the very concept of "medical liability" is only the product of contemporary reflection and that it was almost absent, at least in explicit form, in the past.

With regard to Padova, an example relating to its first Hospital, San Francesco Grande, active between the fifteenth and eighteenth centuries, could be particularly significant. Initially judged as one of the best European hospitals, in the course of

time it experienced a progressive institutional and—from what was reported in the press of the time—moral deterioration. Already at the beginning of the seventeenth century the financial situation aroused serious concerns (Ongaro 2007, p. 41). From this period various measures were followed, on the part the Hospital's managers, in order to rectify the situation, on the basis of detailed reports about the healthcare and economic management of the structure. Indeed, going over these reports, the treasurer appeared to be one of those most responsible for the infractions (Antonelli 1885, p. 45), while those responsible for the kitchen, the basement, the provisions and the cleaning—not to mention the nurses—also played a prominent role. What is extremely significant is the discovery of a failure in the midst of many accusations, namely that of the body of *physicians* in the healthcare structure.

As reported in a historic reconstruction of the nineteenth century, in the hospital it was noted that:

> […] the abandonment of the sick to subordinates, extremely serious and at times fatal oversights and misunderstandings; very scarce linen and furnishings, unclean beds, fetid wards, careless, incapable or inhumane nurses, in short such disciplinary and moral disorder that even the custom of abandoning to the servants the garments of the poor, in lieu of other income, had been introduced, and it is horrifying to read that such a custom was prohibited, because the iniquitous greed of these servants has arrived at such a point that it is in fact permitted—to humanity's horror—to procure death without delay, instead of assisting health, in order to fill their coffers through the sale of the garments of the poor (ibid, pp. 47–48).

In the midst of this degradation, in which commerce was even done with corpses, it is only the doctors who remain unnamed, even if the responsibility could be imputed to them for their "abandonment of the sick to the subalterns". This is clear proof of how much strength and immunity the profession enjoyed, to such an extent that it seemed barely conceivable to attribute to them any responsibility in such a blatant case of "medical malpractice".

The art of healthcare is screened against the judgment of "others" on its work almost exclusively through the constant reference to its "scientific basis", according to the various meanings that this term has assumed over the course of time. Medicine, beyond basing its immunity on the morality of the task entrusted to it, namely that of curing and healing, has founded its privileged status upon "science", on the exclusivity and technicality of the knowledge on which its work has always been based. Ever since Galen, the father of Roman Medicine and the unavoidable reference point for all the medieval doctors until the dawn of the nineteenth century, the doctor's medical expertise was also a guarantee of his morality (Wear et al. 1993, p. 3) and, consequently, absence of responsibility in the case of an unsuccessful treatment or the aggravation of an infirmity.

It must be admitted that, if the concept of medical responsibility belongs only to medicine, jurisprudence and the most recent bioethical reflection, it is equally true that doctors have always questioned themselves on this issue—it is enough to think of the Hippocratic Oath—and have always been confronted with concrete cases in which the issue of their responsibility toward patients and the community was

clear. Moral philosophy, in addition, has had a predominant role in University courses of the "Arts", of which medicine formed a part, since the beginning of the University itself (*ibid*, p. 1). And it is not by chance that the same Hippocratic Oath became an authoritative and normative reference text, thanks to the activity of the Universities of the Renaissance (Nutton 1993).

In the oath, for example, a paragraph reads as follows.

> I will make use of dietary measures for the benefit of the patients according to my power and my judgement and I will abstain from harm and injustice.

In this passage we find perhaps the two most fundamental issues of the problem of medical liability. First of all, to maintain that the doctor must abstain from "harm" and "injustice" means that he can be responsible for them; it means that this profession is constantly exposed to the possibility, and the risk, of causing harm and injustice. The doctor, then, must found his practice on his own "judgment", in its turn based on a technical–scientific knowledge in some way unique, protecting him, and which has protected him, in fact, from criticisms directed against his work on the part of patients and "non-doctors".

Since the concept of medical liability only emerged some decades ago, a history of such problems in the healthcare field does not even exist. Certainly, histories of medical ethics do exist, but none of them focused so clearly on the issue examined here. As a consequence, in this essay, we will not confront the issue in a systematic way, reserving to future studies and research the task of presenting a complete history of medical liability, but will limit ourselves to analyzing some paradigmatic cases of the past in which doctors have discussed their responsibility or have put forward their reflections on the subject. These cases will be drawn primarily from the history of the Faculty of Medicine at the University of Padova, chosen from among those with the most paradigmatic value, reassured by the fact that Padova, for many centuries, was one of the most important and attractive centers of study in Europe, particularly, but not only, during the Renaissance.

We will analyze, first of all, the figure of Gabriele Zerbi, doctor of medicine and philosophy in Padova and Bologna, as well as renowned Medical Practitioner in Rome and Venice, as the author of one of the very first manuals of medical ethics, *De cautelis medicorum* (Zerbi 1495). In spite of the "caution" that Zerbi professed, the Veronese doctor was a victim of the wrath of the relatives of his famous patient, the Turkish Sultan: they eventually ordered his brutal execution.

As for concrete cases we will analyze the events connected to Melchiorre Guilandino (1520ca–1589) and Girolamo Mercuriale (1530–1606). The first was Prefect of the Botanical Garden of Padova from 1561 and Professor of Botany (*Simple Reading*) from 1567. In 1574 the Council of Ten, the government of Venice responsible for the security of the State, commissioned him to prepare a poison in order to eliminate a spy from Constantinople. The case is exemplary due to the fact that the doctor, as well as being equipped with the technical knowledge required for healing, can also make use of it in order to kill or cause suffering.

With regard to Mercuriale, we will analyze the famous medical consultation of the 9th of June 1576, provided together with his colleague Girolamo Capodivacca

(† 1589), requested by the Venetian Senate concerning the plague, which had been claiming victims since August of the previous year. The two doctors, on the basis of Hippocratic reasoning quite removed from reality, maintained that it was not a real epidemic. The Senate, accepting their opinion, delayed putting into practice the customary hygienic and prophylactic measures, which facilitated the outbreak of an epidemic that would kill more than fifty-thousand people. Finally, concerning the reflections on issues of responsibility, we will consider the collection of aphorisms and the so-called "rules of etiquette" for eighteenth and nineteenth century doctors, such as Giuseppe Pasta's (1750–1825) "Rules of Etiquette for Doctors" and Ferdinando Coletti's (1819–1881) "Rules of Etiquette for Doctors and Patients". We will refer, in particular, to the "Aphorisms" published by Alessandro Knips Macoppe (1662–1774), since they were widely available in the eighteenth century as well as the subsequent century, and inasmuch as they contain some original and, we believe, extremely important concepts.

2.2 Cases

2.2.1 Case I. The Doctor–Patient Relationship Between "Ethics" and "Cunning": Gabriele Zerbi

Gabriele Zerbi—or "Zerbus", "de Zerbi", "Zerbo", "Zerbis", "Gerbo", "Gerbi", and "Gerbus" according to the customary variability of surnames in former times—was born in Verona to a noble family. He probably studied medicine in Padova, where he was professor of philosophy from 1467 at just 22 years of age (Münster 1950, p. 69). In 1475 he moved to Bologna, where he remained until 1483 as professor of medicine and also, from 1480, as professor of philosophy (*ibid*, pp. 73–74). He subsequently moved to Rome, where he stayed until 1494. Finally, toward the end of 1504 or at the beginning of 1505, Zerbi departed with his son on the "fateful journey to Constantinople", which will be discussed in more detail later (*ibid*, p. 77).

Zerbi was also well known, in addition to the manual of medical deontology that will be the focus of our analysis, for the essay on geriatric pathologies, the *Gerontocomia* of 1489, and for his contributions to anatomy summarized in the *Liber anathomie corporis humani et singulorum membro rumillius* of 1502.

The *De cautelis medicorum* was not the first ever treatise of medical deontology, since, for example, some years before, also in Padova, Alessandro Benedetti (1450cc–1512) had published a collection of medical-deontological aphorisms, the *Collectiones medicinae* (Benedetti 1493; Ongaro 1981, p. 89). In addition, guides to the practice of medicine similar to that of Zerbi had also been circulating in manuscript form since the thirteenth century. Very famous, from the beginning of the fourteenth century, was a text with the same name—*De cautelis medicorum*—attributed to Arnaldo di Villanova (1240–1313) (Münster 1956, pp. 63–65; Linden 1999, pp. 31–34).

Fig. 2.1 Allegory of prudence. Oil on canvas, Titian, about 1565, The National Gallery, London

The caution of which these manuals were the mouthpiece roughly corresponded to the concept of "prudence". Returning to the analysis of David Linden, we remember that the medieval and renaissance allegories of Prudence depicted it with three faces. Since it also contained the faculty of memory, intelligence, and foresight, it was also, through each one of these, linked to the past, present, and future (Fig. 2.1). In the ancient world precisely this kind of knowledge was of the Muses, visionaries, and *medicine*, inasmuch as it "Declares the past, clarifies the present and predicts the future" (Linden 1999, p. 19).

Medical ethics, which has crossed centuries of medical history almost unscathed, is certainly the product of the union between Hippocratic and Catholic ethics. If the fundamental deontological precepts remained almost unaltered through time, the figure of the doctor was to change profoundly. One of the crucial moments was the late Middle Ages, in which it was increasingly asserted that the "medical class" was a social entity. In what came to take shape as "class consciousness", the duties of the physician were no longer the preserve of a single

individual, but were the expression of the entire guild to which he or she belonged. Becoming part of a specific social fabric and for the most part a citizen, the doctor took on roles involving new duties, such as caring for the sick in the event of an epidemic, treating the destitute, and performing other medicolegal tasks (*ibid*, p. 62). Consequently, for doctors the risk of being accused of not taking *responsibility*, or of being *responsible* for shortcomings in relation to their social and institutional duties increased. Their social position, usually quite privileged, also made them more vulnerable to jealousy, envy, and competition, which increased the risk of accusations and aggression.

So, the *De cautelis medicorum* is perhaps the first complete expression of an ethics founded on the awareness that the doctor belongs to a particular class, with its own rights and duties, and is in need of specific tools so that his preservation and prosperity are assured in a community constituted of other classes of potential competitors (Münster 1956, p. 61; French 1993). In this treatise, as will be briefly discussed below, one finds a very peculiar mixture, in addition to that between Hippocratic and Catholic precepts, of a certain amount of cynicism and astuteness, which the doctor must exercise in order to preserve himself; subtleties that render the text, among other things, extremely vivacious and alive.

All of this becomes somewhat evident from the Prologue, in which Zerbi explained what he meant by "caution" (we will use here the translation published by Clodomiro Manicini 1963).

> Caution is the avoidance, through diligent attention, of deception, i.e. fraud, infamy and dishonor, which happen to the doctor in the act of operating on the human body […] like those called to fight, blocking with a raised arm and defending their face with their hands in between like a trench, so the doctor must always be intent in his soul and in his work with every type of caution against the strength and petulance of the malicious (Zerbi 1495; in Mancini 1963, p. 16).

The doctor, therefore, had to know how to defend himself against the "malicious"; caution was the tool needed in order to avoid, essentially, being held *responsible* for errors or evil actions. In this sense, we believe that the concepts of caution and responsibility were, albeit implicitly, linked by a profound nexus.

The treatise is subdivided into five chapters, in addition to the Prologue. The first is concerned with what the physician's body and spirit must be like. The second describes how he must behave in conformity with Christian principles: to be, that is, pure of soul and even to advise the patients to purify their spirits, since illnesses are fought, above all, with the help of God. The third chapter regards the general behavior of the doctor, from everything that he should not do, to how he should walk and dress. The fourth concerns specific behavior with regard to patients, where the problem of responsibility emerges more clearly. The fifth deals with the behavior of the doctor in relation to his assistants and collaborators, those who assist the patient and the public (some authors believe that the latter subject constituted a separate chapter, but the issue is not relevant here).

As Robert French argued, Zerbi's rules were essentially fashioned by Zerbi to support and reinforce the guild of doctors to which he, as a doctor and university

graduate, belonged, in the fight against competing groups in the healthcare market. This is evidenced by the importance given by Zerbi to the preservation of the good *reputation* of the doctor (French 1993). Good *reputation*, in its diverse forms, constituted, after all, the fundamental defense against possible accusations of *responsibility* in case of death, damage, or the failure of the treatment. Reputation was guaranteed, mostly through *solidarity* among the members of the guild of physicians, and it is not by chance that Zerbi provides a series of suggestions along this line concerning "the behavior of the doctor towards other doctors charged with the same responsibility", such as that of never speaking badly of a colleague in public and, if he has committed an error, to correct him in secret (Zerbi 1495; in Mancini 1963, pp. 65–68). It is no coincidence, we believe, if this aspect was taken up again and explored in greater detail also in the first text in which the term "Medical ethics" was coined, namely the *Medical Ethics* published by Thomas Percival (1740–1804) in 1794 (Wear et al. 1993, p. 4).

The following phrase of Zerbi, regarding reputation, is paradigmatic.

> In fact, most patients are more confident in the doctor whose fame is great, and the confidence that the patient has in the doctor is worth, in terms of health restoration, even more than the doctor's actual capacity […]. The acquisition of good fame, or its conservation, is complete if the doctor is equipped with good manners, conducting a praiseworthy life (Zerbi 1495; in Mancini 1963, p. 27).

Reputation, beyond style of life, was based on a good physical constitution, as revealed in the first chapter.

> As for those things regarding the body, it is a great benefit for the completion and perfection of the doctor that he be of a good complexion and temperament, approaching, as far as possible, the correct average in terms of physical constitution and stature […] neither ugly nor deformed, so that he is not despised by all, but halfway between the two extremes, as virtue is (*ibid*, p. 24).

Good constitution, which would necessarily mean good health.

> Finally, the doctor must take care to monitor his own health, so that, if by any chance he happened to become ill, they do not say to him with derision: physician, heal thyself (*ibid*, p. 34).

The reputation of the doctor also had to be based on the observance of very strict Christian precepts, as highlighted in the second chapter (*ibid*, pp. 25–26), or reinforced by dressing in a dignified manner, decent and clean, as underlined in the third chapter.

> As for those bodily things, the doctor is clean and far from any dirt and must behave cleanly and honestly to the highest degree, be both elegant and adorned in dress, but in any case not occupy himself so much with cleanliness and clothing that he forgets the science (*ibid*, p. 34).

The reputation of the doctor, as underlined in the fifth chapter, also had to be defended even by his assistants and nurses, and for this the doctor had to know how to choose them, pay them, and treat them well, or know how to render their friends in the case that they were imposed (*ibid*, pp. 63–64).

To protect his reputation and defend his responsibility in case of damage or negligence, the doctor could use real "cunning" (Münster 1956, p. 69). One can find some stratagems suggested by Zerbi that are, at times, at the very limits of morality.

The doctor, for example, could use parables and proverbs:

> […] doctors should not be ashamed to be called chatterers by jurists, since by other non-doctors, no matter how very literate, the subtle and difficult things of medicine are not understood if they cannot be spoken of as parables (Zerbi 1495; in Mancini 1963, p. 29).

Other cunning, when one was accompanied by relatives in visiting the patient, consisted of informing oneself of everything possible on the way and, having reached said patient, carefully observing the possible presence of some particular food or herb, so as to give the impression of having already guessed the characteristics of the illness at first sight (Münster 1956, p. 70):

> [...] the doctor, taken to visit a sick man, uses sound caution in going: he must, in fact, question his accompanier on the illness of the patient and on anything that has occurred in relation to his appetite, sleep, to the benefit of the stomach and the like. […] He also uses another kind of caution, when he enters into the place where the patient resides, namely, looking around in case he sees fruits, herbs or some fomentation that has been prepared from which to make conjectures about the illness of the patient […]. In this way the good doctor will be judged knowledgeable and the patient will confide in him eagerly, as an expert on his illness and the author of his salvation (Zerbi 1495; in Mancini 1963, pp. 40–41).

One interesting stratagem also consisted in measuring the pulse for a long time, even more than was necessary, in order to give the impression of being particularly scrupulous.

> It is also a good precaution to spend a long time over the touching, in order to be able to understand the pulse even with weak pressure and in addition to be thought more attentive, diligent and gracious by the patient and the bystanders (*ibid*, p. 42).

Delaying for as long as possible the prognosis, in order to have time to observe the evolution of the illness and in this way reduce the risk of error, but, above all, to always remain vague in providing it, so as to avoid being accused, in retrospect, of having committed an error, is an essential precaution.

> If good signs prevail one declares health, but in the opposite case, death: nevertheless, in declaring his opinion the doctor will always be ambiguous (*ibid*, p. 47).

Such advice concerning ambiguity, it seems to us, is somewhat unscrupulous and is certainly difficult to align with Christian principles, especially since Zerbi insisted on this point, arguing that the doctor should always remain indeterminate, even if pressed to give a clearer response. Consistent with this was the advice never to put a prescription in writing so as to avoid being accused in case of damage to the patient (*ibid*, p. 70).

Along the same line of moral unscrupulousness is the precaution, as preached by Zerbi, of presenting as *serious* a *doubtful* prognosis, both to avoid being held

responsible, in the event of a fatal outcome, for such inevitability and in order to earn greater esteem in the event of the termination of the evil.

It is worth quoting the entire passage:

> [...] and if the illness will not be of the number that are completely good, nor mortal, but, as they say, suspicious, which makes the doctor hesitate in his judgment, it is safer and, as they say, more praiseworthy, to consider the illness dangerous and worsen the case; in fact to announce the danger of approaching death in the patient, even if this illness, among those that are suspicious, is weak, mild or phlegmatic, depending upon a small amount of non-malignant substance; so that if the patient, by his own error or those who assist him, or due to extrinsic causes, takes a turn for the worse, the doctor will be lawfully excused for this. Neither will he be suspected by friends and relatives of the patient. In addition the doctor will be excused, and everybody will say that from the beginning he had seen and judged correctly. If instead the patient is saved, the common people will say that it was precisely the doctor who cured him and who gave the patient his health back, and the doctor will obtain greater praise and a larger prize. And, to say it briefly, the doctor must exaggerate the suspicious illnesses and, inversely, cast doubt upon the mild ones (*ibid*, p. 49).

The doctor, essentially, must know how to *dissemble* in order to preserve his honor, and this is also the case in many other circumstances. For example:

> [...] at every visit the doctor tries to do something new, ordering or exchanging or subtracting or adding, so that it does not seem that he has visited the patient in vain (*ibid*, p. 53).

In some way, almost paradoxically, Zerbi advised the doctor… not to use medicine, i.e., drugs. This, in the final analysis, precisely in order to avoid responsibility for damage to the patient:

Nevertheless, if the use of medicine becomes necessary, the doctor uses the blandest and the most suitable by nature. Thus, he will use the medicine based on diet rather than on real medicine […] (*ibid*, p. 53).

Other cunning, at the limits of morality, in order to avoid being held responsible for negligence or error, consisted, according to Zerbi, in blaming the patient or the circumstances in the event of failure of the "solutive" drugs, if it were essential to use them.

> It is well that the doctor, if there is no effect after having given the solutive drug, blames those who are assisting the patient, or the bad regimen of the patient, or because he has slept, or because he has not slept, or because he did not sleep after taking the drug, or because he has been exposed to the air or the wind, or because he was irate, or for other such things (*ibid*, p. 56).

These last recommendations are all found in the fourth chapter (with the exception of the one about not writing prescriptions), which, dealing with "On the behavior of the physician toward the patients and especially the sick", is perhaps the most important in relation to the concept of responsibility. Highly moral precepts, derived above all from Catholic ethics, are mixed in this chapter, in a highly emblematic way, with strategies and tricks, discussed above, which seem anything but moral. It was a mixture that led French to ask himself, with an amusing turn of phrase, how ethical this medical ethics was (French 1993, p. 72).

In this chapter Zerbi also advises dealing only with the sick, and not with other things in their house, and not to praise them in order to obtain approval (Zerbi 1495; in Mancini 1963, pp. 35–36); never to postpone a visit to the day after, since the doctor must not be sparing of his gift, that of curing, given to him by God (*ibid*, p. 37); never to prescribe a drug hurriedly and to visit for the love of God, more than for the reward (*ibid*, p. 37); to continually assist the patient in the event of acute illness, since conditions can change quickly (*ibid*, p. 37).

The doctor who postponed a visit, or who did not sufficiently assist a patient, in effect, could have been held responsible for negligence; while in the case of an incorrect drug, which resulted in an even worse evil, the responsibility could be even more direct. And, with regard to drugs, this is the chapter in which Zerbi returned to the famous Hippocratic prohibition on preparing poisons or causing miscarriages (*ibid*, pp. 57–58). Concerning that last point, Zerbi advised the doctor always to give bland drugs to pregnant women, and to give them in the presence of family members, in order not to be suspected, in the case of sudden miscarriage, of having caused it on purpose (*ibid*, p. 57).

Other recommendations were that the doctor always nurse the hope of the patient, also because "[…] the complexion of the body is always connected and subjected to the state of the soul" (*ibid*, p. 39), but did not take on "ancient and malign" illnesses left by others and did not promise, in these cases, recovery. That before visiting the patient, he rested for a moment, and let the patient rest, in order not to risk that tiredness and emotion might alter his judgment (*ibid*, p. 41) and that, once rested, he examined first of all the face (*ibid*, p. 42); that he interrogated with great care and attention not only the patient, but also the relatives and friends, in order not to be tricked by the patient and that, for the same reason, he did not fear to ask him anything, even intimate, that could be useful for understanding the disease (*ibid*, p. 44); that, in any case, he never uttered in front of the patient himself that he should "distrust his health", so as not to influence his spirit (*ibid*, p. 49); that, in the case of certain death, the doctor announced it to him with "simulated sadness" (*ibid*, p. 50).

An interesting passage is the one in which Zerbi advises the doctor to sample, smell, taste, and measure the things that had to be administered to the patient, according to his directions, through diet.

> In this way the doctor will be judged more accurate and will avoid the blemish of negligence and inadvertence. Nevertheless, the doctor observes the measure of these things, in a way that his honor will be saved, by not performing the task of women and of those who assist the patient, because in such a way he would demean himself (*ibid*, pp. 52–53).

Zerbi advised that the doctor, finally, not deliberately prolong the duration of the illness with the prospect of gain. To this purely moral concept, nevertheless, was added a more utilitarian one, still aimed at the preservation of the reputation of both the individual practitioner as well as the entire guild.

> When illnesses are prolonged they do not leave the doctor immune from infamy, especially among the common people (*ibid*, p. 58).

That the doctor was paid, and paid well, remained, in any case, an indispensible necessity, motivated by the fact that the patients and the relatives, in order not to waste the money disbursed, could not but be diligent in following the doctor's instructions:

> […] medicine bought at a dear price is wont to benefit many, but if it is given for free it is not useful (*ibid*, p. 58).

With this last quotation we can symbolically close our analysis of *De cautelis*.

It might be interesting, however, to briefly relate the tragic end of the Veronese doctor, as narrated by his contemporary, the humanist Pierio Valeriano (1477–1558). As mentioned in the *Introduction*, Zerbi was called, on the basis of his fame, which evidently extended beyond the borders of the place in which he worked, to treat the Turkish Sultan, who was suffering from a serious form of dysentery. Here is the passage of Valeriano.

> In the meanwhile it happened that one of the first visitors to the Sultan, who was unwell with incurable dysentery, addressed himself to the well-known Andrea Gritti, now our Doge, so that there be sent as soon as possible a talented Italian doctor, assuring him great rewards in proportion to his merit, as well as the voyage and the importance of the treatment. Zerbi assumed the task and, already brooding over an immense fortune in his head, set off for Constantinople, taking with him his young son. The Ottoman Minister thus cured and happily restored to health, he [Zerbi] was generously remunerated with gold, garments, gems, silver vases of fine china and many other rich ornaments, so that, if he had brought them home, he could have contended, in terms of wealth, with any European ruler. In fact, the cure proceeded with the greatest success and the Vizier himself confessed to owing both his life and health to the valor of Zerbi; the which, because he had received the salutary advice to maintain his health from then on, honorably took his leave. Zerbi, loading various beasts of burden for his precious furniture, came to a castle at the border of Turkey, where he had to linger for some days, waiting -under the guarantee of the Law of Nations—for an opportune encounter with a Christian ship that would take him to Dalmatia. In that brief time it happened that the Sultan, neglecting Zerbi's advice, and by nature disposed to excessive incontinence, returned to his old ways and become even sicker than before, which in a few days led him to the grave. His children, gathering together, in order to get back the precious gifts their father had given to Zerbi, spread the word that the doctor had poisoned him. They then sent some emissaries to lead them to him. In fact, they found Zerbi and imprisoned him together with his son and, taking charge of his effects, brought them both back: and, impudently slandering the father, they tortured him, making use of a new and barbarous technique, by firstly placing the youth between two tables and sawing him in half in front of his father's eyes, on whom they then inflicted the same atrocious torture (Valeriano in Mancini 1963, pp. 6–7).

We do not know what really happened, although the version presented here does not leave room for many interpretations, and we also hope that further studies may shed light on the reasons for such a horrible ordeal, but what is surprising, almost shocking, is that the Veronese physician was the victim of his patient even though he, Zerbi, should have been an expert at knowing how to protect himself against such events.

2.2.2 Case II. Melchiorre Guilandino and the Strange Cure

One of the constants of medical ethics is the prohibition of *harm*, especially if actively practiced with actions that are damaging to health and with the administration of toxic substances. The Hippocratic Oath prescribed the absolute prohibition on preparing poisons, and the prohibition was reiterated many times, even in the earlier cited *De cautelis medicorum*by Zerbi: "[…] do not prepare [the physician] or administer any potion apt to cause death or miscarriage" (Zerbi 1495 in Mancini 1963, p. 38).

> Observe the commands of Hippocrates in his Oath. The doctor does not administer a deadly poison to anyone, even if requested, and does not recommend it to anybody, nor prescribe it, nor talk of it; and he does not give, nor advise, to pregnant women, potions in order to kill the fetus, in fact he promptly denies it, nor says to anyone what it is, and accuses and reproves the inquirer. If the reprimand does not have effect, it is necessary to rise against such people with a harsh face (*ibid*, p. 57).

But as for all human activities, even those regulated by apparently rigid and unalterable rules, there can be exceptions. It was precisely Zerbi, among other things, who foresaw the possibility that the doctor might also be forced to prescribe, if not actual poisons, at least very strong and potentially dangerous drugs (a border, that existing between a drug and a poison, which has always been perilously fragile). In such a case he advised being present at their preparation and, above all, that the prescription never be in written form, in order that the doctor not be accused of anything (*ibid*, p. 70).

In this section we will look at the interesting and very significant events that involved Melchiorre Guilandino and the Republic of Venice in relation, in fact, to the preparation of a deadly poison. The biography of Guilandino is as rich in science and culture as it is in academic and personal disputes, journeys, and love; which makes it an exemplary case of the "spirit of the age" of the Renaissance, a combination of "soul" and "flesh", "earth" and "sky" at the same time.

Melchiorre Guilandino, the italianized name of Melchior Wield, was born in Königsberg around 1520, apparently the illegitimate son of a priest, even if this hypothesis is based on the accusations of Pietro Andrea Mattioli (1501–1578), the renowned botanist with whom Guilandino had been engaged in a bitter dispute (Ferrari 1959). A precocious genius, he set off for Italy in order to study: he graduated in Bologna in 1555 (Trevisan 1995, p. 59). In Rome he became the protégé of the Venetian ambassador Marino Cavalli (1500–1573) (De Toni 1923, p. 73), an influential diplomat who, between 1550 and 1558, also took on an important position in the Administration of Venetian culture in general and, in particular, the University of Padova, being included among the "*Studiorum Reformatores*" (Olivieri 1979; Preto 1989–1990). Cavalli presented Guilandino to Gabriele Falloppia (1523–1562), at that time professor of anatomy at the "*Studium Patavinum*", who welcomed him into his home (Favaro 1928, pp. 122–123). A very strong friendship arose between the two of them, based on coexistence and sharing, which some, in retrospect, saw as evidence of one of the first homosexual

"unmarried couples" of the Renaissance (an idea made public by a journalist who dared to do what the historians would not; Visentin 2007), perhaps in this also driven by the Mattioli's accusations who, in an extremely bitter letter to Fallopia, defined Guilandino as a "whore". In any case, when Falloppia died prematurely, it seems that Guilandino had these heartfelt words inscribed on his grave (even if the attribution of the verses is not certain, seeing as the grave no longer exists: Favaro, 1928, pp. 158–159; Visentin 2007).

> In questa tomba non verrai sepolto solo
> con te viene sepolta anche la nostra casa
> (In this grave you will not be buried alone
> with you will also be buried our home).

We do not know the real origin of the bitterness between Guilandino and Mattioli, which had so much weight in the personal life of the Prussian botanist. Besides academic disputes owing to the interpretation of certain passages of classical authors on the subject of botany (Ferrari 1959), it seems that Mattioli was rather hostile toward foreigners, enough to write in a letter:

> […] what good these treacherous barbarians have they learn from Italy, where they arrive as beasts and leave as men (Mattioli in Ferrari 1959, p. 40; Trevisan 1995, p. 59).

Mattioli was also a close friend of Falloppia, and was perhaps somewhat jealous of the very close friendship that had arisen between the great anatomist and Guilandino. It even seems that Guilandino had found a letter of Mattioli addressed to Falloppia, in which Mattioli advised him to kill Guilandino with poison, without this unusual and violent counsel arousing any reaction in the recipient (Favaro 1928, p. 128). This demonstrates how the use of this "method" at the time—and not only—was quite common, and how deeply medicine was involved in its use, as medicine was among the main repositories of knowledge for producing different types of poisons.

It is certain, in any case, that Guilandino published a pamphlet denouncing, in strong words, the errors in the works of Mattioli, who wrote a terrible letter to Falloppia in which he defined Guilandino as:

> […] that sad wretch of a priest and a whore (does he think that I do not know about his dirty genealogy?) (Visentin 2007).

Falloppia did not respond to the accusations Mattioli, who continued to slander the two friends by claiming, as already mentioned, that they were homosexuals (Favaro 1928, p. 128), until Falloppia was forced to advise Guilandino to leave Italy, officially for a study trip to collect new species of plants in the East, but, in reality, more likely in order to avoid the possibility that the Inquisition might have become interested in their case.

Guilandino, after some years of peregrination, was captured by Algerian pirates and, in addition to his liberty, also lost all of the scientific material that he had collected, but he was not abandoned by his friend Falloppia, who hurriedly collected 200 gold crowns and departed, even though he was by then seriously ill

(suffering from a rather advanced stage of syphilis), and managed to rescue his friend (Favaro 1928, pp. 131–132; Preto 1989–1990, p. 233; Trevisan 1995, p. 60).

Upon returning to Padova, the disputes with Mattioli were settled (Ferrari 1959, pp. 411–412). Guilandino, always supported by his Pygmalion friend, was appointed Prefect of the Botanical Garden of Padova in 1561 and under his guidance the Garden became famous throughout Europe (Gola 1947, pp. 13–14).

Now, the adventurous life of the Prussian botanist was enriched by an event that is usually not reported by biographers, but which we find very important, almost emblematic, in relation to the subject being dealt with here and which has been reconstructed by Paolo Preto (whose reconstruction we make reference to: Preto 1989–1990).

The antecedent involves the sending of a certain Mustafà dai Cordoani to Venice, a Cordovan leather craftsman, then ambassador to the Turkish Sultan, first in October of 1574 and then in June 1576, in order to officially request the restitution of some escaped slaves (Pedani 1994, p. 194). The "Baili", that is, the Venetian ambassadors in Constantinople, nevertheless considered him a spy of Pasha Mehemet, charged with plotting against the Republic or the Papal State.

After some deliberation, the Venetian "Council of Ten" (Fig. 2.2), magistrates responsible for the defense of the city, decreed that Mustafà should be poisoned and for this appealed to the offices of Guilandino. Here is how Preto summarizes the events, drawing on quotations from the documents found in the State Archives of Venice.

> Finally, on October 16th [1574], having made their usual statement that "looking for the good service of Christianity and particularly of our Republic, the life of the disowned Mustafà will be taken from him, hardened spy of Turkey, who at present is located in this city", the Council deliberated that "it can be done secretly, by poisoning Mustafa at a predetermined time, either in this city, or outside in the army" and summoned "our faithful Marchi ò Vilandrino [Melchiorre Guilandino], who awaits at the horticultural garden in Padova.": the sage of the mainland Sigismondo Cavalli, charged with conducting him to Venice, will explain to him that, due to a fire in the Ducal Palace, the "recipes for poison" have gone missing and therefore will ask him to prepare two or three of them "and also make such compositions to be kept in storage", in the certainty "that for the intelligence that he has of these things, he will make this composition that will undoubtedly have the effect for which it is composed, and that he will faithfully keep everything very secret" (Preto 1989–1990, p. 234).

So, in front of the *categorical desires* of the Council of Ten there was no Hippocratic Oath that could withstand. Sigismondo Cavalli (1530–1579), in addition, was the son of Marino, the old protector of Guilandino who had introduced him to the friendship of Falloppia: it could also have been, therefore, a personal debt of gratitude. The fact remains that Guilandino went to Venice, provided the poison recipes—contradicting, in this, also the "caution" professed by Zerbi, according to which the doctor must never leave a trace of prescriptions for dangerous drugs, much less, therefore, for poisons expressly created in order to kill—and the Council commissioned Vincenzo Degli Alessandrini (whose dates of birth and death are both unknown), the former Venetian ambassador to Persia, to administer the poision to Mustafà.

Fig. 2.2 "The Council of Ten" (in *red gown* with *black sash*) while witnessing the beheading of Doge Marin Faliero (1285–1355). Oil on canvas, Francisco Hayez, 1867, Pinacoteca di Brera, Milan

The ambassador, therefore, administered the poison twice, on the 10th and the 19th of October 1574, but "unfortunately" it did not have any effect. On the 20th of October, in fact, the Council wrote to the Governor of Constantinople, informing him of the imminent arrival of Mustafà in the Ottoman city, and asking him to attempt to render him less hostile to Venice and, at the same time, discredit him in front of the Pasha (*ibid*, p. 235).

Nevertheless, the Council of the Ten did not give up. They requested the counsel of another doctor, a certain "Comasco" "who—as Preto reports—has at other times confidently provided this counsel on similar occasions" (*ibid*): which proves, again, how this service of the doctors, with regard to poisons, was

customary. The poison, in any case, did not arrive in time and the attempts to kill the spy during his return voyage to Constantinople came to nothing.

On June 1576, as already mentioned, Mustafà was again in Venice. This time his journey was fatal. A certain Captain Trec, evidently disdaining the subtleties of poisons, strangled him. The assassination, at that time, was given a fortuitous, if tragic, cover: the plague was spreading—the same epidemic that we will look at in the following section. The epidemic might perhaps have acted, however, in place of the assassins, or at the least would have made the action more maskable. Indeed, on the 18th of August, a letter was sent to the Governor of Constantinople informing him of the death of Mustafà, found lying dead in the street from the plague, (*ibid*, p. 236). Preto concludes thus:

> [...] the noose of the expert Captain Trec worked better than the "water" of the renowned Guilandino (*ibid*, p. 236).

A brief comment is necessary. We do not know whether Guilandino deliberately chose to prepare a poison that was not completely effective. This would have been a very wise and shrewd "caution", but there is no evidence of any kind in its favor. Regardless of this particular fact, however, we can maintain that the case of the Prussian botanist clearly demonstrates how much medicine can become involved in the political and diplomatic plots of its milieu, thanks not only to its technical knowledge concerning the preparation of poisons, but also, more generally, concerning the structure and functions of the human body. Emblematic, for example, is the case of physicians who participated in the bloody interrogations of the Inquisition, to which we intend to devote more extensive research. This means that medical ethics has found itself confronted with extreme cases from its very beginning, and this, perhaps, has favored the emergence of a pragmatic ethics and mentality, which is indeed typical of medicine. A mentality able to hold certain principles as inviolable, but also aware that the shifting world of reality can also require, at times, their violation.

2.2.3 Case III. A Healthcare Commission and Reason of State: Even Luminaries Make Mistakes

Girolamo Mercuriale, born in Forlì on the 30th of September 1530, studied medicine in Padova and obtained a doctorate in medicine and philosophy on the 17th of April 1555 at the Venice "*Medicorum Physicorum Collegium*", the only Institution, besides the *Studium Patavinum*, that had the power, in the Veneto, to confer degrees in medicine (Ongaro and Forin 2008, p. 31; Ongaro 2009, p. 620). While continuing to liaise with the *Studium Patavinum*, after his graduation he settled in Forlì, where he practiced medicine and deepened his study of Greek. In Padova, particularly, he was the student of Vittore Trincavella (1476–1568), the student and friend of Gabriele Falloppia (1523–1562), while his acquaintance with Guilandino (Ferrari 1959) provided a polemical background.

In 1561 Mercuriale was sent to Pius IV in Rome as a member of a diplomatic mission and remained there until 1569 as a pupil of Cardinal Alessandro Farnese (1520–1589) (Ongaro 2009, p. 620). In Farnese's house, Mercuriale was able to study important documents and ancient books, fundamental sources for his renowned work *De arte gymnastica* (*ibid*, p. 621; Palmer 2008, p. 51). Thanks to the support of the Cardinal, on the 6th of October 1569 Mercuriale was called to the full professorship of Practical Medicine, where he remained for 18 years, from 1569 to 1587 (Ongaro and Forin 2008, p. 32). During this period Mercuriale published most of his works, consolidated his fame as a Medical Practitioner to such an extent that he was called upon to consult the Emperor Massimiliano II in Vienna. In 1587 Mercuriale accepted the proposal, on the part of the "*Bolognum Studium*", of a chair in Theoretical Medicine, with the highest salary ever conferred to one of its Professors, the sum of 1220 gold crowns a year. In 1592 he moved to the University of Pisa, attracted by an even richer contract, offered by the Grand Duke of Tuscany, Fernando I de' Medici, also becoming the latter's family doctor (Ongaro 2009, p. 623). In 1606 Mercuriale finally retired to Forli, his city of birth, but not before attempting to return to Padova in 1599, following the death of Alessandro Massaria (1510cc–1598), who held the chair of Practical Medicine. The University of Padova, however, did not accept this, for various reasons that one can only conjecture about: his advanced age, the memory of his abandonment of the University in 1587, his huge demands concerning money and, what is more, the memory of his error during the terrible plague of Venice from 1575 to 1576, which we well look at subsequently (Ongaro and Forin 2008, p. 50).

Mercuriale represented a typical genius of the Renaissance period, an age in which the innovatory dawn of the experimental approach to nature went hand in hand with the rediscovery and cult of the classical world. An eclectic age, one could define it (Rippa Bonati and Zampieri 2010, p. 74), in which various explanatory approaches, which to our eyes might even seem opposed, coexisted, and almost interpenetrated each other, such as the magical-hermetic tradition, experimental practice, and empirical observation (Piaia 2008, p. 5). Mercuriale, as well as being a great doctor, was also an antiquarian and a scholar of the classical world. Besides the extremely numerous citations of the classic *De arte gymnastica* and the function that this text had in the rediscovery of ancient hygiene, let's remember that Mercuriale published interesting philological works (Ongaro 1964–1965; Nutton 2008) and was the editor of the works of Galen and Hippocrates (Fortuna 2008; Jouanna 2008). This combination of the empirical practice of medicine and the cult of the classical authors is very much at work in the events at the heart of this section, which saw Mercuriale involved in the handling of the terrible pestilence that struck Venice between 1575 and 1576 (for an analytical reconstruction of the event see: Rodenwalt 1953), and is well summarized by Zitelli and Palmer.

> The events of 1576 reveal the ambivalence of medical science in the Sixteenth Century. On one side, it gave new prominence to experience and observation, as Padova demonstrated with its anatomical research and the establishment of the Botanical Garden. On the other side, the humanist movement, of which Mercuriale was an exponent with important

> editions of Hippocrates and Galen to his credit, promoted a profound reverence for the authority of the classics (Zitelli and Palmer 1979, p. 27).

From May of 1575 a plague epidemic had spread from Trento, more specifically following the Fair of Saint Giovanni, an occasion in which many merchants from various Italian and foreign cities were gathered together. The reports of the time even provide a date and a specific event for the introduction of the plague to Venice: the 25th of June 1575, following the entry of a mountain dweller of Trentino into the city on the lagoon, his subsequent death from the plague and the contagion of the family that had hosted him (Preto 1978, pp. 13–14).

In Venice, therefore, between the 1st of August, 1575, and the end of February 1576, there were 3696 deaths (Palmer 2008, p. 52). During the following winter mortality remained at a fairly low level, but at the beginning of June 1576 the death rate rose sharply enough to trigger alarm in the city administration.

Thus, on the 7th of June, the Venetian Government called a team of professors from Padova for a consultation on the spreading sickness. Mercuriale found himself at the head of this group of professors—a kind of healthcare *task force*—that also included Girolamo Capodivacca, Mariano Stefanelli and Niccolò Corte (secondary chairs in Practical Medicine in first and second place), and Bernardino Paterno, a professor of Theoretical Medicine (Palmer 2008, p. 53).

We can argue that Mercuriale, even before visiting the city, had the preconceived idea that there was no plague epidemic, based on his classical theoretical knowledge and the few elements that had been provided concerning the epidemic in progress. As early as May 1576, in fact, Mercuriale had written to the Venetian doctor Niccolò Comasco († 1578):

> […] if we want to pay attention to the documents of the ancient doctors and the history of past plagues, we are forced to say that the plague is necessarily a disease of the people, in which many become sick and where many of the sick die. Very few are those who grow sick apart from the poor folk, those badly nourished and governed. I would certainly never call it the plague (Mercuriale in Palmer 2008, p. 53; Rippa Bonati and Zampieri 2010, p. 76).

The simple fact that the pestilence in Venice, during that period, was still not seen as an epidemic, had led Mercuriale to this incautious underestimation of its virulence. An underestimation supported by the Hippocratic distinction between specific illnesses, endemic, and epidemic, according to which the first struck individuals and essentially depended upon the lifestyle of the patient; the second were typical of a single populace and broadly depended on diet or the particular place in which that populace lived; and the third struck entire areas and different populations (Rippa Bonati and Zampieri 2010, p. 74). Still on the basis of the Hippocratic conception, the plague could not be depicted as an epidemic disease, because it depended upon the "corruption" of the air of a given zone (Palmer 2008, pp. 53–54).

On the afternoon of June the 10th a renowned debate was held in the *Sala del Maggior Consiglio* in the Ducal Palace of Venice between the Padovan doctors, the Venetian doctors and the governors (Fig. 2.3). Niccolò Comasco, the same one with whom Mercuriale had corresponded a short time before, opened the debate by

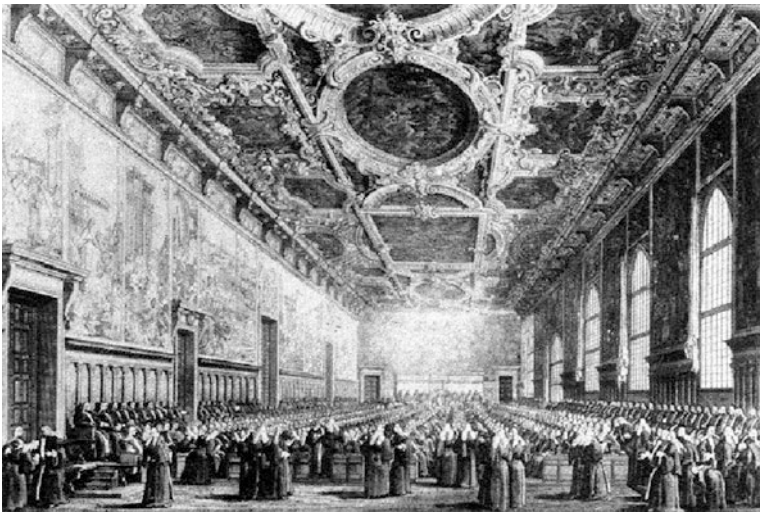

Fig. 2.3 The "Sala del Maggior Consiglio" in the Palazzo Ducale in Venice, from an engraving by Giovanni Battista Brustolon (1712–1796) based on the painting by Canaletto (1697–1768)

arguing that the disease in question should be considered a genuine plague and was followed by a certain Ludovico Boccalini who argued, almost as if it was a dialectical dispute, the diametrically opposite thesis, on the basis of the same arguments proposed by Mercuriale in the letter to Comasco. According to Boccanili one had to speak instead of a "malign fever", perhaps caused by contaminated water (*ibid*, p. 55). After other speeches, it was the turn of the Padovan professors, three of whom did not give a categorical verdict, but tended toward the "denialist" stance. Stefanelli was inclined to deny the presence of a genuine plague; Paterno and Corte argued that it was not a plague, but the beginning of one or a disease that could become the plague.

Mercuriale and Capodivacca, however, strongly denied that it was the plague. The Doge and other functionaries of state present at the discussion were easily convinced by them, and so neglected to take the restrictive measures provided in the case of an epidemic. The conviction demonstrated by the two Padovan Professors was important, and they were so certain that it was not a genuine plague that they had even offered to personally treat some of the sick.

Nonetheless, there also had to have been more strictly political reasons at work. As Preto rightly pointed out:

> [...] commercial city par excellence, linked by intense economic ties with the Islamic East, but also with the nations of Continental Europe, always its indispensable hinterland for traffic of every kind, Venice knows that it cannot allow, except at the expense of extremely high economic, social and political costs, an excessive interval of inactivity and isolation, from which competitors and rivals could derive unexpected and lasting advantages (Preto 1978, p. 30).

We have chosen, in such a way, to mention the "reason of state" in the title of this section: to decide that there was an absence of genuine pestilence, in fact, resulted in an apparent advantage for the economy and affairs of state that would otherwise be blocked altogether.

Fig. 2.4 Image of a doctor visiting the a plague victim in "Fasciculo de Medicine" (1494) where we see the doctor holding a sponge in front of his nose and mouth, in order to protect himself from the "corrupt" air coming from the patient

After spending some days in Padova, Mercuriale and Capodivacca returned to Venice, where they were welcomed with great enthusiasm, almost as divinities, for the very fact that their work had brought significant hope to the city. Every morning they left with their assistants in five gondolas, together with two Jesuits for possible confessions; every house that they visited was aired and fumigated with essences and perfumes, and the two doctors did not disdain to touch the sick, nor employed any of those typical precautions against the plague, such as the use of a sponge soaked in vinegar or other substances for the protection of the nose and mouth (Fig. 2.4).

The *Provveditori alla Sanità* of Venice, that is, the Venetian public health officials who, on the contrary, claimed that it was a genuine plague and were in favor of implementing the important measures of isolation and quarantine of the city and the afflicted, were astonished by such behavior, also because they held precisely that course of action could turn out to be decisive in spreading the epidemic (*ibid*, p. 57). The *Provveditori* of Padova were also profoundly opposed and feared that Mercuriale and Capodivacca would even spread the disease to the mainland. Delegates of both magistracies tried to dissuade the Venetian Senate from its support of the ideas of the two professors in Padua, but were not heeded.

Finally, it was the ever-increasing mortality rate that led to the spontaneous resolution of the dispute. At the beginning of July the two professors were ordered to stay in quarantine in Venice and were viewed by the majority of the nobles, administration, and population of the city as being the main cause of the epidemic. Eight years after the event the Scribe of the Venetian Magistracy of Health, Cornelius Morello, wrote as follows.

> This caused the evil to grow and spread quickly through the city, both for what they practiced in each area, as I have said, and also because they had said that there was no plague in Venice, the populace, believing this to be the case, persuaded by the authority of these excellent men and from having seen them practice so freely, did not want to obey the orders and provisions created by the Healthcare Office, which caused a lot of scandal, confusion and disorder, which was perhaps the main cause of such high mortality and ruin (Palmer 2008, p. 61).

In this case, there is no doubt about the fact that Mercuriale and Capodivacca were at the time held fully *responsible* for a serious error of judgment, which had led to almost incalculable economic and human damage, given that more than 50,000 Venetians died in the dissemination of plague.

The two doctors, therefore, protested against the imposed quarantine in a petition addressed to the Doge. In this they argued that it was God himself who had inspired them, leading them to risk their own lives in visiting the sick, and they asked to be able to return to Padova in exchange for the preparation of a detailed report on the epidemic. It is interesting to note that the two doctors defended themselves against the accusations of responsibility by recalling the divine origin of their actions, which, as such, could not be accused of any evil. In the compendium of a chronicler of the time, moreover, a certain Francesco Molino (1546–1596), this divine inspiration assumed the opposite sense: God had blinded the judgment of the two doctors, inspiring the wrong diagnosis, in order to punish

the Venetian populace which, due to excessive wealth, had become impious (Preto 1978, pp. 73–74). Also in this case, however, Mercuriale and Capodivacca evaded responsibility.

In their subsequent written report the two doctors recognized for the first time, albeit in an implicit way, that the disease could be traced back to the plague, in that they describe it as "pestilential fever":

> From all of these incidents one can easily grasp the real nature of these evils to be pestilential fevers, and also in a certain sense one can call it plague, but not precisely, being that the genuine plague emerges, according to the teachings of Hippocrates, Galen and Avicenna, from a pestiferous and poisoned air […] so that, inevitably, many of every kind grow sick and many among the infirm die and it is fitting to say that until now it is not a genuine plague in Venice, because one sees that the air is in no way poisonous […] (Palmer 2008, p. 62).

Mercuriale and Capodivacca also advised that the poor of the city, as most at risk, be moved to the mainland, that the houses and the streets be cleaned and purified with aromatic fires, and that those who felt sick be isolated. With this the doctors hoped to rehabilitate their reputations and to earn a decorous return to Padua from Venice. The Venetian Senate released the two professors without any mention of their error of judgment, but rather with appreciation for their charity and readiness to serve the Venetian people (*ibid*).

After claiming tens of thousands of victims in Padua and Venice, the epidemic began to subside during the winter of 1576, until it disappeared altogether. Significantly, the Venetian Senate, as early as September 1576, when the epidemic was only showing some faint signs of decline, ordered its ambassadors to Constantinople to announce the end of the plague. On the 8th of the following November, as reported in the study of Paul Preto, the Senate deliberated that:

> […] one can say that the pestilence has altogether ceased so that every day people arrive here from all parts of the world and the traffic and commerce of every nation is returning to the former and usual ways (taken from: Preto 1978, p. 33).

The desire of the Venetian administration to declare the end of the plague was as great as its determination to deny its onset in the previous year; a situation that was decisive, therefore, for the favorable acceptance of the theories of Mercuriale and Capodivacca.

Mercuriale, finally, prepared a series of lectures on the plague that were held in Padova with his students in January of 1577, lectures that, transcribed by the city doctor Girolamo Zacco, were published in the same year with the title *De pestilentia* (Mercuriale 1577) and in which Mercuriale, in addition to flaunting a very large erudition and a certain openness to the latest theories, developed arguments that could have been an implicit defense of his position in the Venetian affair (Nutton 2006).

Thus, *De pestilentia*, after a vivid description of the pathology and the accompanying symptoms, proposed a chronology on the basis of which Mercuriale attempted to exonerate himself: indeed, according to the doctor, the disease had only become a genuine plague starting from July 1576, that is, *after* his

intervention. Therefore, the hypothesis remained that before that period it was, rather, a "pestilential fever". Mercuriale went as far as to maintain that any disease, becoming an epidemic, could be defined as a plague: "[…] pestis non est unus morbus determinatus, sed quicumque morbus potest esse pestis […]" (Mercuriale 1577, p. 10).

It is also worth noting that Mercuriale espoused the contagionist theories of Girolamo Fracastoro (1476/8–1553), who had been a student in Padova and a lecturer in Logic in 1502 (Ongaro 2006, p. 43) and who had published in 1546 the *De contagione et contagiosis morbis*, in which he developed the revolutionary idea that contagious diseases did not communicate with each other through a corruption in the air, but through "seeds" that were transmitted from one body to another; "seeds" which were regarded as inanimate particles, not living agents (Fracastoro 1546; Rippa Bonati and Zampieri 2010, p. 75).

Mercuriale spoke explicitly of "pestis semina", following Fracastro (Fracastoro 1546, p. 45; Palmer 2008, p. 64), but performed, at the same time, one of the most complete and structured syntheses between the of Hippocratic-Galenic perspectives and that of Fracastoro: the plague was a disease caused by corruption of the air, according to classical teaching, but it could also spread by contagion, according to the modern theory.

By means of this text Mercuriale was able to completely revive his own reputation, so as to be able to continue, as we saw at the beginning of the paragraph, his extraordinary scientific and academic career.

It was very important, therefore, that Mercuriale's defense against the accusations of responsibility for error of judgment be exercised, from the first report issued with Capodivacca to the Venetian Senate, along two main axes.

First of all, the moral-religious argument, as we could call it, is based on the fact that the two doctors did not spare themselves in visiting the sick, which, after all, was a guarantee of the fact that they had acted in good faith. Whether, in the event of the plague, the doctor had to remain to help those afflicted or preserve his own health by escaping from the epidemic was an ethical question widely debated in this period and until the pestilences of the following century, also because the issue remained ambiguous on the same basis of Hippocratic and Galenic texts and their relationship with Catholic ethics (Grell 1993). The actions of Mercuriale and Capodivacca, in any case, were ethically unassailable and, at least from this point of view, the two doctors were safe from any kind of accusation.

Second, and perhaps even more importantly, there was what we could define as the argument of *authority*, based on the fact that the theories of Hippocrates, Galen, and Avicenna could not but lead to the judgment of those diseases as pestilential fevers and not as expressions of a genuine plague epidemic. Mercuriale, in a certain sense, was not content to be held innocent on the basis of his good faith, but wanted his behavior to be recognized as having been, in substance, dictated by a correct interpretation of scientific knowledge, which, evidently, remained the only means by which he could feel completely vindicated.

In any case, we must underline the difficulty, both for us and for Mercuriale's contemporaries, of judging his behavior, because such a judgment cannot remain

insensitive to the consideration of what happened *afterwards*. It therefore concerns an a posteriori judgment that, as such, risks not being altogether objective. This fact constitutes a sort of universal education; so many are the circumstances that determine any behavior, especially in the case of a complex behavior such as that of the medical act, that judging whether responsibility exists or not is extremely delicate and difficult.

2.2.4 Case IV. The Cynical Doctor: Alessandro Knips Macoppe

As briefly explained in the first section of this text, the period between the fourteenth and sixteenth century saw the first major flowering of "rules of etiquette for physicians", perhaps to coincide with the profound methodological transformation of medicine that, during these centuries, laid the foundations in order for it to become an experimental science, and certainly after the progressive fusion of Hippocratic ethics with the new Christian-based deontology. The period between the eighteenth and the early nineteenth century is the one that saw a second flowering of such a scientific-literary kind.

In order to understand the reasons for this rebirth the claims of a Paduan doctor of the late eighteenth century, a certain Girolamo Forti (1740–1796), could prove useful. It is a phase in which medicine became a scientific and objective public profession—thus just as objectively capable of being judged—in contrast to the previous dogmatisms and sectarianism.

Forti claimed that medicine, in that period, after having abandoned theoretical sophisms and the obscurity of Latin, which, in fact, rendered it incomprehensible to almost the totality of the population, now had to face the opposite problem, namely, that the even the most ignorant could judge it.

> Now this reduction of the art of medicine to common intelligence, the vulgar expressions that we make use of, the few simple remedies that are in use, bring the clinical exercise not only to the eyes, but also to the judgment of the people, which frankly decides on both the nature of the disease, the medical tools to be used and the conduct of the doctors, who do not only have to face the difficulties of their profession, but also the gossip of the ignorant, being much more annoyed with the anxious care of the relatives and friends of the patient, who, thinking themselves intelligent enough, take advantage of their rights in order to deceive with doubts or with inopportune suggestions about the treatment plan believed by them to be the conduct most praiseworthy (Fioravanti 1793 in Rinaldi 2000–2001, pp. 155–156).

Immediately after, Forti reiterated the necessity of the doctor to defend himself in the face of "sinister" cases, claiming that, if the fatal outcome had been predicted, it did not mean that he could be responsible.

> [Doctors] […] do not allow themselves to be disturbed by slander, nor seduced by inopportune proposals, and explain their concept clearly to those people of good criteria […] they follow with a certain step the road that they have decided upon, triumphing

> modestly from the good outcome of their work, and giving an account of sinister events to those who can judge of them, who must, however, suppose that these were both foreseen and expected (*ibid*, p. 156).

It is precisely due to this pressure from the public, we believe, that the so-called rules of etiquette for physicians flourished, among which can also be counted the Aphorisms of Alexander Knips Macoppe, which will be discussed in this section. These rules of etiquette were in fact handed down by doctors, with a view to refining their behavior so that they would be irreproachable, both from the point of view of morality and professional responsibility. Again, it is not by chance that this is precisely the period in which we see, for the first time, the appearance of the very concept of "medical ethics", made popular by the famous booklet published for the first time in 1794 and reissued in 1803 by the previously cited British doctor, Thomas Percival (Percival 1803).

Knipps Macoppe was born in Padova from a family whose paternal line (of the surname Knips) originated from Cologne and whose maternal line (of the surname Macop, Italianized into Macoppe) probably had Flemish origins (for a complete biography and corresponding bio-bibliographical references: Ongaro 2002, 2004). Graduating in Medicine and Philosophy in 1681, he practiced the profession in Venice with great success, so much that he became the personal doctor of Prince Alessandro Farnese, who he followed on his travels. When Farnese died in 1689, Macoppe, after various peregrinations, settled in Montpellier until 1693. Returning to Italy, he was entrusted with the Chair of Pharmacy and Medicine in 1703 and in 1716 obtained the second place Professorship of Theoretical Medicine, inaugurating the course with a lecture bearing the important title: *Pro empirica secta adversus theoriam medicam*. Finally, in 1727, he was moved to Full Professorship of Practical Medicine.

The lecture of 1716 was written by Macoppe in clear opposition, as the title itself suggests, to that given by Domenico Guglielmini (1655–1710) in 1702: *Pro theoria medica adversus empiricam sectam*. In this way, Macoppe involved himself in the polemic between rational medicine and empirical medicine that had raged in Italy and Europe between the seventeenth and eighteenth centuries, beginning from the dispute in Bologna between Marcello Malpighi (1628–1694) and Giovanni Girolamo Sbaraglia (1641–1710), in which the first argued for the necessity of anatomy and experimental reasoning (based on mechanistic models) in understanding the mechanisms of disease and in treatment, while the second, supported by the natural philosophy of John Locke (1632–1704) and the clinical approach of Thomas Sydenham (1624–1689), argued, on the contrary, that anatomy was not at all necessary, neither for the understanding nor for the treatment of illnesses. To be an empirical doctor also meant, at least in part, being a traditionalist, a scholar of the ancients and, particularly, of the teachings of Hippocrates, while being a rational doctor also meant being "neoteric", that is, a follower of the most recent theories and findings, in particular the Cartesian idea, according to which the human body was a machine, and the idea that such a

theoretical–experimental model would permit a new understanding of the body and illness deeper than before.

Macoppe, therefore, in favor of the "empirical sect", sided with a medicine based on observation, experience, and a therapeutic approach that tended to be simple and not very aggressive, which was also confirmed in the aphorisms whose deontological meaning we are going to discuss. Nonetheless, in this text, Macoppe also showed a certain openness to "neoteric" theories. In aphorism XI, for example, the Padovan doctor claimed that what was essential in medicine was its therapeutic effectiveness, regardless of the modernity or antiquity of the theories utilized.

> With language now bowing to the ancient and now to the modern, it is necessary that you are able to describe and understand the physiopathology of the disease […] The reason being that, whatever the level of our knowledge, it must be directed towards the final aim of restoring health (Knips Macoppe 1823, p. 53).

Also significant in this regard is Aphorism LXX, in which Macoppe argued for the necessity of constant practice in hospitals, which was in line with the empirical medicine which took the form, indeed, of a "pure" clinical medicine, but also of the practice of autopsies, which was a factor supported instead by rational medicine.

> To establish the reputation of the physician it is necessary that he has had long practical experience in public hospitals. It is also necessary for the common people to know that his hands have been frequently covered in blood, as much as from human cadavers during autopsies, as from animals during studies of comparative anatomy (*ibid*, pp. 172–173).

Finally, an aphorism that ultimately reveals Macoppe's predilection for the "ancients".

> Do not pass yourself off as a modern physician–chemist. Even if the moderns and the chemists possess many excellent things, nevertheless these teachings are hateful to the ignorant and cunning: rather, show yourself as an adherent, in practice, of the ancients, and in theory, of the moderns, and that you know how to choose the best of both. In this way the opinion won't spread that you are an anatomist of men and vegetables, or are too devoted to comparative anatomy, because the mob is convinced that all of the genius of the physician is barely enough for his art, and that, being distracted by these extraneous studies, he does not think about the needs of his patients (*ibid*, pp. 219–220).

Arriving at a systematic analysis of this collection of aphorisms, we note, above all, that the text circulated among doctors in manuscript form for many years until, at the request of Giambattista Pratolongo (1745–1810), professor of botany and natural history in Genova, (1745–1810), a correspondent of LazzaroSpallanzani (1729–1799), the text was edited and published by Floriano Caldani (1772–1836) in 1795 (Knips Macoppe 1795) (Fig. 2.5). The text then had an enormous success and wide circulation, enough for it to be reissued and translated many times.

As reported by Giuseppe Ongaro:

> [...] the aphorisms, which profess to be a behavioral code for the young doctor, with the aim of obtaining for him a successful career in accordance with the principles of medical ethics, in reality present themselves, in the judgment of T. Berti, as "a complex mixture of

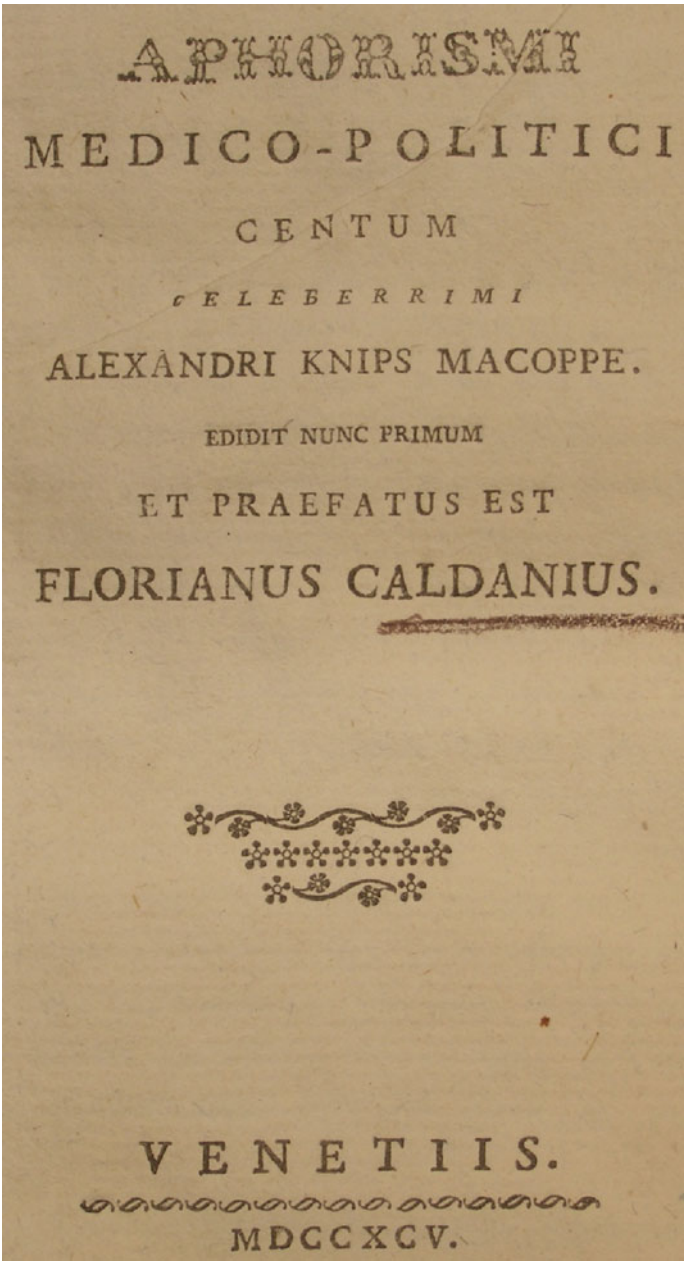
APHORISMI
MEDICO-POLITICI
CENTUM
CELEBERRIMI
ALEXANDRI KNIPS MACOPPE.
EDIDIT NUNC PRIMUM
ET PRAEFATUS EST
FLORIANUS CALDANIUS.
VENETIIS.
MDCCXCV.

Fig. 2.5 Title page of the first printed edition of the aphorisms of Knips Macoppe

> wisdom, cunning and unscrupulousness to the point of cynicism", which could explain the extraordinary success it enjoyed […] (Ongaro 2004, p. 751; Berti 1990).

In fact, one can encounter an essential ambivalence in this text, which is precisely related to the nature and objective of the rules contained therein; a quality, as in the work of Zerbi, which takes the form of a genuine ambiguity. It is an ambivalence clearly revealed, for example, in the *Preface* of one of the Italian translators of the work, the Milanese doctor Iganazio Lomeni († 1838) (the translation we have used for our analysis) in which the following passage is found:

> Herein, selecting dogmas of the purest Catholicism and the lessons of an illuminated experience, as well as deep knowledge of the human heart, and the relationships that exist between doctors, and between these and the sick, the bystanders and the public, the lines of prudent conduct to which those who profess the art of health must follow, in order to reach honorable and constant fame, have been drawn. Macoppe deserves to be called the Macchiavelli of Medicine; but a wise, sober, honest Macchiavelli, who is religious without offending reason, always guiding his pupil towards the formation of a frank heart, but without arrogance in his awareness of himself and in the rectitude of the aims of his work (Lomeni 1826, pp. 7–8).

We see, therefore, that the translator noted the simultaneous presence of two apparently conflicting elements: the observance of Catholic morality, founded, as is well known, on indisputable and strict imperatives, and, at the same time, rationality and "illuminated experience", i.e. factors, on the contrary, at the base of a flexible and circumstantial morality. An ambivalence is also noted in the intrinsic purpose of the work, directed, at the same time, toward the development of an ethics of the absolute good and a series of rules of "conduct" based on "prudence", aimed at ensuring not so much the good, but the "honored and constant fame" of the physician and, in certain cases, ensuring him the means by which to avoid *responsibility* in the event of error and culpability. Macoppe's text, beyond being full of rules aimed at safeguarding doctors—which we will discuss shortly—also contained, in effect, authentically moral precepts, such as not to prescribe costly, ineffective drugs, but instead to donate drugs and treat the poor, and to do so in private, without ostentation (*ibid*, pp. 112, 160); such as being simple, not proud (*ibid*, p. 133); giving assistance to he/she who had also been an enemy (*ibid*, p. 154); the absolute prohibition of poisoning anybody (*ibid*, pp. 151–152) or being greedy (*ibid*, p. 234); and, finally, the maintenance of professional secrecy (*ibid*, pp. 188–189, 214).

The parallel with Zerbi, here, is fitting and immediate, and, in our opinion, uncovers the very roots of medical ethics, which has been constantly torn, from the very beginning, between absolute ethical principles and the necessity to preserve the honorability of the profession, a fundamental condition, in its turn, so that the doctor may have the possibility of putting ethical principles themselves into practice.

Even more importantly, the translator defined Knips Macoppe as a Macchiavelli, thus highlighting the unscrupulousness of the principles developed by the Paduan doctor, by means of a comparison with a political theorist, Macchiavelli,

for whom the end of an action justified the means that were adopted in order to carry it through.

The purpose of the work was made clear by Macoppe himself in his introduction, which was directed at an ideal pupil, considered as the main interlocutor at whom the aphorisms were aimed.

After having revealed the secrets of medicine, Macoppe writes that:

> […] it is necessary for me to explain the secrets of those who practice the medical art, not so much with the object of revealing to you their caution, but to make clear to you the insidious guile and cunning of some, which is not easily perceived by the common gaze (*ibid*, p. 19).

It was therefore about showing to the young both the adroitness and cunning of doctors, where the first quality was, evidently, a force for good, while the second was evil. The fact is that, in the text, it is not always clear where the border lies between the two qualities. The following passage is also very interesting.

> Learn these political canons with the same diligent assiduity with which you learn those of Hippocratic Medicine.
>
> They are inextricably linked to one another, for unto the same commendable aim are they directed, that is, the salvation of the sick, your glory, your advantage. […] Fulfill your duty towards others, but sometimes think also of yourself. Restoring the sick to health and saving your own honor are both exemplary aims in the exercise of medicine (*ibid*, p. 21).

The fundamental ambivalence is completely revealed here: medical ethics are an instrument for both the salvation of the sick and for the glory and advantage of the doctor. The two things, at bottom, seemed inextricably linked: how could a doctor help others if he was not able to help himself? His ruin, in fact, would inevitably lead to the ruin of his patients.

Basically, the parallels with the work of Zerbi are clear and numerous and confirm the intrinsic continuity between Macoppe's treatise and the late-Medieval and Renaissance rules of etiquette for physicians. The themes of professional solidarity and the importance of good reputation are certainly the main ones and are constantly reiterated. Macoppe also made use of religious sentiment to develop a sense of pride and belonging among the members of the guild of doctors, in particular with the first aphorisms of the treatise. As Macoppe maintained in the first aphorism (*ibid*, p. 23), medical knowledge had God himself at its source and was inspired by him. As a consequence of this:

> [...] understand from this—he writes, always addressing himself to a pupil—how eminent your ability is, and how much respect you owe to God and sacred things (*ibid*, p. 26).

Solidarity among colleagues, vital for the preservation of the guild, was assured, for example, with the ban, already found in Zerbi, on arguing in front of a sick person (*ibid*, p. 157) and, more generally, of avoiding "medical quarrels" (*ibid*, p. 50), but also, eventually, with the advice not to criticize new theories or drugs that one was not yet acquainted with (*ibid*, pp. 74–76), to welcome foreign doctors who came to practice in one's own city in a friendly manner (*ibid*, p. 81)

and, finally, to always quote the authors whose theories one had utilized (*ibid*, p. 122).

Aphorism XXXVII, in which Macoppe advises never to judge the work of other doctors negatively, is very interesting, also with regard to the issue of *responsibility*. The passage is as follows:

> [...] called in for a consultation, in order to judge the work of other doctors, do not immediately, with treacherous politics, detract from what has already been carried out […] since your detraction would certainly damage your colleagues, without giving the slightest advantage to the patient. […] When the outcome is fatal, accuse the fierceness of the sickness, not the work of the doctor (*ibid*, pp. 103–104).

The final sentence, we think, speaks for itself.

Finally Macoppe, very attentive to the formation of his pupils, advised one not be reluctant to commend and give credit to younger colleagues (*ibid*, p. 70) and went so far as to suggest praising their achievements and concealing their errors.

> Learn to admire, without envy, the treatment that your rival, the assiduous youth, strives to perform, by praising his good conduct and concealing with strict silence the things that go wrong (*ibid*, p. 77).

For the youth (and not only), in his turn, it could be important to be able to demonstrate that he has a great teacher (*ibid*, pp. 174–175), while for the teacher it should be rule of thumb to acquire "new doctors who follow his practice" (*ibid*, p. 198).

The aphorisms dedicated to the creation, preservation, or consolidation of the good reputation of the physician are also very fine. Macoppe advised his ideal interlocutor, that is, the young student physician, to adjust his "countenance" to the trend of the illness, by showing himself happy when recovery was certain and sad when everything suggested the worst (*ibid*, p. 58); he also advised visiting the patient only when necessary, even without being called, but no on account when it was useless, even to increase the expectation of the patient, so that he was even more delighted at the sight of visiting the physician (*ibid*, p. 60); finally, he advised never to treat incurable illnesses (*ibid*, p. 143).

From the exterior point of view, it was a good rule not to have a beard or long whiskers (*ibid*, p. 90), not to show off bags full of money or diplomas (*ibid*, p. 93), not to walk too quickly or in a cheerful manner (*ibid*, p. 95), not to go too often to the theatre (*ibid*, p. 96), not to boast of one's prizes or successes (*ibid*, p. 97), not to dress in clothes that are too costly, or wear a wig and makeup (*ibid*, pp. 111, 156–157), not to get drunk or carry weapons (*ibid*, p. 114), not to compose verses, above all if vulgar or satirical (*ibid*, p. 186), not to live in homes that are too lavish (*ibid*, p. 195), not to be too taciturn or too talkative (*ibid*, p. 208), not to stipulate payments in advance (*ibid*, p. 209), and, finally, not to wear too much perfume:

> Do not saturate your clothes with musk or amber perfume, or any other similar odor harmful to many women, especially in cloisters, as well as some men: instead of gratitude, you will give off such a terrible smell that you will instead seem like a spruce and lascivious youngster, rather than an authoritative man; and also because, in truth, these perfumes can give rise to head pains, anxieties, dizziness, spasmodic convulsions, or other

> similar disturbances. You will be one who causes sickness, not a doctor. Your behavior, not your clothes, must give off an aura of gentleness (*ibid*, p. 210).

For a good reputation, Macoppe also advised that the doctor made powerful friends in the city where he lived and demonstrated his capacity in public affairs (*ibid*, pp. 140, 197). Entirely novel, compared to Zerbi, was the mention of the utility of frequenting hospitals and autopsies, as already noted in the discussion on the conflict between empirical and rational medicine. It is interesting that this necessity was not supported with reasons of scientific knowledge, but of social usefulness.

In order to conclude, we have found, among Macoppe's aphorisms, ruses that are clearly beyond any possible ethical or moral justification; aphorisms that are, not by chance, extremely important, also with regard to the issue of the doctor's professional responsibility.

Aphorism IX, for example, is among the most interesting. We believe that it is worth quoting it in full.

> Always use equivocal words when predicting the future. Knowledge of the future is the inevitable punishment which only the relatives and acquaintances of the sick inflict upon us, who from the beginning want to know for sure the outcome of the disease. […] They are almost unwilling to see us doctors as men; rather, they would like us to be semi-gods or oracles. […] With clipped sayings, obscure and ambiguous predictions you will keep their souls in doubt, mitigate their ardent longings, and you will set foolishness out to pasture. Your predictions must be so subtle that you always have a rationale to support them. […] There are some two-faced doctors who for the same grave illness predict to someone the recovery of the patient and to another his death. In any case, they have testimony ready that they have not failed in their prognosis, artfully dissimulating the incorrect opinion, or pretending that it was a joke. Others predict a happy outcome, also maintaining the contrary hypothesis, based on the fact that the acuteness of the illness complicates its prognosis: others, on the contrary, see black everywhere, without excluding the hope of a return to health, trusting in the validity of their remedies: thus, if the patient dies, the guilt is attributed to the illness, not to the doctor, since he had predicted it from the very first moment; if, on the contrary, he returns to health, he will praise his savior to the heavens. […] Following these tracks they never lose their balance: you must not aspire to similar conceit, however; instead you must remember that your honor is bound to the fulfillment of your predictions: where you are not able to heal, do not spare any effort so that you may overcome the fallibility of human prognostics […] (*ibid*, pp. 39–41).

Here, Macoppe was not afraid to explicitly declare the necessity, for doctors, to be equivocal to the point of lying, predicting restoration of health for some and for others the opposite outcome. It echoes, without doubt, Zerbi's rules of etiquette, in those passages in which the Renaissance author advised doctors to keep their prognosis "ambiguous" (Zerbi 1495; in Mancini 1963, p. 47) and in which he advised the doctor to exaggerate the gravity of an uncertain disease, so that he would be excused in the event of a fatal outcome or greatly praised in the event of recovery (*ibid*, p. 49). Macoppe showed how he considered ambiguity and deception to be necessary reactions to the excessive expectations of the patient and those nearest to him. Very importantly, Macoppe counseled his ideal interlocutor not to exaggerate, but to always remember that the doctor had to concentrate all of

his efforts on making an exact prognosis, attempting, in this way, to overcome the "fallibility" of predictions. In any case, it is clear that this cunning does in fact protect the doctor from assuming heavy *responsibilities* in case of error.

XIV is another interesting aphorism.

> If an unfortunate event follows on from the imprudent or erroneous use of a particular remedy, and somebody calls into question your competence, reject the accusation with a harsh and dignified face, quickly making use of subterfuges and stratagems to aid you, so that trust is maintained in your work and your medicines. Since the die has already been cast, there is nothing left to do but conceal the mistake […] (Macoppe 1826, p. 63).

In order to divert attention, Macoppe continued, one could invoke particular environmental conditions, or specific failures and errors in the conduct of the patient, the assistants, the servants, or the apothecary. It was therefore clear that the doctor could commit an error and be completely responsible for such an error, but it was just as clear that any means, even immoral, were legitimate in order to avoid acknowledging responsibility. This, in its turn, was justified on the basis of the necessity that the doctor must never, for any reason, lose his patient's trust, which might be conceived as an aim in some way justifiable, almost noble: it was in fact clear that the effectiveness of the cure itself depended a lot on the patient's trust of the doctor, as also emphasized by Zerbi.

Along the same lines is the advice, in the event of a worsening of the disease in an important patient, to join with another physician, in order to diminish the probability that one or the other, or both, will be held responsible for any harm.

> At the worsening of the illness, from which a highly regarded person, your wife, her brother or father die, ask another doctor to perform a joint consultation with you, because if patients of that kind end up in the graveyard, the public and the relatives of the deceased, in designating the cause, sometimes swing between very different and even contrary and always regrettable opinions about the treatment (*ibid*, p. 164).

This is cunning that reveals how much solidarity and collaboration between doctors was an instrumental element in the safety and defense of each one of them.

Just as unscrupulous is aphorism LXXXVIII, which we believe is worth quoting extensively.

> If death takes one of your patients, it is good to proceed with the sectioning of the cadaver. […] However, in case the results of the section would disprove your predictions, in speaking of it with doctors, weigh your words carefully: make the others believe that you have for a long time calculated the cause of death from the discrepancy of the humors, or even in an alteration of the ethereal, nervous and electrical fluids, which you did not mention, since these are above common intelligence, and that could not therefore be found in an examination of the body. On the other hand, there are almost always in the viscera chance formations of bruises formed by an irregular slowing of the bloodstream that only slightly preceded and accompanied death; there are almost always lumps of various shapes and in some cavities there are often found partial collections of yellowish lymph, which are all things which could help to cover your error: if not elsewhere, in the heart there are almost always found clusters of fibers wrapped in whitish bundles that are capable of representing a fictitious, untreatable polyp (*ibid*, pp. 199–200).

The passage, we believe, speaks for itself. We will only add that the sense of an aforementioned aphorism seems here to be fully revealed, that is, the one regarding the necessity for the doctor to show that he knows both the "ancients" and the "moderns". The different theories, in the final analysis, did not function as a way to better understand and treat the illness, but rather as a way to protect and conserve the doctor and medicine itself.

To conclude, it is interesting that Macoppe advised the doctor not to perform medicolegal assessments, in order to avoid bringing upon himself the desire for revenge:

If it so happens that the criminal magistrate calls you to give a judgment in a case of real or supposed poisoning, by means of an autopsy on the body of a deceased, avoid if you can do this odious task, for the most part useless or only damaging. Even if the truth of foul play is confirmed upon examination of the body, the deceased will not return to life: think, rather, that because of this verification, while you are creating enemies and claiming homicide, somebody could decide to take their revenge upon you (ivi, p. 150).

We believe that history, in this case, has vindicated the Padovan physician, at least from the point of view of the phenomenal rise of forensic medicine, in the second half of the nineteenth century (Crestani et al. 1992), which has become a fundamental element of the majority of modern democratic legal systems.

2.3 Conclusion

Our historical survey, as illustrated by the title itself, does not purport to be exhaustive, also because the subject, which concerns the history and evolution of the concept of the professional responsibility of the doctor, is practically unknown and would require the kind of systematic research that is not possible in an essay of limited breadth such as this.

However, we believe that the *case studies* offered here have made it possible to isolate some of the basic elements which have characterized the history of the issue.

First of all, professional liability is an issue that has re-emerged, at least in modern times, whenever medicine has met with a transformation of its theoretical models and, consequently, of its work, as well as whenever the social role of the doctor has undergone major changes. These changes have also led to a consequent transformation of the criteria by which the proper execution of healthcare precepts and, at the same time, possible errors and failures, are judged. It is probable—but this is a question for professional legal doctors to answer—that the issue of responsibility is today so relevant for the very same reasons.

These changes, second, have also brought about a necessary rethink of the strategies through which doctors defend and preserve themselves. As in any other professional guild, medicine also strives, and has always strived, to defend it own members. Considering the delicacy of its task—the restoration of health—and its

object of study, namely the diseased man, doctors have been particularly sensitive to the elaboration of rules of conduct that allowed them to avoid being the object of unjust accusations on the part of the public, or other guilds that they are in competition with. It is important to emphasize, regardless of the actual use that doctors have made of these precepts, the uncertainty of the results in the medical treatment of diseases, which are often independent of the doctor's actions.

Finally, let's remember that, due to its very position, medicine has always been involved, in spite of itself, in actions that could lead to serious accusations against the doctors who were compelled to perform them, such as the poisonings ordered by the secret service (Guilandino), or the failure to take the correct position in case of disease epidemics (Mercuriale), or, more generally, the role of doctors in any type of state process or religious inquisition.

These rules of conduct, in addition, have also, by their very nature, lent themselves to other less neutral or edifying uses from the moral point of view, namely the ability to preserve the doctor even in the face of objective responsibility in case of professional errors and omissions.

This has been the source of a fundamental ambiguity which, as seen in both Macoppe and Zerbi, has not only characterized the history of the concept of responsibility, but also that of medical ethics as a whole. An ambiguity also due to a possible moral justification, or moralization, of this kind of deception and falsehood, based on the idea that medicine, even where it is mistaken, must preserve itself, otherwise the requisite trust in its practice would be lost.

The number and the complexity of these elements render the problem of medical responsibility difficult to resolve, both from the historiographic point of view and from the point of view of the daily practice of legal medicine. It is right to remember, in addition, that ethics itself, by its very nature, is not a precise instrument, but the expression of common sense that is not reducible to mere rational rules. We hope that our text has provided some useful indications for a preliminary historical framework of the issue, a framework that, once brought to fruition, can only have useful consequences, also for the development of contemporary debate.

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Chapter 3
Praxis et Mala-Praxis Medica

Ivone Cacciavillani

Abstract This chapter discusses the issue of Medical Practise from both a legal and normative point of view, including codes of conduct and therapeutic protocols which regulate both the structural and professional practice of healthcare providers. The first chapter discusses law and norms, outlining the nature of primary and secondary sources of law, the latter including the notion of *consuetudo*, as well as codes of conduct and practice. The second part of the chapter is concerned with the medical profession itself, focussing on the nature of the therapeutic protocol, the work contract and the employment relationship, while the third part examines medical practice from the perspective of both structural and professional practice. The fourth part of the chapter looks at the function of healthcare practice in terms of the worker's exemption from medical liability and the importance of the healthcare user's trust. This chapter concludes with a discussion of bad healthcare in private and public healthcare, bad practice, and the issue of the lack of responsibility of insurance companies.

Contents

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3.1 Introduction

This chapter intends to illustrate the notion and legal significance of *medical practice* described in the general theory of law as a minimum expression of normativity. In the hierarchy of sources normative is situated at the lowest level and is rendered important in intersubjective relationships for the role that medicine performs as a science of living. Very far, in any case, from the theory of the illustrious Padovan Pietro d'Abano, who denied them the character of science, *quoniam scientia est de incorruptibilibus et perpetuis*, *sed ea de quibus ponitur esse medicina sunt corruptibilia omnia*.

With a premise that is "geographic" in nature: the work as a whole is located in the European scientific area, characterized by marked homogeneity and common technical, didactic, and operative institutes. Here, we move into a completely diverse field, the legal one, divided into a multiplicity of jurisdictions which, very slowly and amid a thousand contradictions, appear to have begun with a certain homogeneity, in which one still struggles to identify common principles underpinning the normative disciplines that regulate the materials progressively examined.

The plurality of legal disciplines resulting from the plurality of jurisdictions interacts with the particular historical moment in the area of the European Union (hereinafter referred to as the EU), especially in the discipline of professions defined at one time as "liberal". The crisis factor is induced by the interventions of the EU, in particular the 1992 Maastricht Treaty, amending the founding 1957 Treaty of Rome, the former being modified in its turn by the 2001 Treaty of Nice, which has still not fully entered into force. Furthermore, as a partially mitigating factor directed specifically at the medical sector, the provision of the third paragraph of Article 47 of the Maastricht Treaty (formerly art. 57 of the Treaty of Rome) is effective, according to which "as regards the medical, paramedical and

pharmaceutical professions, the gradual abolition of restrictions will be subordinated to the coordination of the conditions required for their exercise in single States". That third paragraph must be viewed in the second item of the third Heading of the Treaty, entitled "freedom of establishment", and in the whole of Article 47, which in the preceding paragraphs aims at liberalizing the exercise of the "liberal" professions through full modifiability of certified academic qualifications in the entire area of the EU. A kind of niche of exemption from the most radical innovations is therefore created for the medical profession, which one attempts to introduce into the professional world in general amid thousands of contradictions and much resistance.

This allows for a pertinent and congruent treatment of the designated theme, of the value of "medical practice" in the legal field with reference to both sufficiently reliable operative and systematic precepts, in terms of intrinsic–or objective–validity and that of "duration in time", in the sense that they are not subject to impending lapse in any foreseeable way.

It is understood—but is a broadly institutional emphasis due to the plurality of systems—that the jurist who wants to tackle issues concerning the discipline of professional healthcare must take refuge in notions and principles of a general nature, with reference—mainly illustrative—to the Italian legal system, in order to give impetus to the verifications of the shifts that in various fields the individual national legal system can present with respect to that model.

3.2 Primary Sources

3.2.1 Law and Norms

In general public sentiment, law is the rule of inter-subjective relationships. The operational tool of the law is the *norm*, the binding nature of which is connected to the mode of its appearance in the legal system and whose function is to impose on the Associates the behaviours deemed necessary for survival.

In the infinite inter-subjective relationships are the rules which must be observed; among them the *summa divisio* is between legal norms and meta-legal norms; the distinctive feature is given by the *prosecutability* of the related violations; the assessment of possible violations of legal norms is assigned to a body with the power to judge and impose sanctions.

The binding nature of legal norms is independent of the subject who is required to comply with them and their violation is only detected in the objectivity of the action, quite regardless of the actual intent pursued by the agent. In this area the fundamental principle of Roman law that *de internis non curat Praetor* is still in use.

From the second half of the eighteenth century the system of *codification* was initiated and today the written form is considered to be such an essential feature of legal norms that one ends up considering only the written form as a norm; which is

nothing other than a prejudice. Aside from the fact that in the history of law the written rule appeared rather late, even today there are many matters governed by unwritten rules, but the related violations are not for this less illegal, less binding, and less significant, even if their repression is not always guaranteed by systems of *prosecutability*.

This emphasis affects the entire research, aimed at demonstrating the juridical nature of the practice, made significant by identifiable traits that render it a component part of the system.

The first point to examine in order to identify its content and function is that of how it is distinguished from other norms in the hierarchy of *law sources*, which is one of the cornerstones of legal science, although

> the expression contains, without doubt, a metaphor and therefore inevitably suffers from a certain degree of vagueness of outline and elasticity; which is not, however, sufficient reason for renouncing reliance upon it, breaking a tradition by now fairly well-established in modern legal science, if only for ease and brevity of discourse (Crisafulli 1968).

The correct placement of the individual norm in the hierarchy of sources is of fundamental importance for the correct formulation of the subject. These are traditionally separated into *primary* (statutory law) and *secondary* (regulations), which can be "general or local" according to the distinction introduced by art. 5 of the "Fundamental Act" of 1865, n. 2258/F.

The fundamental nature of law sources is their rigorous hierarchization: secondary sources cannot contain provisions which contradict a primary source; within the secondary sources a precise graduation must be identified, on the placement of which in the legal system depends the binding nature of the individual norm.

Always in general theory, in the relationship with primary sources, secondary ones can be *contra legem*, *praetor*, or *secundum legem.* For those *contra legem* the problem does not arise: they do not operate and do not acquire any relevance. Those that are *secundum legem* coincide with the prevailing interpretation and merge with it. The problem arises for those *praetor legem*, which integrate the preceptive content of the "overlying" sources, going *beyond* (and not only in a merely interpretive way) the relevant provisions.

3.3 Secondary Sources

Unlike primary sources (the statutes) for which the written form is essential, as far as the provisions on promulgation and entry into force are very detailed, the form in secondary sources is highly varied, often unwritten and the bindingness entirely independent of the form.

3.3.1 Consuetudo (Customs)

In the area of unwritten sources the main one is *consuetudo*, the first to appear historically.

In the classical legal world, even long after the appearance of the written norm—the *statute*—the *consuetudo* was considered the true legal norm: the *lex* was the written and codified norm; *custom* was only the norm as experienced, but not for this less binding. *Diuturna consuetudo pro jure et lege in his*, *quae non ex script descendunt*, *observari solet* (Ulpiano).

Consuetudo binds—becomes a norm—when it represents a widespread custom in a social context sufficiently broad and articulated, whose members feel themselves compelled to observe it, according to a *communis opinion juris ac necessitatis*; when there is the widespread conviction that such behavior is due.

A typical and renowned example of this equivalence of custom with statute can be found in the preface of the Edict of King Rotari of Lombardy (636–652 A.D), promulgated in Pavia in 642 A.D, in which (quoting a passage of Tertullian) it is stated that "for this it appears to us necessary to promulgate the present act, which renews and amends all previous ones and adds that which is lacking and removes what is superfluous". The Edict was the first written law of the Lombard people, previously governed only by customary rules, but it was perfectly equivalent to previous norms and customs considered to be true legal rules (Cacciavillani 2011).

Still in the legal field, even in the most technical and restricted sense, one distinguishes custom from *use*, which has a close technical affinity with the former (widespread behavior, held as being due) and is practiced, moreover, in restricted or specialized circles of workers. An example can be discerned in Article 1486 of the Civil Code, according to which, in the contract for sale of animals, local usage serves as a preeminent normative source for the provisions of that code.

Outside the legal sphere and still in the classical world, the *Lexicon totius latinitatis* of Forcellini (Cacciavillani 1994, 2000) enumerates dozens of meanings of the term *consuetudo*, from the way of life of the single subject in his relationship with the environment; to the habitual frequentation of a circle of people; to custom/behavior that is both individual (use and custom) and collective (usage).

3.3.2 Behavioral Codes

For centuries and in every system—for the most part since the French Revolution, which led to the disappearance of the ancient School of Arts and Crafts professional groupings have been recognized and organized, identified by reason of the consequences that could result from their exercise in the social context.

Some among these—notably and generally those of Doctors and Lawyers, who have always been united in Orders—have captured the attention of the Legislator, which has subjected them to a very rigorous and strict regulation, both with regard to access (admission to the practice) and the mode of their development.

Generally, at least in the modern age, the legal discipline of these groupings has granted them a wide organizational and regulatory autonomy in their mode of operation, in addition to that of the repression of possible deviations. It is concerned with normative systems of considerable size and bindingness, with complete prosecutability by the disciplinary bodies (internal authorities) formed by the Orders themselves (Cacciavillani 2000).

Within legally recognized professional groupings behavioral rules apply *ab immemorabili*, both with users/clients and between colleagues (in some jurisdictions—cf. the Bar in France—referred to as *confreres*), which by provision of the act establishing the Order, in a kind of normative delegation, are combined into behavioral codes with internal validity. They are formal autonomous normative sources, since their formation is assigned to the autonomy of the Order; of a secondary nature, since they cannot contain provisions in contrast with statutory (primary) law.

Also for the sake of pinpointing the peculiarities of the medical profession, it is worth noting—as quoted in the foregoing preface—that Article 152 of the EU Treaty (formerly Article 129 of the Rome Treaty), in the 5th paragraph, specifies that "Community action in the Public Healthcare sector shall fully respect the jurisdiction of the Member States relating to the organization and delivery of health services and medical care".

3.3.3 Practice

The nature of law sources is subject both to custom and to the behavioral code that is the recognized *practice*.

In legal dictionaries dating from furthest back the term "practice" is not recorded, unless to refer to *pragmaticus,* an adjective which is often substantive; in this sense the aforementioned *Lexicon totius latinitatis* notes, among other meanings, the opinion of Pliny, according to whom "praxis" *et* "pragma" *idem fere sonant*, were essentially synonymous.

In the famous Venetian legal synopsis of Ferro (Ferro 1781), the word is not even recorded; the Legal Encyclopedia of Foramiti (Foramiti 1839) only records the word *prammatica* (sanctio) in the two institutional and historical meanings.

In the most widespread Modern Italian legal synopses, the *Digest* (Il Digesto 1925; Il Nuovo il Digesto 1939; Il Nuovissimo Digesto 1967) also does not record either of the terms *practice* and *customary* (*prassi* and *prammatica*) while the Encyclopedia of Law (Piga 1968) records the term "administrative practice", with a very precise technical meaning and a useful reference beginning from the *incipit* (opening lines), according to which "it is the widely held view that administrative practice, intended as a constant repetition of procedures and behaviors, has a relatively marginal importance as a legal institute in the technical sense". The opinion is widely shareable in the context in which it is placed, limited to the administrative function.

3.4 The Medical Profession

3.4.1 The Professional Work Contract

As with any legally protected profession—and its special regime of protection established by formal statute—the medical profession is regulated by specific laws (it would be improper to define them as special, since they are simply "matter") governing its activities in the framework of principles usually of constitutional standing. The inspiring *rationale* of such a specific and, in general, highly detailed discipline must be recognized in the absolute primary importance, universally recognized, of protected value, the health of the individual and therefore (an important source of publicity) of the general public. Such importance is usually also formally declared in the Constitution (*the Gründnorm*) of the jurisdictions. In the 1948 Italian Constitution, it is set out in Article 32, according to which "the Republic protects health as a fundamental right of the individual and interest of the community and guarantees free medical care to the indigent" (Cacciavillani 1993).

In the discipline of the medical profession all the normative sources which have been mentioned arise and interact: from material laws and protection of the integrity of the person, including those criminally relevant; to the regulations governing the content and modality of professional services; to the custom up until the practice, which is the direct object of the investigation. Along with this there is a systematic condition of great importance: the typical services of the healthcare profession are regulated by an absolutely peculiar legal source: the therapeutic protocol.

3.4.2 The Therapeutic Protocol

One certainly does not mean to provide a positive definition here, also because it concerns an institute of very vague content, liable to assume, in addition to different denominations, different roles and therefore quite varied significance. Because it concerns a criterion of evaluation of the professional behavior of the oft-cited Physician, it seems useful to outline the prevalent features (or at least those deemed so according to general feeling).

Essentially, it is the cataloging of professional conduct deemed to be due to the occurrence of certain types of pathology, the diagnostic identification of which in a specific case depends upon the comparative evaluation of factors which are the result of the professionalism (training, experience, acumen) of the individual healthcare worker.

The essential character and constitution of every professional expertise is the freedom to determine one's behavior in individual cases. A decisional automatism of the healthcare professional does not exist; if it existed (and it would be

comparable to an anomalous "assembly line" for the solution of cases) it would be the radical negation of such professionalism as commonly understood. There are diagnostic methods that aid the exact identification of the "case" and the therapeutic methodology for its cure; but for the professional a technical scientific preparation must exist earlier in the process, the result of attentive experience and a professional knowledge that goes beyond any manuals, be they descriptive or statistical.

In the dialectic antimony between manuals and professionalism, understood as the freedom of self-determination in the individual case, is where the nobility and responsibility of the Physician lies, just as the choice of defensive line is where the lawyer's professionalism abides. Both professions are torn between manuals and experimentation: differentiating intuition for the Physician; innovative interpretation for the Lawyer (Cacciavillani 2010).

In this line the same *editorial* initiative acquires relevance, which permits a useful clarification of the system. But the therapeutic protocol—or however one wants to denominate it—fundamentally always remains either just a manual of case studies or a statistical review of solutions which have proved to be more or less beneficial, without ever acquiring the nature of a legal norm, not even supplementary of other sources which are also secondary in various ways.

The therapeutic protocol does not go beyond a reference that is more negative than positive, in the sense that it is relevant in the case of an event which is different from the one hoped for and/or pursued in order to parameterize the professional responsibility of the doctor, both omissive in the order of the adoption of remedies provided for in the protocol, and positive, for recourse to their "own" remedies, the result of their own choices. It is a *dictum* of the "scientific community", an extremely vague entity and, by definition, a changeable structure, far from the value that legal precedent can have for the Lawyer (Cacciavillani 2012a).

As if to say that the deviation from the therapeutic protocol involves professional risks that can negatively integrate breach of work contract in private medicine; violation of official duty in public medicine; risks—positive—neutralized only with adequate preventive and curricular documentation of the healthcare worker.

These principles operate fully in private medicine and are notably marginalized in public medicine, due to the diverse legal nature of the employment relationship, in which the publicity of the function absorbs the contractual nature of the service.

3.4.3 The Work Contract and Employment Relationship

The continuous references to the diversity both of layout and exercise, and of the responsibility between private and public medicine, prompt a mention of the systematic approach of this *summa divisio*.

The general evolution of the legal systems, which have even included the health of the individual as a primary public function, has already been mentioned,

allocating significant human and financial public resources and preparing adequate, often impressive, structures.

The personnel assigned such duties are recruited on a differential basis according to the tasks they are allocated; healthcare personnel must be registered with the Order of Physicians, submitting to the dual discipline of both regulative and public employment; the subject will be taken up again from a different perspective.

Alongside and parallel to this the activity of professional private healthcare is carried out, which as such is not exempted from the general system of private law contracts, being as they are real work contracts, involving well-defined services to the person. The legal evolution of jurisdictions, with the assumption of the individual's healthcare as a direct public function, combined with the technical progress of science, has relegated the strictly contractual element to second place, essentially limited to so-called "private medicine" (in order to distinguish it from the one exercised in public establishments) and, in his field, only one choice of Physician, professional behavior being minutely regulated by normative provisions of varying nature and scope, in any case of a matrix ordinarily external to the contractors.

The only contractual consideration corresponding to the choice of the patient is, for professional private healthcare, the obligation to provide adequate information concerning the proposed therapy, commonly identified as *informed consent*. Moreover, its content and role in professional responsibility is more equivocal than certain, even in the jurisprudential panorama related to the pathology of the work relationship.

The integrating source of the professional work contract attributed above to the therapeutic protocol operates mainly in private medicine, while in public medicine different prescriptive sources operate. Indeed, in public medicine the healthcare service, even if qualitatively equal to that performed by private medicine, is the exercise of a public function regulated by rules specific to both Public Healthcare and general rules of public employment relations. For the latter, and continuing the reference to the "Italian case", one may recall the precept of Article 54 of the Constitution, which provides that "the citizens who are entrusted with public functions have the duty to fulfill them with discipline and honor". While the element of *honor* has a direct and immediate meaning, the notion of discipline in the constitutional context is rather severe and includes every normative and preceptive source, as organizational circulars and the order of the superior hierarchy could be, responsible for both the Entity's structure and the concrete exercise of the function.

3.5 Medical Practice

Concerning normative sources operating in the system, it seems important to highlight the specific role carried out in healthcare services. Also here—but one should say particularly here—distinguishing their importance in public and private medicine.

3.5.1 The Structural Practice

In dealing with this subject—of central importance in the research—a clarification of a systematic character is a prerequisite: the Physician who works inside a public structure is subject to a dual discipline, each of these with autonomous prosecutability: the Association's rules for the protection of the professional behavioral code (relationships with colleagues and patients) and the ones of public employment; the situation is extremely recurrent in the regulations: one thinks of the public law profession, which all medium–large Administrations are equipped with, whose Functionaries are in their turn subject to the dual discipline of the Association and Body to which they belong. The relationship between the two normative sources must be coordinated in the spirit of genuine collaboration between public bodies, which today is done through the instrument of the conference of services (Cacciavillani 2012b).

Obviously, the relationship between the two sources—primary, the legislation on the Association and on public employment, and subprimary, the behavioural code—follows the rules indicated above; both prevailing over the practice, which they therefore impede from acquiring the significance of autonomous law sources and which would evidently be *contra legem.* All the findings that come into play are thus placed "downstream" of the two indicated sources.

Since public medicine is carried out in structures that are often very complex, in which professionals with profoundly differentiated legal roles (professional expertise) functionally operate and interact, the *structural practice* must be identified and valorized in detail, which is the consolidated (or even only customary) mode of conduct (outside of the prevailing norms) of the various professionals upon the occurrence of repeated events. That behavior becomes binding (practice) if it is repeated with a certain amount of constancy. Fundamentally, it comes to be considered as a *superior's order*, an institution operating largely within the discipline of public employment and fully discriminatory—unless it is obviously *contra legem*—for the professional who abides by it.

In this structure the operative practice becomes a normative source of great importance in determining the required behavioral customs, creating among all of the professionals, independently of relative professional status, a reciprocal conditioning even in the way of expressing, as well as practicing, the function. Respecting the practice of the structure involves a precise behavioral duty that is legally binding, to the point that its inobservance, on the part of the individual professional, could involve an attack on the performance of the function as a whole, likely to give rise to disciplinary action by the service manager.

The rather delicate problem presents itself in the case in which the professional physician of the public structure intends to depart from the therapeutic protocol, while inside the limits and according to the criteria examined above. It should be noted that it could only be done by involving the entire body of the Healthcare structure, in a collegiality of function that would fundamentally have the nature and role of a real conference of technical service, with respect to the conclusions

of which—whatever the sign—the dissenting doctor only has the right of remonstrance (possibly even soliciting authoritative interventions "from above").

In the relationship with third parties, which will be examined separately, the structural practice becomes a source of legitimate expectation by the recipients of the public healthcare function, whose violation (deviation in the single case) may give rise to civil liability for damages where a causal nexus is proved between the deviation and the damage suffered by the user.

3.5.2 The Professional Practice (Publicity)

The importance of practice within private medicine is more subdued, in any case operating within the limits of the civil law discipline of the intellectual professions. Being predominantly linked to the individual behavior of the single professional worker, it is certainly easier to identify than the structural practice, having to result from the repetition of behavior by the professional worker, a frequent recurrence of events taking place in the normality of their healthcare practice. Except of course that the organization of the private activity is not so structured (or even publicized) so as to engender in the client/user a legally significant trust which directs them in their choice of the worker to whom they will entrust themselves.

When deviation from professional practice is objectively detectable it should be framed within the paradigm of breach of the work contract, usually giving rise only to compensation for damages and not to termination of the contract, given the normal non-fungibility of healthcare services.

In the regulations civil liability for an event contrary to what was agreed in the contract is usually diminished; it is limited to cases in which the unexpected event is not ascribable to the intent or grave misconduct of the professional (Article 2236 of the Civil Code of the Italian Republic provides to this effect). It would be difficult to invoke such exemption where the unexpected event is ascribable to the worker's deviation from professional practice, being—always examined in the hypothesis—a breach of trust legitimately placed on repeated professional behavior and not solutions to therapeutic problems.

The publicity of healthcare services offered and extolled is an independent vehicle and autonomous integrator of professional practice in private medicine, now completely liberalized by laws which are not always adequately thought out. It certainly can not be called into question that the publicity of professional healthcare services has the legal nature of an "offer to the public" regulated by the law "as a proposed" work contract, both in the proactive components and as a promise of the result envisaged. Here, professional practice is not inferred from repeated conduct, but forms the object of a real offer of termination of the work contract.

A real intractability of the offer of healthcare services—something which appears to have been left unexamined—must be considered, since—again for the absolutely general provision of the regulations on the parity of the legal treatment

of the contracting parties (provided by Article 1336 of the Italian Code)—the withdrawal of the contractual offer is valid only "if it is made in the same form as the offer or in an equivalent form". Only in this case is it (the withdrawal) "also effective in comparison with who has not been notified of it".

If these aspects were adequately weighed, perhaps a certain degree of miracle working publicity for healthcare services would be avoided.

3.6 Function of Healthcare Practices

It is understood that, according to the above, the practice would still be valid only if *praeter legem*, it could acquire legal significance under two well-defined aspects: as justification for the behavior according to the practice of the healthcare worker, in the case of contestation of their conduct and therefore as exemption of their responsibility, and as a source of trust for the third party, the user of the function.

3.6.1 Worker's Exemption

Recalling that set out above concerning the importance of the therapeutic protocol and its role as integrator of preferred behavioral rules (set by "higher" normative "sources") carried out by the practice, deviation from it justified by the professional choice of the healthcare worker can give rise to different interpretations, liable to transform into disputes—sometimes even patently instrumental—especially on the initiative of colleagues, which everybody knows are the most acrid and acrimonious kind (moreover the coining of the saying *homo homini lupus, medicus medico lupissimus* is attributed to the celebrated Padova School of Medicine). Precisely where the role of practice, as integrator of norms, can constitute—in good or bad faith—support for endless litigation.

In the case where the professional behavior of the public healthcare worker is challenged in the individual case, if he is able to demonstrate—in the disciplinary headquarters (which could be the Order or the Public Structure upon which he depends) or civil court, where he is summoned by the damaged party—that he followed both structural and professional practice, then no claim may be made against him and no liability is alleged.

3.6.2 The User's Trust

From another point of view the "external" aspect of practice is very important, in the relationship with the various third party recipients of the healthcare service, as

even here the position and the treatment of private medicine from that of public must be clearly distinguished; the first one speaks of *clients* while the second one of *users*.

On the level of professional competition, a considerable part of practice consists of the professional's good name. This—good name—creates a selection of clientele, which when they arrive at that clinic have the right to enjoy a certain type—or level—of service. Under a certain profile good name could be considered the opposite of publicity: the latter magnifies *ex ante* the operator's professional capacities; good name magnifies them ex *post*. On the contrary, good name does not expose the professional to the risk of being sued for failure to respect professional standards, which good fame presupposes.

In this regard the strategic utility of institutional treatment in the first part of this essay emerges quite clearly: by identifying in the good name of the healthcare worker the main consequence of good practice, in the case of deviation by the professional from his/her standard to the detriment of the *user*, there is no (or it is extremely difficult to have) action for damages; here the practice reveals its "weakness" as a normative source: its possible violation is devoid of any prosecutability; if the behavior deemed harmful also incorporates a violation of "higher" norms, such as the therapeutic protocol, there will be an action for compensation, but in this case the violation of the "superior" norm would be absorbed and nullify the violation of practice.

3.7 Bad Healthcare, Bad Practice, and Insurance Coverage

Obliged by reasons of title to also take an interest in the pathological aspects of the healthcare function, while always within the limits of the setting, the radical diversity of the treatment of deviations in private compared to public healthcare continue to emerge quite clearly.

3.7.1 In Private Healthcare

The private practitioner who violates his/her professional duty, both on the deontological and statutory level, is subject to the relevant sanction of prosecutability. For deontological justice, administered by the Order, the accusation of pronounced corporatism is usual and not unfounded; indeed, it must institutionally protect the weaker contractor —normally the client— in the contract between the two parties; thus being—if not against the colleague a priori—certainly independent and not in solidarity with him. This would presuppose an absolute *impartiality* of the "judge", which is difficult to configure when the judged and the judger belong to the same Order (which we don't wish to consider a caste).

Not without observing that—always in private medicine—the loss of good name would be the sanction of the market, which is the most effective deterrence of even a slight possible deviation from practice, in the sense that such a professional would see a reduction in the number of clients and would gradually become marginalized.

3.7.2 In Public Health

The consequences of pathology in the exercise of public health are completely different, connected—the differences—to the legal nature of the public function that this branch of medicine came to assume in all the jurisdictions; to continue the reference to the Italian one, the nature of the function owed to public healthcare derives from the combined provisions of Article 32 and 54.2 of the Constitution. While the relationship established between the *client* and the private healthcare worker is of a private contractual nature, the one existing with a public healthcare structure acquires the nature of a subjective public right of the citizen, in accordance with provisions common to all jurisdictions, specifically made except in their preceptivity within Article 152 of the EU Treaty cited above.

3.7.3 Bad Healthcare and Bad Practice

In the *summa divisio* already traced, it appears obvious that when one speaks of "bad healthcare" one is speaking only of the malfunctions in the public sphere, because private malfunctions are absorbed by "private" and/or disciplinary sanctions, in their turn also bathed in a "corporate decency" that diminishes their uproar, which would—or must be—the most salutary reminder of the social—as well as professional—seriousness of the *medical art*.

Very different—and obviously given the radically diverse nature of the function—is the uproar at the malfunction of public medicine, even if it is not at all commendable that the headlines only cover negative events; but that is an inevitable occurrence, since it dates back to the observation that the sound of a falling tree is louder than that of a growing forest.

To talk instead of *bad practice* is not at all justified; or, rather, the fact that it is spoken of reveals the general moral decline. Practice as the normal exercise of the function could not be anything but a good thing, the expression of the worker's attachment to service; the episodes of deviation from good practice must be extremely rare. Here, we can talk about the unacceptability of *bad practice* as the routinely bad exercise of the healthcare function.

Aside from the fact that acts/attitudes/behaviors which could be considered episodes of bad practice would also supplement the violation of norms far more binding than practice, certainly equipped with a severe prosecutability, it is the phenomenon itself which cannot fail to cause alarm.

If—institutionally—the relationship of public employment, which ties the Healthcare Worker in a public structure to the titular Administration of the function, naturally and institutionally absorbs his/her personal liability for possible damages caused to the user in the exercise of the professional activity, the public structure in which he/she operates is obviously called upon to respond to such damage.

Ordinarily, civil actions for damage compensation due to "bad healthcare" are enormously facilitated by the general attribution of damage/malfunction "to the structure", without it being necessary to identify the individual operator to whom the malfunction is ascribed. This, unfortunately united to a certain frequency of malfunctions within the sector, feeds a bitter and not infrequently instrumental dispute in the search for easy enrichment.

3.7.4 Lack of Responsibility of Insurance Companies

The way out most often chosen in advance by the "public hand"—the Bodies that in the various jurisdictions preside over the function—in order to get around the dispute is the taking out of insurance policies against "risks of malfunction"; where, in the frantic search to eliminate risk factors, rendering the consequences legally harmless is preferred to doing the utmost in order to improve the service in every sector of its operations, from medical to paramedical and technical.

This is the most serious assault on the function as a whole due to the system effects that it inevitably provokes. Not that one can adumbrate that what determines the trust in the professional duty is the threat of compensation for damages resulting from possible deviation, but there is no doubt that also that deterrence contributes to forming the habit of trust, which arises from the social context in which one lives. The release from every personal financial responsibility, caused by the firmly established custom that in any case "another pays" (the structure), contributes to loosening—or at least does not increase—the attachment to professional duty, the custom of fidelity to the function.

The insurance for damages from "bad healthcare", stipulated by the Public Titular Body of the healthcare function, is a real aberration of the system. The Body, called upon more and more frequently to compensate damages—at times substantial—from bad healthcare, which stipulates an insurance for the damages incurred by *users,* implements a real assault on the constitutional order; where the Functionary's responsibility is radically decreased, there having been introduced—sometimes even by law—a real exemption for infidelity to the office.

It is well understood that the Functionary should mind his office with discipline and honor; deterring the risk of having to compete on his own account to compensate the damages for deviance from official duty could be a salutary admonition. Here instead, with much sadness, one begins to talk of bad practice as a custom of unpunished violation of the functional duty.

Truly, *mala tempora currunt*!

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Foramiti F (1839) Enciclopedia legale, ossia lessico ragionato, Venezia, Co' tipi del Gondoliere, Volume IV; it is useful to trace the evolution of the notion summarized therein: in the systematic sense "this expression is removed from the Code of Justinian, in which the Imperial rescripts concerning the government of the provinces were called pragmatic formulas or pragmatic sanctions. It comes from the Latin sanctio and from a Greek word that means business; it is used to express the regulations concerning the most important objects of the civil and ecclesiastical administration, above all when they were deliberated in the assemblies of the nation and with the opinion of jurisconsults"; in the historical sense it recalls the order of King Charles VII of France in 1438, which regulated the "mixed" subjects, between the civil and canonical disciplines; the branch of law that is now commonly called "ecclesiastical law". The ordinance was repealed by Francis I, at the request of Pope Leo X (ibid)
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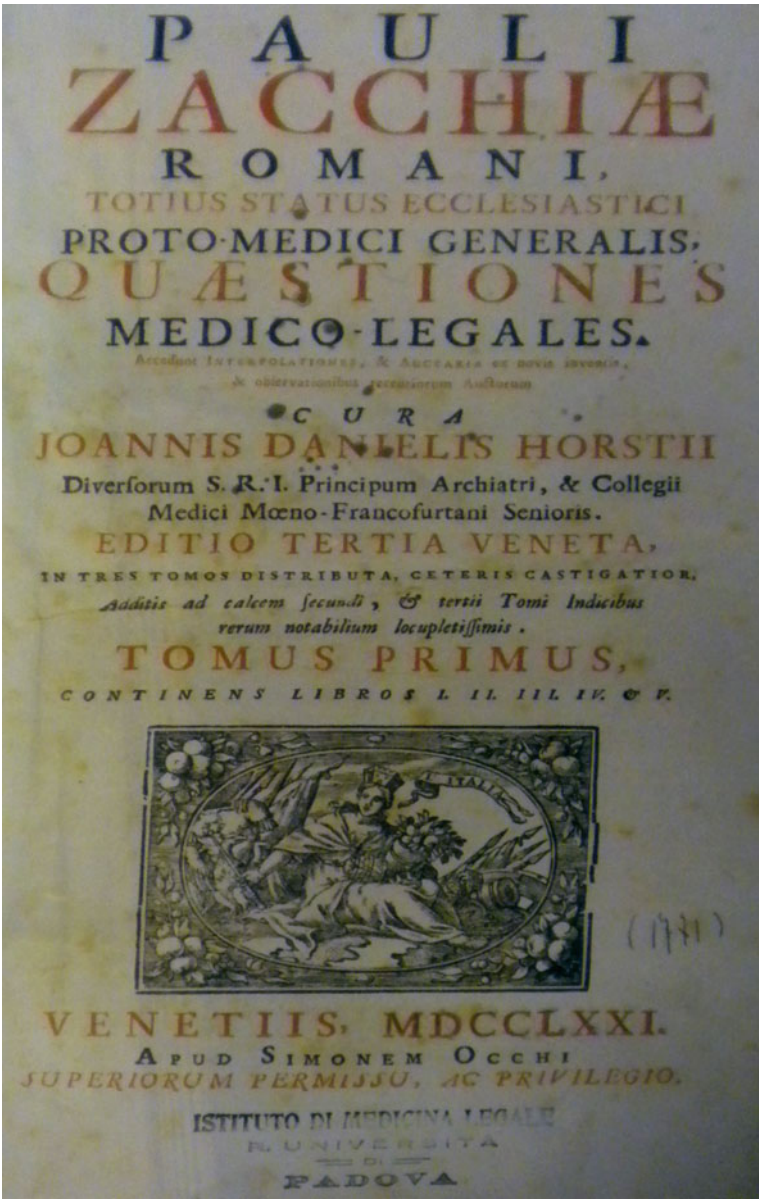
Part III
Legislative and Juridical Background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Zacchia Paolo—Pauli Zacchiae, "Quaestionum medico-legalium tomus primus-tertius Lugduni : sumptibus Anisson & Joannis Posuel", 1701. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

Chapter 4
European Legislative and Juridical Overview

Paola Frati and Matteo Gulino

Abstract The first part of this chapter gives an introduction to what is a comparative overview of medical liability in Europe, while the second part focuses on medical liability in Western Europe in both Civil and Common Law systems, concentrating on Fault, Contractual and Extra-Contractual Responsibility, Standard of Care, and Burden of Proof. The third part of the chapter examines the key role of mediation in Medical Responsibility in Court Systems and Administrative Systems. The following sections discuss, respectively, the models in place in the Scandinavian countries, the French experience of medical liability, and the "Loi Kouchner", including the English experience of the NHS Authority Litigation and the key role of mediation. Finally, medical responsibility in Eastern Europe is discussed, focussing on Bulgaria, the Czech Republic, Slovakia, Russia, and Lithuania, while the chapter concludes with a discussion of the present and future perspectives with regard to the issue of medical liability in Europe.

Contents

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4.1 Introduction

The exponential increase in cases of both medical malpractice and cross-border mobility of health professionals and patients represents a suitable reason to explore the field of medical responsibility, using a comparative approach, also at the international level.

The consolidation of a Judiciary system oriented towards preferential respect of patients' needs and the recognition of compensatory damages—sometimes presuming the existence of a causal relationship and thus without a real fault investigation—suggests to the majority of health professionals the need for a reconsideration of the adequacy of National Compensation Systems.

The comparative analysis of medical malpractice cases allows us to consider that the health systems of many countries are moving toward a no-fault (or no-blame) compensation of the physicians' and/or hospitals' responsibility. That is why a future affirmation of the obligation of result is foreseeable. Indeed, the peculiar system of burden of proof, which is more and more pressing for the physician, leads to a kind of bond issue for which, when the patient does not recover, the health professional can be accused of malpractice and obligated to provide fault compensation. In other words the presumption of responsibility of the health professional can be overcome only by the determination of the unforeseeable event which directly prevents the expected result.

At present, society is oriented towards a substantial process of legislative globalization and harmonization. Clearly, this is also true in the field of medical liability. The quality of the physicians' performance and the patient figure, perceived as an autonomous center of rights, has progressively involved public opinion and media attention.

There are several reasons which have combined to raise the number of judicial proceedings, including the increase of patients' awareness of their rights.[1]

[1] In this regard, we have to recall the 2006 Euro barometer report, which shows that 78 % of EU citizens believe that the issue of medical mistakes is relevant and that 73 % of them learned about mistakes committed by the health system from newspapers and mass media.

Indeed, differently from the past, a high quality medical care paradoxically determines the consequence that, in the case where the expected result is not achieved, the physician is automatically responsible until proved otherwise.

Evidently, the main concern regarding this approach is represented by the establishment of a regulation excessively inspired by a welfare perspective aimed at guaranteeing, as much as possible, compensation for damages through suitable insurance coverage. The existence of an obligatory health insurance (i.e. a financial guarantee) may imply a less rigorous assessment of responsibility, thus determining a higher liability to allow for the fault compensation. On the other hand, the health professional, financially guaranteed by insurance, would feel relieved of his own responsibilities in case of possible negligence. In other words, the concern is focused on the illogical and distorted situation in which the purpose seems to warrant a higher number of compensations, neutralizing in this way the healthcare protection. Indeed, the increased fault compensations may permit the erosion of the principle of fault personalization and favor standard fault compensations, possibly inappropriate to the circumstances of a specific case. Consistently, the European trend is towards the guarantee of the highest number of claiming patients rather than the individual quantification of the damage (Ponzanelli 2003); in France, for instance, through the introduction of the juridical institute of aleatory therapeutics, some typologies of medical error are considered as a social risk that must be shared among the community members on the basis of a central state logic.

However, France (Act 303/2002) and Scandinavian countries consider insurance essential in order to guarantee suitable health-risk coverage. Notably, a situation in which a higher number of compensations would be guaranteed could result in a sort of worrying over-deterrence of health professionals, hospitals, and insurance companies. In other words, an extremely prudent medical approach (defensive medicine) would be likely to take shape, which could limit the freedom of the physician and the health of the patient.

Moreover, the transfer of compensatory damages from the single physician to the health structure, which is pushed to be insured, could lead the physician to develop a reduced perception of his own personal responsibility. Indeed, the physician would act with the awareness that possible fault compensation would be covered by the hospital (or the health institution). Furthermore, the insurance instrument could facilitate the patient's access to compensatory damages and would determine as well the consequence of a minor quantum, being the amount of compensation established "ex ante", before the establishment of the legal question, with the purpose of favoring an agreement between the parties.

As better explained below, the reasons behind the increase in medical malpractice cases (including the related management cost) can be identified in both the legislative lack (absence of specific legislation regarding health responsibility), and the inadequacy of the national compensation systems. In most European countries, we observe a juridical tendency to shift the burden of proof from the patient to the health structure/physician, through principles that only ostensibly belong to different juridical systems: i.e., the *res ipsa loquitur*, typical of the Common Law system and the burden of proof, which is typical of the Civil Law

system. Indeed, these different juridical aspects both derive from the common principle that failure to attain the expected result determines a fault of the professional *in re ipsa*, which is well explained by the statement: "the evidence (failure to attain expected result) which creates a deduction of negligence". Actually, the lack of an expected result, which would correspond to the "normal" result following a correct medical act, automatically places the physician in a fault status, who will then have to prove the contrary data in relation to the presumptive wrong act. Together, these observations open the way to the introduction of the hypothesis of truly objective responsibility, which is now perceived both in Italy and also in France, Spain, Germany, and many other European countries characterized by either Common or Civil Law systems.

Notably, if on one side the impact of the media could really affect the evolution of health cases, it is also true that potential damage compensation is the primary goal of each juridical system facing the issue of health injury.

However, such compensation is related to different elements, such as the nature of the medical-health obligation, the burden of proof law system and, above all, the potential availability of instruments established by the legislator to promote extra-judicial conciliation. In this regard, it is essential to underline that the conflict is often characterized by a lack of communication and discussion between the contending parties. Therefore, it would also be necessary to emphasize the fundamental role played by the extra-judicial phase in the clinical cases.

The necessary involvement of the patient is underlined by the European trend, which considers correct information crucial to obtaining the effective participation of the patient in the decisions which involve his own body and health, and not only with the purpose of relieving the physician of responsibility. In cases in which such a correct patient/physician dialogue was lacking and damage compensation has been requested, an extra-judicial resolution may help, though ex-post.

After all, the idea of the physician as an unfailing subject is nowadays rather anachronistic and is not compatible with the present conception of relative truth, which is intimately connected to the state of current knowledge and technological development. For this reason, regardless of the specific issues of the socio-cultural environment of each juridical system, it would be desirable to adopt international rules shared by several countries according to a perspective of legislative integration.

4.2 Medical Liability in Western Europe Between Civil Law and Common Law

The outlining of a common structure of the European legislative systems with regard to the issue of medical responsibility is not an easy task. In fact we can note that these juridical systems are very different and they do not always adopt the same approach. However, the most complicated issue is deciphering the variety of historic and socio-cultural environments that characterize the different countries,

as well as the political and institutional changes incurred in some geographical areas of Eastern Europe (Birmontiene 1996).

Indeed, every effort aimed at drawing comparisons, similarities, and contrasts in the strict sense would appear inadequate and, above all, irrelevant for the resolution of the discrepancy.

Consequently, the purpose will be not to catalogue in a static way, but to analyze the matter in a constructive and functional way. In other words, it will be necessary to analyze the similarities existing among the different legal orders in-depth, regardless of the typical distinction between Civil and Common Law, in order to trace a common central thread.

As we will subsequently understand, judicial conflict in the field of medical responsibility often represents an ideal area for the infringement of general principles and the adjustment of juridical institutes—usually created for abstract cases—towards the concrete needs of the patient. The first problem is certainly represented by the identification of those criteria in the categorization of the different European legislative systems, in order to find a possible common asset.

We could start by distinguishing between the Roman Law system, the Civil Law system (characteristic of the majority of continental European countries), and the Anglo-Saxon Common Law system (typical of England and former British Empire colonies such as Ireland). Secondly, we could analyze the impact of the different levels of Judges' decision-making autonomy on the rules that govern medical responsibility. English law is an example of the Common Law system, where there is a reduced utilization of the regulatory instrument. The practical training of the Common Law jurist, as opposed to the more theoretic approach typical of the Civil Law system, determines the validity of the *stare decisis* compulsoriness. Unlike the Roman system, in fact, Common Law is defined as a system principally based on the analysis of case law.

The application of such an approach to the medical liability field would determine the prevalence of the judges' interpretative analysis of the clinical cases, though assisted by experts in Law Medicine, at the expense of the written law and the underlying ratio.

However, the comparative analysis based merely on the distinction between Civil Law and Common Law, does not allow us to achieve our purpose, due to the lack of an ad hoc legislation in the majority of European countries, regardless of their Civil or Common Law based juridical system (Grossen and Guillod 1983). In some countries such as Italy, this situation determines the Judges' tendency to exceed their role in applying existing law, often becoming real interpreters or law creators rather than applicators. This concept is well expressed by the Italian Supreme Court in verdict n. 9471/2004, which defines medical liability as a responsibility in action resulting in the identification of standards of conduct, on the basis of which the theories of fault, causal relationship, and damage are subjected to continuous changes with regard to the traditional schemes, under both a substantial and probationary profile.

Certainly, the lack of specific rules in this field represents a common finding about which we must reason according to perspective criteria, also taking into

account that in the last decade the regulation trend has progressively increased (for instance, the matter of damages arising from medical assisted reproduction in Spain) (Act 14/2006).

The analysis of European juridical systems underlines the fact that damages arising from medical malpractice could have consequences under penal, civil, and administrative codes, depending upon specific circumstances. In some countries (France, Spain, The Netherlands) medical liability is regulated by both Private and Administrative Law, according to whether the damage is caused by a physician within a private or public hospital (Serra and Carrara 2005).

At this point, the best approach for a comparative analysis of juridical systems is to reason about the assumption that in every European country the fault represents the fundamental criteria in the establishment of medical responsibility.

First of all, it would be important to identify on what basis the fault is established. Pragmatically, medical liability is linked to the presence of two main elements: (1) the recognized standard of care and the boundaries of the Fault notion (when the physician's conduct is negligent according to a generally accepted standard of care) and (2) the burden of proof regulation, including the related contents.

4.2.1 Fault

Generally, the right of the patient to obtain compensatory damages arises only in the case where the physician has committed a fault. The conduct of the physician could be an act or an omission. In most cases, Medical Liability Law based on fault considers conduct wrongful and guilty when it is negligent and relatively avoidable. Therefore, the fault represents the starting point for the patient's claim either in contract or in tort. In the first case, the fault can be considered as deviating from the standard of care (relating to the hypothetical physician's prudence and diligence, like a sort of rule of best practise) and, in the latter case, as the violation of the patient's right (as, for example, the lack of correct information, i.e., of an informed consent). With reference to the standard of care, the physician has to fulfill his/her duties appropriately, with diligence, and in accordance with the current state of medical art. On the contrary, with reference to the violation of the patient's right, the physician has to inform the patient correctly and precisely regarding the treatment.

4.2.2 Contractual and Extra-Contractual Responsibility

The comparative analysis of the European juridical systems demonstrates that sometimes the distinction between contract and tort, non-fulfillment and tort, as well as contractual responsibility and extra-contractual responsibility, assumes relevance in the issue of medical liability. In fact, there are juridical systems that regulate medical liability on the basis of tort law and others on contract law. In

some juridical systems (e.g. Italy) the case law evolution has been limited to the field of the contractual regulation, while in others, such as Austria, Germany, and England, medical liability falls under both contractual and extra-contractual law (Bernhard and Koch 2003; De cruz 2001; Stauch 2008).

The difference between the institute of contractual and extra-contractual responsibility assumes relevance under several aspects, such as, for example, in the different punishment or compensation purpose (*ratio*) in the statute of limitation, in the damage quantification procedures, and in the burden of proof regulations. Indeed, while extra-contractual responsibility has a punitive purpose (to prevent unlawful acts), the contractual responsibility has the purpose of reestablishing the parties' interests, according to the contract rules. For example, with regard to the burden of proof, while the institute of contractual responsibility facilitates the patient's position, the institute of extra-contractual responsibility instead facilitates the physician's position on the basis of the general principle which establishes that people who go to court must demonstrate the facts relating to their compensation claim. Furthermore, contractual responsibility usually provides for a greater prescription compared to that of the extra-contractual responsibility.

The two frameworks are also different under the profile of fault. In contractual responsibility, the fault presumes the violation of a contractual provision or, more generally, the occurrence of a breach/wrong execution. In extra-contractual responsibility, however, the fault is based on the violation of the general cohabitation principle of *neminem laedere*, which establishes that everyone is obliged to respect the generic duty of not harming the others' juridical sphere. In other words, such a principle provides that any person who causes unfair detriment to another, through willful or negligent conduct, must compensate the victim for any resulting damage suffered.

As mentioned above, in the field of medical responsibility the application of one institute rather than the other one determines relevant consequences, which can facilitate or not the patient's position. However, in the authors' opinion, it is not useful to categorize juridical systems on the basis of contractual or extra-contractual responsibility, due to the actions of the Magistrate, which contribute to the mixture of elements from both categories. In fact, today we are facing the progressive affirmation of a less strict adoption of the typical characteristics of the contractual and extra-contractual responsibility frameworks.

On the other hand, in all European countries the rules of medical liability are mainly of juridical origin. While this consideration is predictable, due to the extra-contractual (i.e. regulated by *Lex Aquilia*) responsibility regulated by a reduced number of rules, the same is not true for contractual responsibility, which now requires the establishment of a Health contract (Italy, Spain, France, Germany, etc.), the content of which is entrusted in full to the juridical verdicts.

On the other hand, the agreement between the hospital/physician and the patient is based on verbal relationships and thus lacks a social contract, including common provisions. Indeed, also in countries characterized by the Civil Law system, the Courts establish—in cases where a contract exists—the contractual parties, the respective provisions and requirements, and the responsibility and proof rules. General rules, although noted, are reinterpreted by judges. Doctrine states that the

contractual obligations of the physician mirror those typical of extra-contractual accuracy (Atiyah 1986).

Over recent years a progressive affirmation of an approach designed to guarantee to the patient (considered a weak person) a privileged position has taken place in most European juridical systems.

In fact, the analysis of the evolution of Case Law in several countries allows us to show how contractual systems restrict the patient's chance of obtaining compensation by the use of the category of obligations of means, while extra-contractual systems open the way to the patient's claim through principles like *res ipsa loquitur*. Although in some countries the general rule is that the burden of proof is upon the patient—according to the scheme of extra-contractual responsibility—it is possible to point out that the trend of making use of the principle of Fault presumption permits an easier acknowledgement of compensatory damages.

As previously underlined, the European experiences have in common a particular attention to the protection of the patient's rights, though in different stages. In fact, while in some countries the patient's rights are protected during the pre-trial phase through specific laws which determine the techniques of distribution of health risks, in other countries this kind of protection is activated directly during the trial phase thanks to the action of the Judges in ordering that the patient be released from the burden of proof.

For example, in France, the first solution has been privileged with the introduction of a specific check of health risks, which is the mandatory insurance for every hospital. Instead, in other European experiences, the purpose of patient rights protection is pursued with the adoption of a probationary system favorable to the patient.

This trend started at the European level, with the introduction of the principles of the inversion of the burden of proof by the provider of a defective service in "market services" of specific fields. To such a provider, the various European Courts compare the health professionals (proposed Directive, G.U.C.E. January 18, 1991 n. C-12). This trend has been further supported by the principle of the right to an impartial trial, which is supported at the European level and aims to warrant all parties the opportunity to present their arguments, avoiding disadvantages with respect to the opposite party.

4.2.3 Standard of Care

In order to ascertain the fault of the physician it is necessary to analyze and evaluate his/her conduct in the execution of a specific treatment. Except for the cases where the physician does not respect operative protocols, the physician's conduct is guilty when he/she did not execute the treatment according to the required standard of care.

The physician must have the knowledge and competence in order to guarantee a good level of care in the treatment of the patient. In this way, the physician has to fulfill his/her duties by observing a professional standard of care, based on the

standard of experienced physicians in their specific medical field. Sometimes the appropriate knowledge and competence can be identified through specific guidelines.

With regard to standard of care, while certain juridical systems make reference to the *bonus pater familias* (good family father), such as in Italy, France, and Spain, others, like UK and Scandinavian countries, use the reasonable physician standard with respect to the accepted medical knowledge (*ars medica*). Obviously, the accepted medical knowledge is established at the moment the treatment is carried out, the discovery of alternative or new therapies set up at a later time with respect to patient care being irrelevant.

Moreover, with regard to the purpose of this work, it is important to highlight some peculiarities introduced in several juridical systems that further complicate comparative analysis. It is sufficient, for instance, to recall the legislation of Germany, Austria, and the German speaking Switzerland, where the patient's right to obtain compensation is balanced with the physician's right-duty to act always on the basis of science and conscience (Bauer and Pollak 2007).

In other words, this means that the physician has the right not to be obliged to apply specific prescriptions issued by other doctors: a legislation that emphasizes the physician's self-responsibility and independence (Hurwitz 1995). Notably, these kinds of legislative choices are based on the principle that a fair medical activity is, by its nature, as free as any other scientific activity.

A different case is represented, for example, by UK, where more importance seems to be assigned to the role of guidelines in the fault investigation.

4.2.4 Burden of Proof

In the case of extra-contractual responsibility, the patient has to demonstrate the physician's fault, the causal connection, and the damage received. However, the European legislative overview provides several interesting examples of jurisprudential creations and juridical constructions often designed to compensate for the differences between the physician's and the patient's position. That is why the patient is in the weaker position, because of the difficulties he/she faces in proving damage. The analysis of the single legislative experiences demonstrates the spread of mechanisms that derogate from general principles of contractual responsibility through praxis introduced by jurisprudential evolution, such as the reversal of burden of proof or the *res ipsa loquitur* institute.

With reference to the burden of proof the causal relationship, which can be defined as the existing relationship between medical malpractice and the damages/death that occurred, is assumed to be of special relevance. The comparative analysis of the European Juridical systems demonstrates that the investigation of the causal relationship follows different procedures, depending on whether the investigation is executed within a civil trial or penal trial.

While in the latter field a rigorous verification is favored, as much as possible supported by scientific laws with respect to the rule of *in dubio pro reo*, in the Civil field we observe a depreciation of the nexus, increasingly founded on the rule, now shared by countries based on both Common or Civil Law systems, of "more probable than not", with increasing openness towards the recognition of the damage following loss or lowering of chance (of recovery).

Therefore, we can generally assume that the injured subjects are willing to choose the civil course rather than the penal one, with regard to complex and important cases as well.

Generally, the civil law adopts probabilistic theories aimed at answering the question of whether there is fault or not on the basis of the "more yes than no" formula and therefore there exists a lower grade of certainty. On the contrary, in penal law the positive answer must be formulated "beyond any reasonable doubt" and then with a major grade of certainty. In other words, while in civil law the causal relationship is ascertained through a probability greater than 50 %, in penal law this certainty has to reach a percentage very close to 100 %.

This differential commitment assumes a critical importance, especially in the medical field, where damages can often also be traced back to other causes that are outside the physician's control (as for example genetic predisposition, inadequate lifestyle, etc.).

4.3 The Key Role of Mediation in Medical Responsibility

The interest within the European juridical systems towards alternative ways of settling medical malpractice claims has increased in the last decade.

Such an interest arises from the excellent outcomes and trends observed in European systems where settlement of medical responsibility claims is delegated to alternative organisms, different from the judicial authority (i.e. the Swedish model).

There has also been a significant interest within the European Union in an alternative way of resolving disputes, where the Directive 2008/52/EC of 21 May 2008 was issued by the European Parliament and Council concerning certain aspects in matters of civil and commercial mediation.

Although not specifically falling into the field of medical liability, the directive mentioned above does underline the importance of access to justice and promotes the employment of extra-judicial procedures (Directive 2008/52/EC).

Within the international literature it is possible to find a new way of categorizing the European juridical system, which is surely useful for thinking about the current situation of medical liability issue.

Two main different systems have been delineated: the court systems and the administrative systems (Essinger 2008).

4.3.1 Court Systems

A court system is defined as a juridical system when patients' claims are mainly settled by courts. The majority of the European juridical systems can be categorized as court systems: Italy, Spain, Portugal, Germany, France (except for the ONIAM field and considering the role of CRIC), Lithuania, Slovak Republic, etc. The main characteristic of these countries is represented by the lack of administrative procedures, as occurs in Sweden. Indeed, in these countries a high number of judicial cases are observed. Ordinarily, the patient claims are settled by Judges who are assisted by experts in Law and Medicine. Patients often discover a lot of barriers before obtaining damage compensation, because they cannot use easy damages compensation procedures. Indeed, when the fault compensation is finally established by the sentence of the Judge, the patient must face, beyond the legal expenses and the judicial taxes, the stress linked to trial duration.

4.3.2 Administrative Systems

An administrative system is defined as a juridical system where patient claims are mainly settled by administrative procedures. In Europe, typical examples of administrative systems-based countries are Sweden, with the Patient Insurance Scheme, England with the NHS Litigation Authority, and France, with ONIAM.

As stated in the Doctrine, among overseas countries typical examples of administrative systems are located in Australia and in New Zealand (Woodhouse 1967–New Zealand); (Bismark and Paterson 2006; Colleen 1999; Bismark et al. 2006; Sappideen 1993). Another interesting example is represented by Germany where the Regional Chambers of physicians established panels to investigate and settle patients' claims. Such panels are regulated by their own statutes. The only difference with respect to the court systems is that the involvement of the court is not required.

The mode of adjustment varies. In most of the cases the damage compensation is subjected to the demonstration of the causal link between the damage and the physician's performance. In other circumstances, a finding of avoidance determined under the "experienced specialist" role is required. In any case the evaluation of the eligibility of the patient to be compensated for the damage is established extra-judicially, without the involvement of the Court.

Often, however, in the international literature, welfare compensation systems (in which the indemnity is guaranteed, e.g., in Scandinavian countries) are considered as No-Fault (Hubbard 2000).

In fact, the only difference that can be identified between these models and the models based on fault is the existence of an easier burden of proof regulation for the patient and the absence of difficulties in accessing compensation procedures (Adelman 2004).

Administrative systems do not have punitive purposes. They focus their attention especially on the compensation for the damage suffered by the patient. Therefore, it is more correct to define them as no-blame systems, such as occurs in Sweden (Pukk-Harenstam et al. 2008).

Furthermore, it is important to underline that these kinds of indemnity systems often operate according to a different logic, which is the grant of compensation according to standards (without a personalization of the injury).

4.4 Scandinavian Countries: Models

The compensation damage models of Scandinavian legislation represent a good example of a system of social security indemnity that, unlike the traditional approach characteristic of the Common Law systems, does not take into account the evaluation of the fault, providing a verification of the predictability and avoidance of the damage as an essential assumption. These systems are in force specifically in Sweden, Finland, Norway, and Denmark.

The availability of statistical data in Sweden suggests a better evaluation of the Swedish model according to a comparative approach.

The Swedish compensation system was implemented for the very first time in 1975, though as a voluntary scheme. Indeed, the introduction of a mandatory system was formalized only in 1997, when the Patient Injury Act (PIA) (*Patientforsakringen*) was enacted. The enacted Law provides for a mandatory insurance for all the hospitals operating in the Swedish territory and it regulates how and when the patient has the right to obtain compensation for the injury arising from medical malpractice. With this Act a burden of proof lower than that necessary under the general Torts Act of 1992 in Sweden was put in place.

Under the PIA the injured patient has to show the relationship between hazards/death due to the physician's misconduct and the avoidable nature of the adverse event. Such a relationship has to result according to a preponderant probability higher than 50 %, recognized as *reasonable certainty*.

The existence of avoidability is ascertained by evaluating the correctness of the physician's performance and by verifying the existence of possible less risky procedures for the treatment of the patient's disease.

It is important to recall that the Swedish Legislator's choice aims to identify six categories of damages entitled to compensation: (1) incorrect health treatment (with the presumption that the injury could have been avoided if the choice had been different), (2) defects in the medico-technical products or hospital equipment used in the physician's performance, (3) absent/incorrect diagnosis, (4) transfer of a contagious substance entailing infection in connection with treatment,

(5) accidents, (6) prescription or provision of pharmaceuticals in contravention of regulations or instructions.[2]

For our purposes, another important aspect is the part of the PIA related to the regulation of the administrative procedures. Such administrative procedures have the aim of guaranteeing to the patient access to the compensation system even without the need to take legal action. The claim is paid directly by the insurance company of the hospital after a medical expert investigation.

The relationship between the injured and insurer is governed by transparency and information. Article 17 regulates the Patient Claims Panel, which was established to promote a correct application of the PIA and issues opinions at the request of a patient, care provider, insurer, or court. The Panel is composed of various members, including medical experts and representatives of the patients' interest.

Although the panel's decision is not mandatory, generally insurers comply with it.

Statistical data show the benefits of the Sweden reform, especially with respect to the excellent outcomes gained in the reduction of the amount of work by the judiciary system. It has been calculated that every year an average of 45 % of the compensation requests are received (and then compensated).[3] Only 10 % of these requests end up in the courtroom. The percentage of the extra-judicial claims settled in the Scandinavian countries amounts to 99 % (Swedish Patient Insurance Association) (Essinger 2008).

[2] Article 6 provides "[…] (1) an examination, care, treatment, or similar measure provided that the injury could have been avoided either through a different performance of the chosen procedure or through the choice of another available procedure which according to an assessments made retroactively from a medical point of view would have satisfied the need for treatment in a less hazardous manner; (2) defects in the medico-technical products or hospital equipment used in the performance of an examination, care, treatment or similar measure, or improper use of the same; (3) an incorrect diagnosis; (4) transfer of a contagious substance leading to infection in connection with an examination, care treatment, or similar measure; (5) accidents in connection with an examination, care, treatment or similar measure, or during a patient transport or in connection with a fire or other damages to health care premises or equipment, or; (6) prescription or provision of pharmaceuticals in contravention of regulations or instructions […]". The English translation has been kindly provided by Carl Espersson, Legal Adviser at The Swedish Patient Insurance Association/Patientförsäkringsföreningen.

[3] Article 18 provides for "the insurers affiliated to the Patient Insurance Association shall together maintain and finance a patient claims panel. The Panel shall include representatives of the patients' interest. Further regulations concerning the Panel's composition will be issued by the Government, which shall also approve the rules of procedure of the Panel. The Panel shall at the request of a patient or other person suffering loss, a health care provider, an insurer or a court pronounce its opinion in compensation cases." The English translation has been kindly provided by Carl Espersson, Legal Adviser at The Swedish Patient Insurance Association/Patientförsäkringsföreningen.

4.5 The French Experience and the "Loi Kouchner": The *Aléa Thérapeutique*

Although in a less incisive way with respect to the Swedish experience, France has to be mentioned among those European countries which have introduced a specific law in the medical liability field with the aim of making the damage compensation system more adequate to patient's needs. Of course, we have to state that the French juridical system represents one of the more complex contexts in which to face the matter of legislative reform in the medical malpractice field. This is due to the coexistence of Administrative Law and Private Law in this field. In fact the French law provides different rules depending on the public or private nature of hospitals. If the hospital is public the procedural rules of the Administrative Law will be enforced; while, if the hospital is private the procedural rules of the Private Law will be enforced. In the first case the hospitals have the right to act against the employee physician.

During the last 50 years, the French doctrinal overview distinguished itself for the extreme variety of submitted legislative reforms, some of them oriented towards the creation of a guarantee fund, while others focused on the conservation of the general rules of civil responsibility through the obligation of result provision. Ordinarily, in the French juridical system, with some exceptions, medical liability is regulated within the civil responsibility institute and is subordinated to the evidence of the physician's misconduct.

However, nowadays it is assumed that medical liability falls within the area of contractual responsibility and that the obligation of the physician must be defined as an obligation of means. The obligation of means is defined when its subject is a performance characterized by diligence, thus independent of the attainment of a specific result. Therefore, in the health field, to fulfill such an obligation the physician will have to carry out his performance correctly, regardless of the useful result expected by the patient. Moreover, at the same time, such an obligation became harsher because of several creations by judges (*obligation renforée, obligation de resultat atténuée, etc.*).

In the French juridical scenario one of the most controversial points is represented by the notion of *aléa thérapeutique*, on the basis of which several debates arose among judges. The resolution of such debates is also made more complicated by the coexistence of different jurisdictions and the risk of final judgement multiplications. For this reason, it is possible to recall several judgements by the Conseil d'Etat and of the Supreme Cour de Cassation.

The Conseil d'Etad defined the *aléa thérapeutique* as that risk which is known but of which the realization is exceptional and there is no reason to believe that the patient is exposed to it in a particular way (Arret Bianchi) (Concil of Europe 2008). However, this definition has not been shared by the Supreme Cour de Cassation, because it is considered to be in contrast to the inspiring principles of civil responsibility. Indeed, according to the Court it would not be appropriate to talk about damage compensation, considering that the *aléa thérapeutique* requires

the existence of an accidental risk related to the physician's performance (which cannot be controlled) (Conseil d'Etat 1993).

The diversity of opinion between the Supreme Cour de Cassation and the Conseil d'Etad has offered to many authors an interesting point to consider. On one hand, some of them have been worried about a possible hardening of the physician–patient conflict, while others have considered it an important issue, because of the spreading and the affirmation of the theory in which the physician's performance is considered as an obligation of results. Lastly, others called attention to the provocative consequences of the *aléa thérapeutique* definition, questioning its interpretative limits.

The French Legislator implemented Act n. 303 on 4 March 2002, named *Loi Kouchner*, with the aim of resolving all the debates about the exact definition of *aléa thérapeutique*, providing a new specific Medical Liability Law. Several innovations were introduced by the *Loi Kouchner*: the consolidation of Fault Responsibility, the introduction of a new Solidarity National Fund, the *aléa thérapeutique*, the introduction of mandatory insurance for all hospitals operating in French territory, and the Regional Conciliation Committees. In this way, some aspects of the Public Health Code (*Code de Santé Publique*) were profoundly modified.

Among the innovations mentioned above, it is important to point out the provision of a pure No-Fault compensation system operating both when there is no fault in the physician's conduct (cases fall under the definition of *aléa thérapeutique*) and when the injury is caused by a nosocomial infection. In fact, in these cases the damage compensation is only subject to the demonstration of a direct link between the treatment therapy and the damage, the fault assessment not being required.

The Loi Kouchner reaffirmed the centrality of the Fault-Based system, giving back to the *aléa thérapeutique* its own exceptional element out of the physician's control (Cassation Civil 2000).

Indeed, Article 1142, paragraph 1, of the French Public Health Code, as modified by Article 98 of Act n. 303/2002, provides a duty of physicians and hospitals to respond to the negative consequences arising from Health Care treatments (prevention, care, and diagnosis) only when fault is declared (Cacace 2003). The second paragraph provides for an indemnity, in terms of national solidarity, operating in No-Fault cases and when the resulting invalidity is higher than 25 % (*aléa thérapeutique*).

The claims regarding injuries due to *aléa thérapeutique* are handled by ONIAM (*Office Nationale d'Indemnisation des Accidents, Médicaux, des affections iatrogènes et infections nosocomiales*), created ad hoc for the Public Fund management. Another important innovation is the provision of a mandatory insurance

for all public and private hospitals and physicians, as stated by Article 1142, second paragraph.[4]

Although the distinction between damages arising from physician fault and damages including the so-called *aléa thérapeutique,* is still valid, the law, in Article 1142, 14th paragraph, and in the following articles, provides for a preventive conciliation procedure, with the aim of filtering out patient claims, thus avoiding their transformation into juridical disputes.

For this purpose, the "*Commissions régionales de conciliation et d'indemnisation*" (Art. 1142, fifth paragraph) have been established[5] and damage

[4] Article 1142, second paragraph, provides for sans préjudice des dispositions du septième alinéa de l'article L. 1142-17, ouvrent droit à réparation au titre de la solidarité nationale: Les dommages résultant d'infections nosocomiales dans les établissements, services ou organismes mentionnés au premier alinéa du I de l'article L. 1142-1 correspondant à un taux d'incapacité permanente supérieur à 25 % déterminé par référence au barème mentionné au II du même article, ainsi que les décès provoqués par ces infections nosocomiales; Les dommages résultant de l'intervention, en cas de circonstances exceptionnelles, d'un professionnel, d'un établissement, service ou organisme en dehors du champ de son activité de prévention, de diagnostic ou de soins.''

26 Article 1142, second paragraph, provided for les professionnels de santé exerçant à titre libéral, les établissements de santé, services de santé et organismes mentionnés à l'article L. 1142-1, et toute autre personne morale, autre quel État, exerçant des activités de prévention, de diagnostic ou de soins ainsi que les producteurs, exploitants et fournisseurs de produits de santé, à l'état de produits finis, mentionnés à l'article L. 5311-1 à l'exclusion du 5", sous réserve des dispositions de l'article L. 1222-9, et des 11", 14" et 15", utilisés à l'occasion de ces activités, sont tenus de souscrire une assurance destinée à les garantir pour leur responsabilité civile ou administrative susceptible d'être engagée en raison de dommages subis par des tiers et résultant d'atteintes à la personne, survenant dans le cadre de l'ensemble de cette activité''.

[5] Article 1142, 14th paragraph, provides for lorsque la commission régionale de conciliation et d'indemnisation des accidents médicaux, des affections iatrogènes et des infections nosocomiales estime qu'un dommage relevant du premier alinéa de l'article L. 1142-8 engage la responsabilité d'un professionnel de santé, d'un établissement de santé, d'un service de santé ou d'un organisme mentionné à l'article L. 1142-1 ou d'un producteur d'un produit de santé mentionné à l'article L. 1142-2, l'assureur qui garantit la responsabilité civile ou administrative de la personne considérée comme responsable par la commission adresse à la victime ou à ses ayants droit, dans un délai de quatre mois suivant la réception de l'avis, une offre d'indemnisation visant à la réparation intégrale des préjudices subis dans la limite des plafonds de garantie des contrats d'assurance.

Cette offre in di quel évaluation retenue, le cas échéant à titre provisionnel, pour chaque chef de préjudice a in si que le montant des indemnités qui reviennent à la victime, ou à ses ayants droit, déduction faite des prestations énumérées à l'article 29 de la loi n" 85-677 du 5 juillet 1985 tendant à l'amélioration de la situation des victimes d'accidents de la circulation et à l'accélération des procédures d'indemnisation, et plus généralement des indemnités de toute nature reçue sou à recevoir d'autres débiteurs du chef du même préjudice. Les prestations et indemnités qui font l'objet d'une déduction du montant de l'offre sont remboursées directement par l'assureur du responsable du dommage aux débiteurs concernés.

Lors quel'offre prévoit le versement d'un e rente à la victime, cette rente est revalorisée dans les conditions prévues à l'article L. 351-11 du code de la sécurité sociale

L'offre a un caractère provisionnel si l'assureur n'a pas été informé de la consolidation de l'état de la victime. L'offre définitive doit être faite dans un délai de deux mois à compter de la date à la quelle l'assureur a été informé de cette consolidation.

L'assureur qui fait une offre à la victime est tenu de rembourser à l'office les frais d'expertise que celui ci a supportés.

compensation procedures have also been unified, regardless of the nature of the alleged health structure (both private and public).

These "commissions" are in charge of starting the compensation file and verifying, through an internal procedure, the patient's legitimate claim to the damage compensation. They could also submit an economic proposal to the insurance company (and/or to the ONIAM in case of lack of fault), that will be verified by the insurer within the mandatory deadline of four months (Art. 1142, 14th paragraph). The commission has to make an important decision: (1) if physician/hospital liability exists (where usually the indemnification is paid by the insurance company), or (2) if that indemnification is due in the name of 'national solidarity' (indemnification by a national organism called ONIAM), or (3) if it is a case where no damages occurred.

Generally, the procedure applies only to care provided since 5 September 2001 (Manaouil et al. 2006).

In the case where conciliation fails, the patient has the right to defend his/her own credit through the Court. The damage liquidation is gained after an internal procedure with the aim of verifying on the one hand the presence of a sustainable risk and on the other hand the prejudicial effectiveness of the event.

The innovations brought about by the Loi Kouchner contributed to endowing the French juridical system with originality, because of the introduction of a hybrid model in which typical elements of the traditional model (exclusively based on fault) coexist with aspects of the No-Fault system (exclusively based on causal relationship).

In conclusion, with regard to types of damage, the establishment of the legitimization of damage compensation (together with the validity of the claim itself) occurs through different juridical paths, depending on whether it arises from the

(Footnote 5 continued)

L'acceptation de l'offre de l'assureur vaut transaction au sens de l'article 2044 du code civil.

Le paiement doit intervenir dans un délai d'un mois à compter de la réception par l'assureur de l'acceptation de son offre par la victime, que cette offre ait un caractère provisionnel ou définitif. Dans le cas contraire, les sommes non versé es produisent de plein droit intérêt au double du taux légal à compter de l'expiration de ce délai et jusqu'au jour du paiement effectif ou, le casé chéant, du jugement devenu définitif.

Si l'assureur qui a transigé avec la victime estime que le dommage n'engage pas la responsabilité de la personne qu'il assure, il dispose d'une action subrogatoire soit contre le tiers responsable, soit contre l'Office national d'indemnisation si les dispositions du II de l'article L. 1142-1 trouvent à s'appliquer.

Si le juge compétent, saisi par la victime qui refuse l'offre de l'assureur, estime que cette offre é tait manifestement insuffisante, il condamne l'assureur à verser à l'office une somme au plus égale à 15 % de l'indemnité qu'il alloue, sans préjudice des dommages et intérêts dus de ce fait à la victime.

Dans le cas où les plafonds de garantie des contrats d'assurance de la personne considérée comme responsable par la commission seraient atteints, l'assureur avise sans délai cette personne ainsi quel'office institué à l'article L. 1142-22.

Pour l'application du présent article, l'Etat, au titre des activités de prévention, de diagnostic ou de soins qu'il exerce, est soumis aux obligations incombant à l'assureur''.

so-called *aléa thérapeutique* or from physician fault. In fact, in the case of damage (more than 25 % of invalidity) arising from the *aléa thérapeutique*, damage adjustment only occurs after the demonstration of the causal relationship between the claimed damage and the preventive and healthcare performance, regardless of physician fault. From a pragmatic point of view, the Legislator in 2002 accepted that some medical mistakes cannot be ascribed to the responsibility of the single physician, due to the great danger of a number of medical performances and the particular technicality of the medical science.

4.6 The English Experience of the NHS Authority Litigation and the Key Role of Mediation

England—a Common Law system—in which physician liability is inspired by strict principles of fault investigation—assumes importance among European countries for the key role that mediation, alternative dispute resolution (ADR), has in claims between patients and hospitals.

In fact, even though it has been introduced with the aim of simplifying and facilitating damage compensation procedures, medical liability continues to be regulated within the system based on Fault.

In 1995 the National Health Service Litigation Authority (NHSLA) was established, which is responsible for the National Health Service financial fund. The NHSLA is the body in charge of the management of public cases in the field of health responsibility (NHSCC Act 1990). The main purpose of the NHSLA is to promote the interaction between the injured patient and the health structure, with the aim of facilitating possible damage compensation. This body carries out its mediation functions through a centralized network of health specialists.

Nowadays, in contrast to Sweden, a mandatory insurance for the health structure does not exist in the UK, even though—factually—they joined the Clinical Negligence Scheme program, which was created in 1995.

This system is entirely managed by the NHSLA and allows health structures to obtain insurance against damages arising from clinical risks, determined by events that occurred after 1995, on payment of an insurance premium (usually established every year on the basis of the maximum expenses estimated for the following year).

Similar to the Swedish system, the damage compensation procedure is left to the administrative competences and the claims are handled by a Panel of specialists. This Panel carries out an evaluation, with the help of medico-legal experts, in order to establish the *an* and the *quantum* of the patient's claims.

However, differently from Scandinavian countries, the verification follows a different procedure, in which the injured party has a greater burden when demonstrating the physician's negligence, the causal relationship, and the damage suffered. The verification of the fault is determined on the basis of an analysis of the physician's performance with respect to the requirement of an acceptable

professional standard in the case of health performance. Consequently, the patient has the burden to demonstrate that the damage suffered is linked to the physician's fault by a causal relationship and that a different medical treatment, if correctly performed, would have caused no harmful consequences or, at least, consequences of minor medical-legal relevance.

Although the UK system does not formally adopt damage compensation principles based on mere causal demonstration, it is inspired by them when it saves money in the cost-management of claims through the utilization of alternative instruments, with respect to the judicial case. Indeed, the choice of centralizing—even in a non-mandatory way—damages compensation procedures in one body (NHSLA), resulting in the simplification of the UK compensation system and in a relevant reduction of the waiting period to obtain relief.

The statistical data underlines the importance the mediation activity provided by the NHSLA has assumed in the last years within the medical responsibility field, especially in terms of the reduction of the number of judicial cases and the relative time for the obtainment of damage compensation.

In this regard, it has been estimated that 96 % of compensation requests have been defined in an extra-judicial manner, without the judge's intervention (Essinger 2008).

4.7 Medical Responsibility in Eastern Europe: Bulgaria, Czech Republic, Slovakia, Russia, and Lithuania

Medical malpractice is now assuming remarkable importance, even within juridical systems belonging to Eastern Europe. The increase in patient claims makes the present situation as critical as that of Western Europe.

Unlike the experience of other European countries, the juridical system of Lithuania oversees the medical liability field through an ad hoc regulation (Birmontiene 1996; Ducinskiene et al. 2006). In fact, alongside general principles provided in the Constitution of the Republic, in Lithuania the rules of the Civil Code and Penal Code enforce the law on the rights of patients and compensation for damage to their health. Here the patient is considered the weak party who has several fundamental rights, the first being the right to health. Furthermore, the patient has the right to access the Health system and the right to expect an informed health treatment complying with the accepted knowledge of medical science.

In Lithuania a Fault-based system is enforced, where the damage compensation is granted after the positive ascertainment of the causal relationship between the physician's conduct and the hazards/death suffered by the patient. In this country administrative procedures for damages compensation do not exist, as in the Swedish system. Patient claims are handled by the Judges, though extra-judicial negotiations could even be carried out earlier. In Lithuania the role of the "Compensation Commission" is very important.

Differently from Lithuania, in the juridical systems of Bulgaria, the Czech Republic, Slovakia, and Russia, a specific regulation with regard to the medical liability does not exist. Consequently, the responsibility of the physician finds its regulation principally in the Civil Code and in the Penal Code. Hospitals are responsible for damages caused by the physician's conduct, because of the principle of employer responsibility for damages caused by the physician employee to third parties.

The juridical systems of these countries can be categorized as Fault-based models, where the compensation is granted after the evidence of the physician's fault, the damage suffered by the injured party and the causal relationship between the medical mistake and the damage. In these countries, no particular damage compensation procedures can be identified as administrative ones. Patient claims are specifically handled by the Courts, even though the Judges have the opportunity to promote the use of conciliation or alternative dispute resolutions, such as arbitration, between the parties (Essinger 2008).

4.8 Conclusion

A comparative overview of the European juridical systems demonstrates that in the majority of countries a specific legislation concerning the issue of medical responsibility does not exist.

The physician's misconduct/mistake is regulated on the basis of the general principles of the civil, penal, and in some cases administrative responsibilities. However, it is also clear that every system has understood the difficulties faced by the patient concerning the burden of proof, resulting in some cases in the jurisprudential context even deviating from general principles in certain situations, and in others with the introduction of administrative procedures for damage compensation.

From the analysis of the European juridical scenario we can outline two different kinds of damage compensation models in the field of medical liability: (1) those systems anchored to a classic model of fault verification (with a burden of proof that seems to be always heavier for the physician) and (2) those systems that may be inspired by the spreading concept of enterprise risk in the health field and that use models established on the idea of damage avoidability, with less focus on the fault concept. Those two systems are also respectively defined at the international level by the terms Fault-based system and No-Fault system.

However, we have to take into consideration that in practice the contraposition between the two models could actually be less clear-cut, since in Europe, apart from the French example (with respect to damages covered by the national solidarity fund), it is difficult to find a pure No-Fault system.

Most of the European juridical systems belong to the first category. However, we cannot underestimate the fact that the legislative reforms adopted by some countries, such as France and the Scandinavian countries, will give rise to great interest at the international level. Systems of damage compensation, based on the

Fault model, are located at the center of Europe, in some North European countries, and in Eastern Europe. While for example, in Sweden, Denmark, Finland, and France (for the aléa thérapeutique damages) there are alternative institutes which cannot be strictly considered as No-Fault compensations.

The main features of the No-Fault systems are the reduction of complications in the ascertainment of the physician's fault (simplifying the burden of proof) and the generalization of the clinical risk, through a healthcare vision. Indeed, these systems only require the direct relationship between the health care and the damage suffered. Therefore, the patient will not have to demonstrate the physician's fault, but only the proof that the damage derives from the physician's performance.

Another purpose is the reduction of the judicial management expenses by administrative compensation procedures of damage compensation. The No-Fault systems are usually joined with insurance coverage, aimed at indemnification in order to avoid lawsuits.

The adoption of one system rather than the other depends on a strategic and financial choice of how we want to face the issue of medical malpractice.

In fact, the institution of a No-Fault compensation system requires adequate financial resources.

Healthcare activities, as well as enterprise activities, constantly involve a margin of error, which exposes the hospitals to the risk that accidents may occur. Risk can be defined as the probability of those adverse events occurring. On average, the No-Fault systems avoid focusing specifically on human errors.

The clinical error is a consequence of the Health system (Reason 1990). Indeed, in this kind of a system, the error is not identified in a single health professional, but in the whole system. The spread of the collectivization of clinical risk shows that Public Health belongs to everybody and that the negative consequence arising from a physician's performance must be ascribed to the whole community itself. On the basis of this consideration there is the logical presumption that it is unacceptable not to compensate the injured patient regardless of whether the physician is guilty of misconduct or not. The whole community must be in charge of compensating the patient's damage, since health care represents one of the main priorities for modern States.

Obviously, a similar consideration can be made in Europe only with regard to the French experience (and exclusively with regard to damages arising from the aléa thérapeutique). In fact, other systems such as the Scandinavian one are hybrids and cannot be considered as an actual part of that policy. No-Fault based models would surely be desirable since they would contribute to the preservation of quality within the Health Service. Indeed, we should not underestimate the psychological damage connected to the trial suffered by the physician both in the mid and long-term period. As a matter of fact, the No-Fault-based systems provide for an approach inspired by the systemic nature of the medical error, without pursuing punishment. In other words, No-Fault-based models approach medical fault by focusing on the misconduct of single health professionals rather than on single human errors. On the other hand, as stated by James Reason, besides overt mistakes made by health professionals, every healthcare system includes latent

errors. Latent errors, though near-misses, can contribute to causing a damaging accident when associated with triggering events.

The No-Fault-based models also contribute to decreasing the risk of the affirmation of a defensive medicine approach, which surely appears as an inadequate remedy to protect patient care and health.

Indeed, defensive medicine consists of diagnostic and therapeutic treatments focused on avoiding the future possibility of malpractice effects, representing a guarantee for the physician's performance rather than for the patient's health. However, it is necessary to underline that provisions such as the obligation of insurance, national solidarity funds, and administrative compensation procedures related to insurances policies could also result in a counter-productive outcome. Indeed, the existence of an insurance coverage could on the one hand decrease the deterrent efficacy of the responsibility rules, and on the other hand represent a practical risk of duplication in the number of compensations. In other words, there is a relevant risk that from a situation of under-compensation (where the compensation to patient damages was marginally due to the scarce sensibility toward the issue of medical malpractice) we will witness a movement toward a situation of over-compensation, meaning an increase in the number of damage compensations (Cacace 2003).

Lastly, it is important to underline that the mediation role (as well as the role of administrative compensation procedures) would greatly facilitate the global situation due to the possibility of creating a more constructive dialogue between the parties. Therefore, for this reason we have to appreciate the efforts undertaken by the English NHSLA which, even though introduced within a Tort-based system, represent a concrete investment in the role of mediation. To conclude, in the European juridical scenario, even though several types of approaches to the medical liability matter coexist, we can highlight the emergence of a common and founded concern of an increasing objectification of the clinical risk especially when considering the judge's attitude, which is not very conciliatory.

Once we are aware of the inherent dangers involved in the physician's performance and the related risk of error (even accidental) within hospitals, we should ask ourselves whether it is more convenient, in the issue of medical responsibility, to play the card of the No-Fault or Fault-based models. Surely, an increased and wide use of administrative procedures would be desirable, with the aim of decreasing the expenses relating to the management of judicial cases and favoring a dialogue between physicians and patients.

In conclusion, it appears reasonable to consider that the consequences linked to the increase in claims in the health field can also be alleviated through an improvement of the informed relationship between the physician and the patient, which is often difficult due to the lack of understanding of medical-scientific notions. The hope is for a framework in which the physician and the patient cooperate in the search for a pacific solution, which should not be a utopian goal, but the result of deep reflection on the different needs of the medical world and the whole community.

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Chapter 5
Causal Value and Causal Link

S. Davide Ferrara

Abstract After an overview of the evolution of concepts of truth, cause and causation in the history of philosophy, this chapter examines the current post-modern conception of material causality in the medico-legal doctrine, aimed at the identification of the core cause and the reconstruction of the causal nexus. The theory of the "conditio sine qua non" and the subsumption under scientific laws, which constitute the common denominator for the imputation of the event, are described in detail. The judicial inquiry and the expert's report, applicable in medico-legal practice of specific causality, are illustrated with particular reference to deductive-nomological and inductive-statistical models, as well as to the necessity of a new "evidentiary regime" for ascertaining professional medical liability.

Contents

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5.1 Principles of Truth and Cause

The *principles* of *truth, cause*, *causation* and *causal chains* are deeply rooted in the history of thought, in as much as expressive of the ontological need of man to give meaning to his existence. These principles evolved, in correlation with those of certainty and probability, from the naturalistic pre-Socratic school to the psychodynamic conception of SOCRATES, to the rational-idealistic speculation of PLATO, and to the rational-empirical-experimental, material, formal, and efficient conception of ARISTOTLE (Ferrara 2004; Ladyman 2007; Aristotle 1908, 2008). According to deductive or inductive criteria of certainty or probability of truth, the speculative evolution of causal principles has been influenced by neo-Platonic or neo-Aristotelian contributions, followed by those of the SCHOLASTICS, through the certainties of faith and reason of ST. THOMAS, from post-Renaissance Empiricism to "formal and categorical" Kantian rationality, before resulting in positivism and neo-positivism (Ferrara 2004).

In particular, in light of the Kantian vision (Kant 1781), causality is a category, such as space and time, applicable to reality, science, and other related disciplines, from medicine to history, ethics, and even politics. The concept of cause is the same in any sphere and dimension of life, and causality is, conversely and for whatever purpose, the means to ascertain the relationship between one event and another.

The inherent values of causation relate to *objectivity*, *regularity*, and *know ability*.

Reality is conceived as *objective* insofar as it exists independently of individual actions and subjective situations. Reality is such, furthermore, inasmuch as it is *regular*, where the existence of such conditions leads to similar effects in different times and places. Reality is ultimately *knowable* to the extent that the modalities of its occurrence are ascertainable. Even if things are not in themselves knowable, the mode of their way of appearing is, and in accordance with this Kantian axiom, NEWTON, and EINSTEIN search effectively for the modalities of appearance of reality (Dobbs 1994).

Nevertheless, the framing of the differences in attributions regarding causation is independent of and transcends the scientific context, up until ignoring and excluding it. Therefore, in accordance with HUME (1751) and REICHENBACH (1951), the cause may not be unequivocally proven in a scientific sense, but be the expression of coincidental occurrence and of a practical basis of explanation of reality, such as a reductionist, rather than holistic approach, where the cause involves the understanding of the totality of circumstances in which an event occurs (Mill 1868). Therefore, it is also the estimate of the *relative* contribution of each of the possible causal factors, or even the evaluation of the contribution of a specific factor to the totality of significant factors in the causation. So that, with a return to the Aristotelian vision of final causality, in the integral dimension of the teleological approach to the natural order of the Universe, the final search for the cause is the search for the first causes of nature. That is, the search for the *episteme*, capable of comprehending causation and identifying not only the phenomenon, but the reason for the occurrence of any event.

From these apparently contradictory assumptions derive concepts of truth and cause and the theories relating to "probability" as the basis of reality, as well as the prechosen system, precisely that of the postmodern society of risk (Cohen 1977).

In these, as highlighted by POPPER (1934), science does not advance through the progressive and continuous accumulation of truths that are gradually acquired through the testing of the hypotheses advanced by scientists (an ideal impossible to achieve for logical reasons), but thanks to attempts to refute the theories proposed. Scientific progress takes place because an error is discovered in a generally accepted theory, and thus the discovery of errors in existing theories obliges the scientist to abandon the previously considered hypothesis in order to propose a new one which is in accordance with all of the known facts (Ferrara 2004). Extremely distant, therefore, from the Manichean illusion of the Enlightenment of DESCARTES (1637) and the Scholastics of ST. THOMAS and AUGUSTINE, where good and evil, truth and error were clearly distinguishable and distinct (Ladyman 2007). Where the development of scientific understanding, as GRMEK (1998) noted, one of the greatest medical historians of the past century, was envisioned as "a staircase that rises triumphantly toward the temple of science, with each step representing a new level of scientific development, a truth reached, albeit partial, which should be considered definitive" (Ferrara 2004).

Contemporary epistemology has led to the subversion of the positivistic conception of technological and scientific progress, arriving at the conclusion that "science is nothing but a cemetery of errors" (Stella 2003). Fundamental, in this sense, are the contributions of KUHN (1970), in whose thought the idea of the foundation paradigm prevails, that is, of a formal science based on revolutionary discovery that creates a new paradigm; of LAKATOS (1968), for whom science is founded on research programs competing with one another and continually subject to methodological falsificationism; of LAUDAN (1996), for whom science and the research tradition are a set of general assumptions about the extent of processes, problems and theories of a domain of study; of CARNAP (1950), for whom the complete verification of a law is impossible even in the face of millions of positive examples; of FEYERABEND (Horgan 1993), for whom scientific progress is the result of continuous violations of mandatory principles and methods; and finally, of POPPER (1934), for whom nothing is certain in science, based on the triad of problems–theories–criticisms, and the only concrete possibility for the scientist is to hunt for errors (Ferrara 2004; Reichenbach 1951).

Science, therefore, anchored by the laws and paradigms equivalent to mere hypotheses, whose truth it will never be possible to ascertain, cannot offer any certainty (Blaiotta 2004). Almost as if to conclude a pluri-millennial historical cycle that restores value to "sophistry", a proponent of the inductive criterion of probability as synonymous with possibility and, therefore, uncertainty. Returning, with that, the value of *Art* to the science of risk, which medicine inevitably is as a matter of priority, called to govern the patchwork of differing sequences and *interconnected causes* or *contributing factors*, in particular the almost infinite variety of those factors which are *etiologic*, exogenous, endogenous, mono, poly, necessary, sufficient or insufficient, exhaustible or inexhaustible, static or dynamic,

genetic, anatomical and physiological, pathological, preexisting or contemporary or supervening, concurrent, exclusive, adverse or antinomic, known or unknown, *determining a pathogenesis*, *mono or multi-specific*, of a disease, symptomatic or asymptomatic, fatal or indifferent, known or unknown and, if known, predictable and/or preventable, controllable, or not, with etiological or symptomatic therapy (Ferrara 2004). All of this contributes to a Chaos, whose domain is based on descriptive data and methods (casuistry, statistical, logical-connective, formal) which show insurmountable limitations and exclusive reference to Criteria of possibility (Salmon 1992), and where probabilistic logicism is affirmed.

According to Jeffreys (1966), the unitariness of scientific knowledge is based exclusively, in fact, on elaborated and applied methods, rather than on the heterogeneity of acquirable data. Such unitariness is founded on the theory of induction, aimed at satisfying at least three logical conditions: the production of a general method; the abstraction from the world "in itself"; the use of postulates or rules that deduction cannot prove.

The rules, distinct from their empirical content, must in their turn: be applied to observational data; express themselves in a formally congruent manner with regard to each other; provide that the product of the inference may be erroneous, so as not to deny *a priori* the practical applicability of any empirical proposition.

In accordance with these principles, the principle of causality is defined as a "complex determinant" of the uniformity of nature, or as "similar antecedents able to produce similar consequences". The "antecedents", in differentiating themselves from the categories of time and space, exclude the utilization of chronological and topographical criteria in the identification of the cause and the reconstruction of the causal relationship.

The conjugation of inductive empiricism and probabilism, in assimilating the inference to the "degree of confidence" and "probability" (both "variables" according to observed or experimental cases), involves surpassing the historical limit of philosophical and scientific empiricism (Hacking 2001). All of this entails, therefore, the affirmation of the *principle of probability* as an *exclusive basis for the identification of the causative agent* and the *relationship of material causality*. As an extension of logic, including all of its principles, probability theory assumes the role of indisputable *interpreter of concrete reality*.

In contrast, and consistent with the above, the historical evolution of the principle of probability is explained by means of: *classical theory*, as demonstrated by the works of NEWTON, GAUSS and BOYLE (Anstey 2000; Dobbs 1994; Dunnington and Waldo 1955), and others; *frequentist theory*, of strong impact on the science of risk, from biomedicine to medicine and genetics; *logicistical theory*, adopted in the nonquantitative sciences, such as biology, sociology, psychology, economics, and theoretical informatics; *subjectivist theory*, characterized by reciprocal relationships with quantum mechanics and particle physics.

Despite the apparent multiplicity of the above theories, the concept and the principle of probability preserve unitariness in their practical applications, valid in order to provide solid ideological or computational support to diverse scientific disciplines.

5.2 Juridical Construction, Evidence, and Medicine

In the juridical framework some theories conceive the cause of an event as a necessary condition of the effect, while some view it as a sufficient condition among others. Regardless of the theory or vision adopted, the cause is a combination of factors to which one always owes an identical effect.

Human *responsibility*, correlating and linking causation to the law, offers its own close correlation and causation in the identification of natural events. Therefore, the definition of the effects of individual conduct necessitates the identification of the cause or the correlation of the reality before and after the explication of its conduct, methods, timing, and circumstances. Causation is an essential means to render the individual responsible for the modification of reality. Responsibility is a means and pragmatic value, useful for attributing and defining the history and consequential outcomes of individual actions, as well as for forming the identity and character of individuals. They are responsible as they intervene in reality, modifying it. Causation applies to individual responsibility, insofar as one is aware of the consequences that such a responsibility exerts on reality and on the life of single individualities (Mendelson 1998, 2000).

The holistic conception, or "judicial justice", finds in the judge the restoration of the right balance in the "bipolar relationship" of rights and entitlements which have been erroneously altered. It is a conception and holistic system where the identification of the material causes performs a classificatory function.

In *Law* the classification of a cause, as direct or indirect, determines the homologation of the cause of the action to the cause of the facts.

In *Medicine* the identification of efficient and precipitating causes is vital for the diagnosis and treatment of the imbalance and disease that derive from them.

In both disciplines the causal analysis is retrospective, from the current medical condition, or the legal context of the circumstances, to the origin or the act which has caused the transition, of the psychophysical or economic well-being, to the disease, disability, and final damage. In both disciplines, moreover, the cause of the pathological process, disability and/or damage must underlie the *Evidence* arising from observation and experience, classifiable on the basis of gradation levels. In the case of evidence based medicine (EBM), levels range from (1) the "Systematic Review of all reliant randomized controller trials", to (2) "At least one properly designed randomized controller trial" and "Cohort study, case control study", (3) "Historical controls", up to (4) "Case series" (Sackett 2000). The applicability of levels of evidence, the strength of the association between cause and disease and the accuracy in the estimation of risk must also underlie the careful evaluation of individual variability, the diverse implications of evidence obtained from other individuals and, therefore, the peculiarity of the individual and the specific circumstances, expressed by genetic predisposition, gender, age, comorbidity, drug use, degree of exposure, mode of survey and identification of the disease. The manifold variability in the level of scientific information on causation, never static but always and more frequently subject to frenetic

evolution, is influenced today not only by genetics, but rather by systems biology, that is, by genomics, transcriptomics, interactomics, proteomics, metabolomics, and so on.

The tumultuous evolution of scientific knowledge, in comparison with the pragmatic view of the judicial system and of the parties to the proceedings, brings up the problem of selection, qualification and the roles of the *expert witnesses*. In particular, it suggests the need for the impartiality of the expert witness, to be anchored to scientific and technical data, independent of the interests of the individual parties. That is, in the defense and representation of science, rather than of the parties involved in the proceedings. All of this is achieved through the careful evaluation of the scientific quality of the evidence produced, in the clear differentiation between fact and opinion, in addition to the *intellectual honesty to claim causal uncertainty when the cause is unknown*, *due to lack and/or non-reliability of the data* or for *inadequate application and/or knowledge of statistical probability*. And, therefore, with recognition of the continued validity of the assumptions of Roman law regarding causation and fault, not deeming the latter sufficient for the assertion of responsibility, especially in the field of malpractice and medical liability. This is equivalent to affirming, even in the contemporary era, the validity of the assumption to avoid, on the subject of medical causation, reductionist or one-dimensional approaches. This, again, is equivalent to saying that the multidimensional and epistemologically impure nature of causation put forward in court involves extensive sharing, both in legislative-juridical evolution and in the development of social and private insurance regulations.

Also in light of the foregoing, there is a meeting, a *confrontation between biomedical science and law*, dominated by the erratic chaos of uncertainty and error, the second necessitating certainty, which is essential for the attribution of the damaging event, the identification of the offender and the reconstruction of the material causal nexus between conduct and event, including a degree of conviction of the judge *beyond any reasonable doubt*. This in order to guarantee and protect victims, the innocent, safeguard inviolable individual and collective rights, good name, reputation, freedom (as understood in its broadest sense) and the values transcending and founding the most advanced democratic societies. Societies in which the cause is a necessary condition, and in which recourse is wisely made to a legal construction of scientific knowledge.

Since no agreement exists between philosophers of science on a single scientific method, and as the current methodology proposes diverse and contrasting research methods, the need to ensure the highest degree of certainty has imposed the enunciation of a clear legal rule: the court must only take into consideration reliable *scientific hypotheses that have received the degree of confirmation required by the inductive* conception of the scientific method and, furthermore, which conform to the requirements set out by *the falsificationist conception*, possibly supplemented by the criterion of general consent. What is important, given that there are no certainties in science, is strict adherence to the scientific method. The judge will need to decide on the question of the reliability of the scientific hypothesis relevant to the process, making sure not only that hypothesis

has received confirmations from various empirical checks, but also that it has withstood the necessary attempts at falsification.

A juridical construction of science, therefore, in which scientific knowledge by hypothesis, contingently true, acquires validity according to the specific aim pursued, and in which, for the Sciences of risk (including bio-medical), the general and/or specific (individualizing) causality is confirmed or denied, depending on the error rate and probability. Being able to recognize the value of truth (thus far resistant to falsificationist confirmation) *only* at the beginning of the causal chain based, *exclusively and uniquely*, on the confirmed corpuscularian and quantum–mechanical theory (Freckelton 2002).

This conclusion, exposing the fragility of certainty of knowledge, reaffirms the, albeit noble nature of the *Medical Art*, rather than that of science, imbued with the hyper-technological contents of the post-modern era. Thereby recognizing the value of juridical knowledge, whose principles and models on the subject of causality are certainly more of a guarantee for the protection of the individual and collective primary goods, inasmuch as culminating in the rule of *Beyond any reasonable doubt*, often obsolete in the ranks of the Sciences of risk, to which belong medical art and any of its specialist use of adjectives, including those of legal medicine. In reality, thereby having to confirm that the nosographic classifications, the etiopathogenesis and physiopathological interpretations, the diagnoses, prognoses and treatments, the evaluative epicrises, belong to a system of knowledge whose reliability, truth, or falsity depend on the transient systematic theory and practice of the Bio-Medicine of the time, the progress of which lies in the discovery of errors and the development of new theories. With this, fully confirming the Hippocratic Oath of the third millennium which, *in founding the ethical role of the doctor's professionalism* across cultures and social contexts, recognizes the aforesaid assumptions and states that the new contract of the *Doctor*, stipulated with the individual-patient and with society, must be based on the assumption of a new role, that of the *Researcher*, *constantly in pursuit of Errors*, the discovery of which reduces the uncertainty of science, enhances professional formation and improves the "Quality System" (Ferrara 2004, Ferrara and Pfeiffer 2010).

5.3 "Conditio Sine Qua Non" and Scientific Laws

The *conditio sine qua non* or *but-for cause*, theory of universal use, constitutes everywhere the *indispensible minimum* for the objective allocation of individual harmful events. So it is, in effect, in European Criminal Justice Systems, starting with Germany, where the equivalence theory of causes is now accepted as the first and essential criterion for criminal charges and where it is assumed that any other causal theory (such as that of *adequate causality*) or objective criteria of importance (i.e., *the increase of risk*), requires as an indispensible minimum the subsistence of a

condition that can withstand counterfactual reasoning, namely that it can not be eliminated mentally without the elimination of the event (Freckelton 2002).

In the same situation as Germany one finds, just to cite some of the European Countries, the United Kingdom, France, Spain, and Italy. In the UK, in fact, the use of the *but-for cause* is generally accepted, both in doctrine and in case law, in line with the approach of all or nothing, which is typical and traditional in *common law*. Even in France and Spain it is accepted that the *conditio sine qua non* constitutes the basis for criminal charges for damaging events, recognizing also the postulate of equivalence of conditions. For Spanish criminal lawyers the triumph of the conditionalistic theory played down the significance of the causal problem, at least in the field of criminal law. The existence of causality continues, in fact, to be a requirement in all criminal offenses: in crimes of endangerment, because it is necessary that the author has caused the risk, as in a harmful offence, since these presuppose that the offender caused impairment of the legal right of the victim, the proof being insufficient that the conduct has created a risk (Barni 1995). Thus, also in the Italian legal system, where material causality has its normative foundations in the Criminal Code, (art. 40–41) based on the theory of the necessary condition, also known as the equivalence of causes, supported by the theory of scientific laws of coverage and tempered by so-called causal regularity.

Even in the system of adequate causality the *conditio sine qua non* remains the essential prerequisite, built on the following principles:

1. the event must be a consequence of the conduct and the behavior is considered to be the cause only when it constitutes a necessary condition for the event;
2. the behavior of a man can only be one among many necessary conditions of the event so that, from a logical point of view, the cause must be understood as a totality of necessary conditions, not as a sufficient condition, and from the point of view of criminal law, the cause does not coincide with the "sufficient" condition, but with the "necessary condition";
3. the human conduct is never a necessary condition in absolute terms, but it is in contingent terms, or rather in a specific context of concrete conditions; since it is not possible to grade the effectiveness of every single condition, all those indispensable to the occurrence of the event are considered equivalent to each other and equally causal, i.e., with the same legal significance;
4. the demonstration of the causal nexus, being a posteriori or *ex-post*, aims to determine whether human conduct has been a contingently necessary condition for the occurrence of the event;
5. the criterion of the adequacy of the cause—that is, of adequate randomness—operates in addition to and not as a substitute for the conditioning nexus;
6. the counterfactual reasoning is indispensable in order to establish whether particular human conduct is actually a necessary condition for the occurrence of the event, and to proceed to the mental elimination of such a condition, verifying, always mentally, if the event would have happened anyway.

5.4 From the Theory to the Practice of Specific Causality

The above mentioned theories find logical-conceptual support and corroboration in the *scientific laws of coverage*, in *universal scientific laws or statistical laws*, able to prove with certainty or various degrees of probability that a particular condition is invariably followed by the verification of a specified event. Although belonging to the category of scientific laws, the statistical laws provide propositions and offer causal links only in terms of probability, not certainty, meaning that a particular event is accompanied by another event only in a certain percentage of cases, with the consequence that such laws are much more equipped with scientific validity, inasmuch as they can find application in a high enough number of cases receiving confirmation from rational and controlled testing methods (Barnes 1983).

It is universally accepted in medical legal doctrine that the subsumption under scientific laws of coverage is applicable both in terms of causality by commission or omission. In both areas, the logical procedure utilized for the causal reconstruction makes use of two fundamental explanatory models:

- the *deductive-nomological* model, in which the *explanandum* is derived through a deductively valid reasoning from the *explanans*;
- the *statistical-inductive* model, in which the *explanandum* possesses a high inductive probability with regard to the *explanans*.

The assessment based on the *deductive-nomological* model employs *universal laws* and permits deductive conclusions and, therefore, theoretically substantial *certainty*. The preliminary criterion, which should always be applied, is that of the so-called *scientific possibility* of a *causal nexus*, also defined as (ex-ante) *capability of causing harm.*

The medico-legal expert, who is called upon to decide on the possible existence of a causal nexus between conduct and material damage, in the absence of scientific laws of universal coverage, will often be forced to resort to the use of statistical laws, pointing out, however, that the demonstration of the nexus with a criterion of high probability-near certainty will be possible only where there is a high degree of logical probability or rational credibility (Cohen 1977). In other words, one will be able to hold that the conduct of the agent constitutes a necessary condition of the event, only if, without the agent's behavior, with a high grade of logical probability, it would not have occurred; or rather, when it is possible, with any reasonableness and rational justification, to exclude the involvement of a different causal process (i.e., "counterfactual reasoning"). This model is applicable to cases which involve commissive conduct, where there is clear and convincing evidence of the applicability of the general laws of physics, chemistry, and biochemistry, physiology and knowledge of general pathology. Knowledge that can well be regarded in the same manner as universal laws (Ferrara et al. 2010; Ferrara and Pfeiffer 2010).

The logical process of assessment by the *inductive-statistical probabilistic model* is based on the use of statistical laws or maxims of experience that,

integrated with each other, enable a probability of a causal nexus to be inferred, almost always in terms of prevalence, which is difficult to quantify on the hypothesis of improbability. This model is very often applied in the biomedical-legal field and concerns, in particular, cases of ommissive conduct typical of professional medical liability, environmental damage and damage to the product.

The inductive-statistical explanatory model can also benefit from the application of additional and indicative medico-legal criteria of evaluation regarding the causal relationship. They are criteria that, if utilized appropriately and critically, still represent a useful applicative tool in the logical-probabilistic-inductive procedure. In the doctrine, these criteria (topographical, chronological, phenomenological continuity and exclusion of other causes) are frequently listed without a hierarchical order and in varying numbers, while it is appropriate to use them in an articulated manner, as a guide for the organization of a case study. If the current scientific knowledge of the data of the specific case makes the accreditation of a causal link impossible from the outset, the assessment should be interrupted. Only two conclusions are possible: the exclusion of the nexus or the impossibility of its ascertainment (Barni 1995).

The first and most important criterion, which is that of *harmful efficiency* or *capability of causing harm*, refers to a nomological paradigm, while the other criteria require concrete proof in order to demonstrate the appropriateness of the scientific law. Among the criteria described above, the exclusion of other causes deserves particular emphasis, being fundamental and, in general, more complex than the others, as it is potentially a harbinger of misconceptions, since it is involved both in the process of identification of the entire causal chain, necessary and sufficient, and in the assessment of the necessity of the individual causal conditions of all the etiological factors. This fundamental medicolegal criterion corresponds to the differential diagnosis in medicine, in which the hypothesis that survives among the various hypotheses put forward, through the procedure known as "MODUS TOLLENS", requires, in its turn, the search for evidence in its favor, making use of an inductive approach of an eliminative type (Blaiotta 2004).

The use of customary and well-established medicolegal criteriology must, in the final analysis, be directed toward the reconstruction of the intermediate causal links, with the aim of giving concrete form to the scientific laws of coverage in the specific case, in a transition from the ambit of general causality to that of individual or specific causality. It involves, therefore, an accurate search for evidence that allows the reconstruction of the complex *causal puzzle* and the necessary transition from factorial adequacy to (almost) causal certainty. The cause, conserving and accentuating its epistemological contractions, cannot but distinguish itself as the basis of a medicolegal judgment founded on the evidence (Stella 2003).

In order to identify with high probability the existence of a material causal nexus, the demonstration of damage eligibility *ex-ante* is not sufficient, which is an error that, unfortunately, many of the various bio-medicolegal and/or forensic "experts" still commit. It is a sort of inherent flaw that has considered the concept of cause in an autonomous way, detached from the point of view of the law and therefore from the concept of a necessary condition, replacing it with the concept

of *capability of causing harm*, or rather, "adequate causality". It is an adequate causality which is wholly foreign to the world of biomedicine and legal medicine. The criterion of eligibility or causal adequacy is certainly not sufficient, but rather a prerequisite, for the medico-legal opinion on the existence of a causal link between the event and the damage, which is equipped with high probability-near certainty. Clearly, there is a strong need to find the particularistic evidence of the nexus, seeking a mechanistic explanation by means of chains of cause and effect, in which individual events are explained in a deterministic sense.

In the absence of a transition from the general causality to the specific causality, the model of subsumption under the laws of science would remain a hollow expression: the failure to verify the concrete antecedents, including the concrete *but for* antecedent, subsumable under the abstract antecedents, provided by the law of coverage, render vain any reconstructive attempt. In other words, there is a need to formulate an *ex-post judgement* linked to particularistic evidence of concrete expression, and not based on bare statistics.

Still more difficult is the problem of the reconstruction of the causal relationship in the ambit of *omissive causation*, where the finding of real and objective data, which permit the reconstruction of the causal intermediate links, is extremely rare and the reconstruction is largely based on hypothetical and/or prognostic judgments which, supposing the dutiful act has been carried out, ask whether the harmful event would have occurred anyway. In order to recognize the causal nexus, even in the field of omission it is necessary to achieve the highest possible degree of probability, thereby finding that the dutiful act, if accomplished, would have been able to prevent the event with a probability close to certainty (Stella 2003).

In the medical-surgical area, and specifically in professional *medical*-healthcare *liability*, the problem of omissive causality reaches the highest vertices of complexity, since the maximum part of the explanations offered is based on probabilistic laws with a low coefficient, which are not capable of providing mechanistic explanations. Therefore, when assessing by counterfactual reasoning what the consequences of the correct alternative medical conduct, omitted by the attending physician, would have been, the degree of probability by which to assess the effects on the health of the patient are not to be referred to mere statistical probability derived from previous trials, but the concept of logical probability, which must be close to certainty. The logical probability, in its turn, must be constructed by epicritically assessing all the circumstances of the specific case as they appear from the collected evidence (Stella 2003; Barni 1995).

Consistent with the principles of probability the conclusions are equivalent to the assessment of the degree of probability, the expert being unable to express opinions that would compel the judge to make a decision, which is only assumable on the basis of the whole spectrum of information derived from the various sources of evidence. Applying probabilistic logicism, where the production of evidence is based on experimental or observational data, the expert interpretation must be founded on principles and expressions of probability, rather than on descriptive adjectives. In the unfolding of the production of proof the acceptability and the utility of scientific evidence assume great importance in the trial, where the

qualification, experience and competence of the expert, as well as the "peer-review" of the opinions expressed by other experts, acquire relevance.

More specifically, in relation to the criteria of procedural *acceptability* of scientific evidence, the selection of scientific concepts and methods must arise from the consensus of the scientific community as to the limits of the demonstrability of the assumptions and the evidential value of the methods and conclusions. In order to clarify in the context of the individual case the probabilistic value of the observational or experimental evidence. In line with the process of preordained validation of scientific evidence through "standards of acceptability" previously established on the basis of "consensus documents", or derived, rather, from judgments of significant innovatory impact (Daubert v. Merrel Dow Fharmaceutical, Inc., 113 S. Ct. 2786–1993), thereby rejecting the principle, sometimes widespread in the judicial contexts of some countries, of the proclaimed "legal and judicial autonomy" of the validation of the acceptability of scientific methods and conclusions.

The application of probabilistic logicism, the sharing of criteria of *admissibility* and the unanimous acceptance of methods and results of scientific evidence all find common ground in margins of uncertainty, intrinsic structure, means of production, and the interpretation of the same results. All of these are subject to possible dispute and balanced debate between the parties, for which the identification of causality is the expression of degrees of probability.

It is implicit, however, that the *quality of evidence* must be supported by the degree of general and specific reliability of its production, by means of verifying: (1) the assertive effectiveness of scientific data; (2) the diversification of evidence; (3) the conformity or discrepancy of knowledge arising from evidence; (4) the availability of alternative tests capable of modifying the judgment already acquired. From the entirety of the means of production, eligibility and acceptability of the methods and acquirable outcomes in the form of scientific evidence, there emerges indicative guidance on the explication of best conduct on the part of the Judge and the Expert.

It is advisable for the *Judge* to keep in mind that: (1) the truth can not always arise from a single piece of evidence or a grouping of evidence; (2) uncertainty is desirable; (3) the evaluation of the context "a priori" and the proof must be founded on the rules of probabilistic logicism; (4) the weight and individual quality of each piece of evidence must be evaluated separately from the general context; the decision, never relying on a single piece of evidence (to which it would remain hostage), must be the expression of multiple reciprocally independent scientific findings; (5) the quality of the evidence provided by the Expert should be subject to verification in itself and in the general evidential context (Pascali 2011).

There are a number of key elements that it is advisable for the *Expert* to keep in mind: (a) to prove the hypothesis and not absolute truth; (b) to ignore the procedural evidence of nonscientific value; (c) to disregard the nature of the proceedings, be they penal or civil, as well as the party (prosecution or defense) for whom one is working; (d) to express numerical evaluations of the value of

evidence according to scales of shared measurement; (e) to search for and assess multiple evidence, ensuring reciprocity and independence; (f) to provide, on an exclusive basis, evaluations and opinions that correspond to one's proven expertise; (g) to show any discordance in the resulting evidence; and (h) to admit the objective impossibility or incapacity to provide evidence in the context of a specific case (Pascali 2011).

In spite of the trust that the public places in the scientific process, there exist many objections to the quality of evidence adduced by forensic scientists and the validity of the above guidance of probabilistic logicism. It would therefore be particularly necessary that a *new evidentiary regime* permeate the scientific evidence produced during the trial, beginning with greater uniformity between national or continental judicial systems, and in particular between "North America and Europe", where, in the latter, the activity of the forensic expert is often the expression of an autonomous profession. Often there is, in fact, diversity in conceiving expert testimony and practicing rigorousness in the methods and the standards of evidence. It concerns limits which are particularly relevant in the category of medical expertise, where the ascertainment of material causality is focused on the demonstration of the cause-effect relationship between harmful means, injury and/or death. The medical examination of the living or deceased person, in creating a collection of data, is equivalent to the obtainment of recorded rather than experiential evidence, thereby proposing a clear separation between circumstantial and medico-technical evidence as a fundamental paradigm of any inference. The Expert should reason, therefore, only on the basis of medical data, leaving to others the logical combination amongst these and other data which are not pertinent to the medical field; avoiding the commingling of plans and consequent inferential confusion, for which it is easy to commit abuses of logic with significant consequences concerning the acceptability and admissibility of scientific evidence.

The process of formation of medical evidence finds obvious and particular significance in the category of cases of professional "medical liability", where much of the non-empirical evidence is derived from the interpretation of health records. There subsists, in fact, a profound difference between the neo-production of a test (of genetic fingerprinting, toxicology, molecular-biology, etc.) and the utilization of evidence from previous clinical, instrumental, laboratory results, etc. In identifying the cause there exists a profound difference between the phenomenic explanation, through the interventionist criterion or through the descriptive criterion of pre-existing evidence. The experimental evidence is, in fact, aimed at satisfying the requirements of inference. The evidence arising from past unselected data, insofar as produced by others (but inferable, for example, from health records), is foreign to the direct satisfaction of inferential purposes, with the result that the interpretations of preexisting medical data can be characterized by a high degree of potential ambiguity and are therefore difficult to classify, with consequent extraneity to the experimental acquisition of evidence, on which the probabilistic logicism must be based. From such a limit, as well as from the difference of subjective interpretations and the frequent lack of rigor in the logical inference

of the clinical-therapeutic ascertainment methodology, there arise difficulties, delays and disagreements in the expert evaluations and opinions on the subject of alleged medical professional liability, which can be remedied only through the application of rigorous, shared and widely applied guidelines regarding ascertainment methodology and criteria of evaluation.

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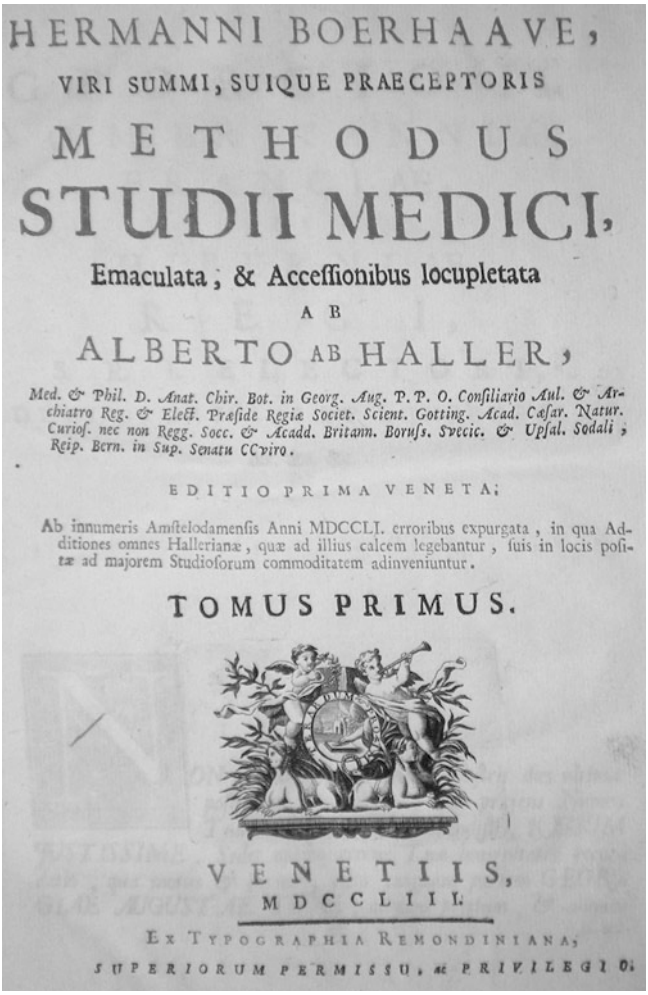
Part IV
Major European Countries and/or Areas



HERMANNI BOERHAAVE,

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METHODUS

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Emaculata, & Acceſſionibus locupletata

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ALBERTO AB HALLER,

Med. & Phil. D. Anat. Chir. Bot. in Georg. Aug. P. P. O. Conſiliario Aul. & Archiatro Reg. & Elect. Præſide Regiæ Societ. Scient. Gotting. Acad. Cæſar. Natur. Curioſ. nec non Regg. Socc. & Acadd. Britann. Boruſs. Svecic. & Upſal. Sodali; Reip. Bern. in Sup. Senatu CCviro.

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TOMUS PRIMUS.

VENETIIS,
MDCCLIII.

Ex Typographia Remondiniana;

SUPERIORUM PERMISSU, ac PRIVILEGIO.

Herman Boerhaave - Hermanni Boerhaave ... Methodus studii medici, emaculata, & accessionibus loclupetata ab Alberto ab Haller ... Venetiis: ex Typographia Remondiniana, 1753. Courtesy of historical "Vincenzo Pinali" Medical Library, University of Padova

Chapter 6
Medical Responsibility and Liability in German-Speaking Countries: Austria, Germany, and Switzerland

Thomas Bajanowski, Walter Rabl and Tony Fracasso

Abstract The first section of the chapter analyses the judicial and normative situation of medical liability in German-speaking countries (Austria, Germany, Switzerland), along with the institutions involved and their operative roles. The ascertainment methodology in both living individuals and cadavers is presented, with special emphasis on the differences between penal and civil procedures. The core part of this chapter examines the evaluation criteria adopted in German-speaking Countries for identifying the injury, dysfunction and invalidity, reconstructing the medical conduct (both real and ideal), identifying any potential medical error, and evaluating the causal value of the identified errors using both the equivalency and adequacy theories. A classification of the most common types of medical errors encountered in Austria, Germany, and Switzerland and the typical structure of a medical expert's report are provided. This chapter ends with a discussion of future perspectives and the probable reformations that could occur in the regulations and procedures adopted in extra-judicial ascertainments.

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Contents

6.1 Judicial and Normative Overview

The general rights and responsibilities of medical doctors (MDs) with respect to patients are laid down in Germany in *Professional Ordinances* (MBOÄ) (Bundesärztekammer 2006), in Austria as part of the *Physicians Law* (ÄrzteG 1998) (Aigner et al. 2001), and in Switzerland in the specific regulations of the various cantons (Zollinger 2007). These ordinances and laws emphasize physicians' independence and self-responsibility. This means that all MDs are free of technical directives from other MDs (Bauer and Pollak 2007). MDs themselves are responsible for the results of their own work. This includes malpractice resulting in health impediments or death.

Irrespective of legislation, practical investigations in cases of malpractice are similar in all three countries. In Germany, the term malpractice is defined as any medical error resulting in disturbed health, injury, or death of a patient where MDs have not exercised the care which would have been objectively necessary to treat the patient. The reference level of care in this context is the "accepted knowledge in medical science" (Jansen 2010).

MDs are responsible for their own professionalism. In the event of an error leading to adverse events/health impediments or a patient's death, MDs may face consequences pursuant to the applicable penal code, civil code, or administrative legislation regarding physicians. Legal liability pursuant to the civil code can be assumed if conditions of contracts were broken or if a legal violation is given. In both cases, the action may have been performed inattentively or intentionally. In general, the patient has to prove that a mistake made by the MD caused the adverse event or health impediment.

Medical experts are called upon to fulfil a number of important tasks in the course of this process. They should have special experience in their field of medicine. If requested by one of the regional medical associations, a civil court, the prosecutor or a judge, medical experts must compile and submit an expert

report. This report is to include an analysis of all medical documents and actions leading up to the adverse event/health impediment/death, and any pertinent additional examinations (clinical, laboratory, X-ray, etc.) to demonstrate the present situation, and finally an assessment of all facts. The report may include the results of additional investigations done by the expert to describe the present status of the injured patient. The main questions which have to be answered are: (1) Did the MD make a mistake? (2) Did the patient show an adverse event/health impediment; in fatalities: what was the cause of death? (3) Is there a causal relationship between the mistake/s made and the health impediment or death (Dettmeyer and Madea 2007a)?

Today, everyone agrees that patient safety is an important quality parameter in any health system. In addition to the doctors who treat the patients, medical experts play an important role in the investigation of individual cases of malpractice as well as in developing the health system, when it comes to admitting that mistakes occur, identifying risks, minimizing the number and impact of mistakes, and supporting patients' rights (Mierzewski and Pennanaen 2007).

In all three German-speaking countries, cases of malpractice can be heard either by a criminal court, civil court, or an extra-judicial institution. Criminal trials are based on criminal law and are therefore subject to the Code of Criminal Procedure. In Switzerland a national Code of Criminal Procedure has been introduced in 2010 and has been applied since January 1st 2011.

If the doctor is found guilty, he may be imprisoned or required to pay a financial penalty. Civil court hearings are based on civil law and follow the Code of Civil Procedure. If the MD is judged to be responsible for disturbed health, physical injury, or the death of the patient, he is required to pay compensation to the patient or to relatives named by the court. Furthermore, patients or physicians can also avail themselves of extra-judicial investigations. For such purposes, the regional Physicians' professional organizations have set up expert panels to investigate cases of suspected medical malpractice. The work of these panels is based on their own statutes which are approved by the Ministries of Health of the relevant German states (Weltrich 2004; Rheinisches Ärzteblatt 1981). Patients and/or MDs can either accept the decisions made by these panels or they can take the case to a civil court to ask for an independent decision to be made by the court. The statistics show that this route is taken in only 10 % of all cases (Mierzewski and Pennanaen 2007).

6.2 Judicial and Extra-Judicial Institutions and Operative Roles

If patients or relatives suspect that disturbed health, physical injury, or death was caused by malpractice, they have the possibility to report the matter to the local police or state prosecutor. But, there is no legal obligation to report such cases. Once the prosecutor has been made aware of such a case, he is required to instigate

proceedings. The police investigation department acts by order of the public prosecutor. Both institutions are obliged to investigate the circumstances leading to death. If disturbed health or injury of a patient may be caused by malpractice the prosecutor investigated the case if there is a public interest or if the patient asked for an investigation. If death has been caused by malpractice, the physician who is called upon to perform the external examination of the corpse has to determine the manner of death as unnatural or unclear. In Germany, the physician who performs the external examination of the corpse is obliged to inform the police if the manner of death is unnatural or undetermined. The police and/or public prosecutor are authorized to ask MDs and other staff involved in the medical treatment to describe the circumstances and details of the treatment. A judge or court have the right to seize relevant medical documents, including the results of X-ray examinations (CT, NMR), reports on surgical treatment, and reports by other physicians (histopathological findings in tissue specimens, results of clinical chemistry, investigations done by physicians of other fields). Subsequent investigations may also be ordered. In cases of physical injury, the objective may be for an independent expert to evaluate the patient's present state. In the case of a patient's death, an autopsy may be necessary to clarify the cause of death, to describe the process leading to death or to document the actual situation of the patient directly prior to death. In addition, the public prosecutor can ask specialists from any field of medicine to investigate the case and to submit a report answering open questions. Finally, the judge has to decide whether the case constitutes malpractice and whether or not the MD appears guilty of causing the damage. If he considers it be the case, he has to decide which consequences are given by law. In Germany he may impose a monetary penalty or bring the case to a criminal court.

If patients or relatives do not wish for such an investigation by the prosecutor or the police to take place, they can go to a civil court and request financial compensation for health impediments or death caused by medical malpractice. In such a case, the patient has to prove malpractice. Only in cases of severe error on the part of the MD or if mistakes of documentation occurred is the onus of proof placed on the physician.

Relevant medical documents including the results of X-ray examinations (CT, NMR), reports on surgical treatment, and reports by other physicians (histopathological findings in tissue specimens, results of clinical chemistry, investigations done by physicians in other fields of medicine) have to be presented by the parties in dispute. The court itself can ask witnesses to clarify specific matters. Both parties have the right to present reports by medical experts with specialist knowledge in the relevant fields of medicine. Legal experience is beneficial, but they do not have to be medico-legal experts. The trial ends either in a settlement (the defendant's insurance company pays out a defined sum of money, and the claimant accepts) or a judicial decision. Both, penal procedure on one hand and civil one on the other hand may not run in parallel. Usually injured patients or relatives have to wait for a decision made by the prosecutor or penal court before starting the civil procedure. The penal procedure is without charge for the patient

or the relatives. In civil court usually the defeated party has to pay for the investigation.

The third alternative for patients and MDs is to approach a panel of experts at a Chamber of Physicians. The aim of the procedure is to provide a short and uncomplicated means for patients to assert their rights and for MDs to reject inappropriate claims. The members of such panels are experienced physicians from all fields of medicine, who are nominated by the chamber and work on a voluntary basis. The investigation is without charge for patients and MDs and commences upon written request. Decisions are made based on medical documents and the written statements of both parties. Witnesses are not heard. The result is a detailed written report which is given to both parties. Both parties participate in this process on a voluntary basis (Weltrich 2004).

Medical experts/specialists play an important role in all types of investigation. Nevertheless, a special qualification is not required as a prerequisite of nomination. Prosecutors and the judges are free to nominate MDs who are qualified in special fields of medicine. In civil court both parties may suggest experts for nomination.

6.3 Ascertainment Methodology

6.3.1 Living

If living persons or their relatives suppose that the person was damaged by medical malpractice, all three routes (penal, civil, and extra-judicial) are available to clarify the circumstances. Nevertheless, the main objective in such situations is to obtain financial compensation for the victim. A court penal procedure can be the first step toward ascertaining the facts. The advantage is that this procedure is instigated by the prosecutor, and it is without charge for the patient and for relatives. The prosecutor has the right to question the patient as well as the MD who is accused. He may ask a judge or court to seize medical documents. He has the right to order expertise from medical specialists, interview witnesses, and order additional investigations to determine the medical state of the patient from an objective point of view. Sometimes, additional X-ray, CT and/or NMR, or other medical examinations may be necessary. The main prerequisite to perform these investigations and to analyze these documents is the patient's written consent.

The qualification, the rights and the responsibilities of experts in general as well as medical experts are defined in Chap. 7 of the Code of Criminal Procedure (Germany: §§72–82, Austria: §§126,127) and in the Code of Civil Procedure (Germany: §§402–414). The results of these analyses can be incorporated in subsequent civil hearings or extra-judicial investigations.

There are no recommendations for standardized investigations in such cases in German-speaking countries. It is up to the public prosecutor, the judge, or the panel of medical experts to decide what additional investigations may be of

assistance and which medical professionals should be included in the investigation. The nominated expert/experts has/have the right to perform additional investigations if necessary and if the patient agrees. Specialists in legal medicine can be involved as specialists from all other fields of medicine. The possibilities and responsibilities are similar to those described below for examining a corpse. The legal basis is again the Code of Criminal Procedure, the Code of Civil Procedure, and the regulations of the national, and regional medical associations. In Austria a medical expert has to be included if special (medical) knowledge is necessary to investigate a case (*Strafprozessreformgesetz* 01.01.2008).

In General, the following documents can become subject of the analysis:

- protocols of the emergency doctor (prehospital phase);
- emergency room protocols (hospital phase);
- clinical history of diseases;
- results of physical examinations;
- protocols on and results of further diagnostic procedures;
- documents on drug treatment;
- results of other specialists who were requested by the responsible MD;
- reports of additional investigations (X-ray, ECG, EEG, lab, …);
- preoperatory examinations;
- report of anesthesiologist;
- reports on invasive and surgical diagnostics and treatment;
- post surgical monitoring (ICU);
- reports on pathological investigations;
- informed consent documents;
- final reports given to inform other MD.

6.3.2 Fatalities

6.3.2.1 Criminal Code

In all three German speaking countries, the state prosecutor has the right and the obligation to investigate cases of death suspected to be caused by criminal offence. This includes cases which are suspicious for medical malpractice which are by definition unclear with regard to the manner of death (or unnatural if there is a concrete indication for malpractice).

In all German states and in all Swiss cantons, MDs have to perform the first external examination of a corpse directly after the death occurred or directly after they were called. MDs have the task to diagnose the death. They have to examine the body and to certify the death on the death certificate. Furthermore, they have to declare the manner (natural, unclear, unnatural) and the cause of death. In Austria,

only licensed MDs[1] have the permission to perform the first external investigation of a corpse. A natural death is caused by preexisting diseases while an unnatural death is due to external violence.

In Germany, Austria, and Switzerland, the conditions for this first external examination are regulated in special laws of the states and cantons.

Pursuant to the German Criminal Code, invasive medical treatment is deemed to constitute physical injury, justified only by the informed consent of the patient. If such treatment causes death, the death must be classified as unclear or unnatural. Consequently, the MD performing the external examination of the body is obliged to notify the police of all unclear and unnatural deaths. The prosecutor seizes the body for the duration of the subsequent investigation. A preliminary evaluation of the case is made by the police, under the direction of the prosecutor. If no elements of criminal relevance emerge, the criminal proceedings are generally closed. In many cases, however, the preliminary analysis does not bring forth enough information for a decision, with the result that a medico-legal investigation can be ordered. In any case, the civil and/or extra-judicial proceedings may continue independently of their penal relevance.

Forensic autopsy is an important part of the investigation, and as such, can be requested. The legal basis of forensic autopsies is found in the respective codes of criminal procedure in Germany (§87 ff StPO), Austria (§128 StPRG), and Switzerland. The people who are responsible for performing these autopsies are specialists in legal medicine employed at university institutes in Switzerland, or in the case of Germany, at public institutes of legal medicine or pathology. In Austria forensic autopsies may be performed by freelance specialists. In all three countries these specialists receive special education and training in this field of work. In Germany and Switzerland two MDs are required to perform the examination together. German law states explicitly that all three body cavities are to be opened (Code of Criminal Procedure StPO §87). Based on the findings of the autopsy, specialists must write an autopsy report, which must display a prescribed structure. The first part describes all the findings of the external and internal investigations. The second part contains an initial, interim assessment of all the findings. Additional investigations are listed which are deemed necessary for answering particular questions.

Prior to the autopsy, a number of different types of X-ray examinations (X-ray, CT, and NMR) can be performed; this is particularly common in Switzerland. In some cases, it may be beneficial to take swabs at the beginning of the investigation for subsequent microbiological examination. In some cases, a test to detect air embolisms may be advisable. During autopsy, all the materials that can be used to answer specific questions have to be sampled. This includes tissue specimens, sometimes whole organs for histology (the brain for neuropathology, and the heart for an examination of the cardiac conductive system), wounds for determining age

[1] Municipal authorities are responsible to organize the external examination of a corpse. These authorities nominate MDs to do the investigation on behalf of these authorities.

by histology and immunohistochemistry, body fluids and tissue specimens for toxicology, and swabs and tissue specimens for microbiology and virology. All these additional examinations can be performed at the request of the prosecutor. In particular, in the case of surgical maltreatment, it is advantageous to have all the medical documents available prior to the autopsy, in order to gain a full overview of all surgical operations and techniques.

Finally, it should be noted that in Germany, guidelines exist governing external examinations and forensic autopsies. These guidelines are published by the German Society of Legal Medicine as a member of the Working Group of Medical Scientific Societies in Germany (AWMF) and are available from the AWMF homepage, External Examination (AWMF 2001a), and Forensic Autopsy (AWMF 2001b). These guidelines form the basis of the standardized examination of corpses and are accepted by all German institutes operating a quality management system (DAkkS 2011).

Medical documents on the clinical treatment of the patient may be seized by the prosecutor or coroner either prior to or following the autopsy. The analysis of these documents can be very important in assessing the medical treatment and together with the results of autopsy they form the basis for further judgment. Additional or final expertise can be requested from specialists in various fields of medicine. In Switzerland, the review is often interdisciplinary, with specialists in legal medicine working together with clinical experts. In Germany and Austria, it depends on circumstances of the case whether or not a specialist in forensic medicine or a clinician is asked for a final statement. In each case, the prosecutor is free to select one, or if necessary, a number of specialists.

6.3.2.2 Civil Code

The instruments of ascertainment in civil cases are more or less similar to those used in criminal trials. The main difference is that the representatives of the victim's relatives and the accused physician or his representatives have to participate directly instead of the prosecutor while the legal proceedings are carried out by a civil court. Usually, the patients' relatives engage a lawyer who files a statement of claim which has to be presented to the court. The accused physician has the right to defend himself or to ask a lawyer for professional help. The court can ask witnesses to clarify the situation and can engage medical experts from different fields to review the situation. In most cases, the expert analyses medical documents on the clinical treatment. This may include the results of a legal autopsy or a clinical autopsy, if performed, as well as the results of additional investigations, as listed above. Clinical autopsies are usually performed by one pathologist in the department of pathological anatomy of a hospital. The autopsy can be performed if the patient (prior to death) or relatives agree. Additional histological investigations are usually performed. The final report is attached to the medical documents. Relatives have the right to be informed on the results.

6.3.2.3 Extra Judicial Institutions

In Germany, the tribunals held by regional Chambers of Physicians can be asked either by relatives of the victim or by the accused doctor for an extra-judicial investigation of a case. The same is true in Switzerland. If a patient's relatives consider that the death was due to medical malpractice, the Swiss Medical Association or a private expert can be asked to appoint an expert or a team of experts to evaluate the case. In such a situation, the procedure is completely transparent: the physician (if a member of the SMA) is obliged to give the necessary assistance and information; at the same time, he has the right to know the arguments and evidence presented by the patient. The insurance companies can also be involved in this procedure. As a result the parties may reach an extrajudicial agreement. If not, a judicial procedure is still possible. The main difference to the civil code investigation is that witnesses are usually not heard. The decisions are based on all the medical documents which are available to review the case. Again, this includes the results of a legal or a clinical autopsy as well as the results of all additional investigations carried out.

In addition to the panels of experts at the regional chambers of physicians, other experts may be involved in the investigation of medical malpractice: medical experts working by private assignment, medical departments of health insurance companies, private institutions, or experts employed at public institutions.

6.4 Evaluation Criteria

The investigation of any case based on the suspicion of medical malpractice follows a certain structure, which is independent of the quality and quantity of physical damage, and independent of whether or not the patient died. The first stage involves demonstrating that a dysfunction, injury, invalidity, or death has occurred. In the next stage, the medical treatment has to be analyzed to ascertain whether or not mistakes were made by MDs and/or other medical staff. Finally, the question of a possible causal link between the malpractice and the dysfunction of the body, an injury, invalidity, or death must be addressed.

This investigation is usually described in a medical expert's report. Such reports may be integral to all types of proceedings (criminal, civil, and extra-judicial). The term *medical expert's report* may be defined as a report that utilizes medical knowledge and experience to assess a defined case (Rieger and Krieger 2010). The medical expert's report is based on an analysis of facts and contains diagnoses and scientific conclusions. Pursuant to the Professional Code of MDs (§25 MBOÄ) the medical expert has the obligation to work with all due care based on his best knowledge and medical conviction (Bundesärztekammer 2006).

Table 6.1 Definition and terms used in the literature, some examples (Von Laue et al. 2003; Hofer et al. 2000; cited in Thomeczek et al. 2007a)

Term	Definition	Reference
Adverse event	An injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both	Brennan et al. (1991), O'Neil et al. (1993), Wilson et al. (1995), Thomas et al. (2000), Vincent et al. (2001)
Adverse event	An incidence resulting in, or having the potential for physical, emotional or financial liability to the patient	Fischer et al. (1997)
Adverse event	An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis, and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable	WHO (2004)
Complication	Any illness that results from a diagnostic procedure or from a therapy and that was not a natural consequence of the patient's disease	McGuire et al. (1992)

6.4.1 Identification of any Injury, Dysfunction, Invalidity, or Cause of Death

The first step in this process, the detection of a dysfunction of the body, an injury, invalidity, or death, may be difficult because of the vagueness of the definitions used, something which is particularly true of the word *error* or the phrase *adverse event*. Von Laue et al. (2003) investigated the use of these definitions in the scientific literature and found a number of differences (Table 6.1).

These short examples demonstrate the necessity to use a unique definition of terms. This is an important prerequisite to compare data from different countries.

Even the Council of Europe has used two nearly but not quite identical definitions of the generic term *patient safety* (Council of Europe 2006):

- freedom from accidental injuries during the course of medical care; activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care;
- the identification, analysis, and management of patient-related risks and incidents, in order to make patient care safer and minimize harm to patients.

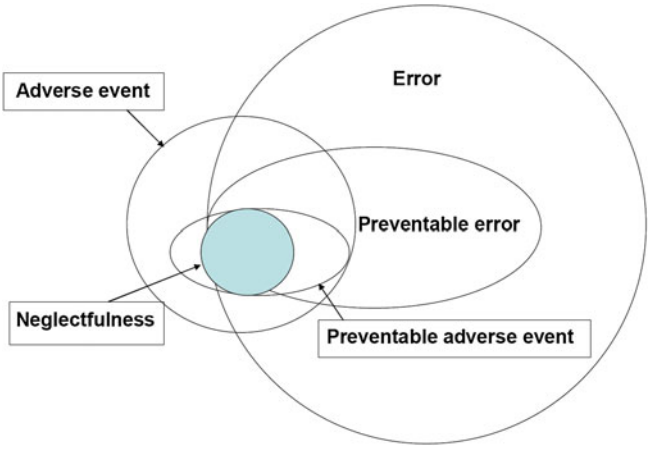

Fig. 6.1 Relationship of the terms *error* and *adverse event* (from Hofer et al. 2000). Note the overlapping areas for different definitions

To make the problem easier to understand, Hofer et al. (2000) devised a diagram to illustrate the relationship between the terms *error* and *adverse event* (Fig. 6.1).

If the patient dies, one main aim of the autopsy is to identify the cause of death, and the pathophysiological process leading to death.

6.4.2 Analysis of Medical Treatment

The second stage requires the medical expert to analyze all documents describing the medical treatment of the patient. This includes the first diagnosis, which is often made outside the hospital by a general practitioner, and leads to hospitalization. The analysis of the medical treatment in hospital starts with the first examination, including an analysis of the patient's clinical history. Depending on the first diagnosis made in hospital, additional examinations may be necessary regarding clinical chemistry, X-ray (including CT, NMR, and sonography); ECG, microbiology, virology, and other specialized invasive and noninvasive diagnostic procedures. All treatments, including surgery, have to be documented in written form. The medical expert has to appraise all these steps as well as the final diagnosis. Depending on this diagnosis, a defined treatment (surgical or conservative) is indicated, which should be arranged in accordance with current medical knowledge and the facilities available at the hospital. The patient has to be informed of the diagnosis, and the therapeutic concept to enable him to give his informed consent. If the hospital lacks the specialized staff or equipment to treat the patient appropriately, it may be necessary to include other MDs or hospitals in

the process. Furthermore, it may be necessary to investigate syringes used, technical equipment, and blood units. The main objective of this phase of the investigation is to identify mistakes made by physicians and/or other medical staff. The standard for all medical actions is the current knowledge in medicine as far as it is generally accepted. For a number of diseases, guidelines have been devised by medical scientific societies on how to diagnose the disease and how to treat the patients (AWMF 2011). These guidelines are based on an extended analysis of the international and national scientific literature, including a thorough evaluation of evidence for each paper. In conclusion, the current knowledge is summed up as a *guideline*. The medical expert has the task of analyzing whether or not the diagnostic procedure is in accordance with existing guidelines or standard diagnostic procedures, whether or not the diagnosis is correct, and whether or not the medical treatment is in accordance with standards and guidelines. If a mistake occurred the expert has to answer the question for a possible causal relationship between the mistake made and the injury sustained or the death.

A list of current guidelines published by the working group of scientific medical societies in Germany can be found online (AWMF 2011).

In general, medical malpractice is deemed to have occurred if an MD fails to undertake the type of care which is objectively necessary, based on the current knowledge of medical science and under the current circumstances, and the MD does not work with the care generally required of a dutiful physician. Different forms of medical malpractice can be identified (Dettmeyer and Madea 2007b):

- mistakes in the organization of processes;
- takeover mistakes;
- mistakes in cooperation with regard to distribution of work;
  - horizontal distribution of work means the interdisciplinary cooperation of MDs, the cooperation of specialists and general practitioners and of the MD who is responsible for the treatment of a patient and other MDs who are asked for consultation;
  - vertical distribution of work includes the teamwork of MDs and the teamwork of MDs and other staff in hospital;
- no medical treatment (intentional or neglectful omission of a necessary medical treatment);
- irregular treatment (therapy which is not in accordance with current medical knowledge).

Typical examples of mistakes made by MDs are (Dettmeyer and Madea 2007b):

- insufficient investigation (clinical, lab, X-ray, ECG, specialist);
- wrong diagnosis;
- wrong indication;
- lack of control;

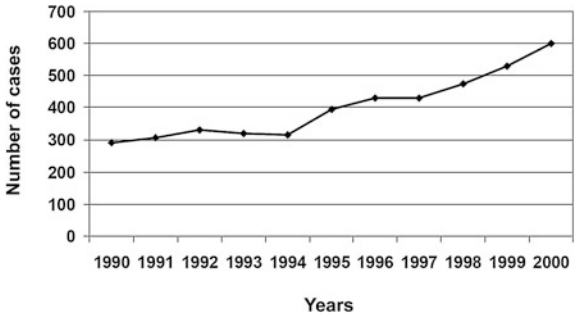

Fig. 6.2 Number of fatal cases of medical malpractice in Germany investigated in 17 institutes of Legal Medicine (Dettmeyer et al. 2007)

Table 6.2 Cases from different surgical subdisciplines (Dettmeyer et al. 2007)

Surgical subdiscipline	Number of cases (total $n = 1{,}266$)	Frequency (%)
General surgery	522	41.2
Accidental surgery	456	36.0
Neurosurgery	106	8.4
Cardiac surgery	157	12.5
Paediatric surgery	11	0.8
Facial surgery	9	0.7
Cosmetic surgery	5	0.4

- wrong therapy (medication);
- wrong surgical techniques;
- complications are not recognized or are recognized too late;
- wrong or insufficient hygiene practices;
- defective medical equipment;
- mistakes in the administration of injections, infusions, and transfusions.

Furthermore, mistakes regarding informed consent and internal cooperation are of significance. If the frequency of mistakes made by specialists of different fields in the lead up to forensic investigation is analyzed, surgeons are on the top (nearly 40 % of all events) followed by general practitioners (20 %), specialists in internal medicine (17 %), and gynecologists (13 %) (Dettmeyer and Madea 1999). In another study the same authors (Dettmeyer et al. 2007) analyzed cases of medical malpractice which had happened between 1990 and 2000 (Dettmeyer et al. 2007). In this multicentre study a total of 4,450 fatal cases of medical malpractice from 17 Institutes of Legal Medicine in Germany were included. The number of these cases increased continuously from year to year (Fig. 6.2), with a total of 1,266 cases which could be attributed to different subdisciplines of surgery (Table 6.2).

6.4.3 Relationship Between Injury/Death and Medical Malpractice

In the next stage of the investigation, the medical expert has to ascertain whether there is a causal connection between the medical malpractice and the injury/death. Different theories have been developed to describe such relationships:

- equivalence theory;
- adequacy theory;
- relevancy theory, and;
- theory of real inclusion.

These principles will be explained in detail (Dettmeyer and Madea 2007c):

According to the equivalence theory, an action (medical error) is causal when it is necessary to obtain the result (injury/death). In other words, if the action had not taken place, the (negative) result could not have been attained. In criminal cases, the medical expert then has to indicate the result that would have been achieved if the MD had not made the mistake.

The adequacy theory requires (as does the equivalence theory) an action which is a *condition sine qua non* to attain a certain effect. Conditions are causal when they are in general suitable to achieve the effect (injury or death). This means that causality is not fulfilled in cases with a totally irregular (inadequacy) course.

In the relevancy theory, causality and legal obligation are differentiated. The causal relationship has to be fulfilled following the principles of the equivalence theory. In criminal cases, the concrete responsibility of the accused has to be proven. In civil law, the responsibility is given only for conditions which are necessary for causing the event.

In criminal cases, the causality between a mistake made by a medical doctor and the injury or death of a patient must be fulfilled *without any doubt* or with the highest degree of confidence (probability approaching certainty).

In cases of medical malpractice, the injury/death of a patient is usually the result of a neglectful action. Neglectfulness is the trait of neglecting responsibilities and lacking concern (Dettmeyer and Madea 2007b). Therefore, the following two questions have to be answered by the medical expert in analyzing a case of malpractice:

- was it possible to avoid the mistake leading to injury/death?
- must the mistake have been avoided if the MD had worked considering the necessary care as well as the actual scientific knowledge in medicine?

The result of the medical experts' investigation is a written report which should maintain a specific structure (Table 6.3).

Finally, a short overview on the work of the expert panel of "North Rhine" is presented here. The panel was set up in 1975. In its first 30 years, it investigated more than 20,000 cases. In about 35 % of these, the analysis of the cases proved medical malpractice. This frequency is comparable with that obtained in civil

Table 6.3 Typical structure of a medical expert's report (Dettmeyer and Madea 2007c)

Questions to be answered
Materials and documents analyzed. • Official documents including other expert's reports. • Findings of the police investigation. • Medical documents. • Previous history, as far as of interest for the analysis. • Extracts, summaries from other expert's reports. • Extracts from medical documents. • Results of previous investigations.
Own investigations and findings • General clinical investigation. • Additional specialized investigations. Analysis of other requested expert's reports.
Own expertise • Reference to current medico-scientific knowledge. • Discussion of specific case with regard to this knowledge. • Answers to questions given. • Critical discussion of other expert's opinion (if necessary).
Summary
Attachments, references.

courts. In only 10 % of cases investigated by the expert panel did the patient subsequently go to a civil court to ask for a judicial decision, and in only 1 % of these cases, did the civil court come to a different decision, demonstrating the high quality of the work of these expert panels (Ärztekammer Nordrhein 2004).

6.5 Future Perspectives

Mierzewski and Pennanaen (2007) (Council of Europe) stated that "health care has become a topic on the agenda of many national and international forums …the time has come to take a protective, preventive, and systematic attitude to the problems of patient safety: to admit errors happen, to identify and manage risk points of processes, to learn from mistakes and minimize their effects". This process includes the development of mechanisms of "professional medical responsibility" which could be understood as (the last) instrument to increase patient safety. The whole process may be supported by politicians but has to be realized by MDs and all other health professionals. Central questions have to be answered in a European context while each of the European countries has to develop its own structures. Two important questions in this process are the

demarcation of patient safety and quality of medical treatment (Thomeczek et al. 2007b). In general, the improvement of the quality of medical treatment should result in improved patient safety. Patient safety may by "measured" by different indicators described in the literature (Romano 2007; Scobie et al. 2006). Nevertheless, the results in individual cases ultimately depend on the proficiency and responsibility of each MD who treats patients. The best result for patients is to avoid mistakes. In order to do this a number of hospitals in the German speaking countries introduced systems to identify and to avoid mistakes. Such "learning" systems should help to monitor the quality of care and should therefore be set-up in all hospitals in near future.

At present, because of the increasing number of cases which have to be investigated the extra judicial way becomes more and more important. This procedure has some advantages. First, cases can be investigated in a relatively short time. Second, both parties save money compared to the civil court investigation. Third, independent on the result of this investigation both parties have the possibility to go the judicial way. Forth, courts are relieved from a significant number of cases.

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Chapter 7
Medical Responsibility and Liability in the United Kingdom

Peter Vanezis

Abstract The first section of the chapter offers an overview of the Medical Acts which regulate medical liability in the context of the UK's common law system, along with a description of the types of enquiries carried out and the recent trends in the number of claims made in the UK. The second section of the chapter examines the diverse judicial and extra-judicial institutions and operative roles in the UK, with emphasis on the assessment of alleged medical negligence cases by doctors and others, legal procedures, no-fault compensations and the Civil Procedure rules of 1998. The third section of the chapter describes the ascertainment methodology in living persons and cadavers, while the fourth section discusses the evaluation methodology, including the standard of care, causation—the "but-for" test and the doctrine of material contribution—and the forensic use of clinical guidelines. This chapter ends by discussing the future perspectives and probable reformations that will occur in the regulations governing the assessment of medical liability in the UK.

Contents

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7.1 Overview

7.1.1 The Medical Acts and the General Medical Council

Medical professional responsibility in the United Kingdom is principally regulated by the General Medical Council, which receives its authority from the Medical Act 1983. It also falls within the judicial system in its broadest sense, which encompasses both English and Scots Law.

The General Medical Council (GMC) was first established under the Medical Act 1858 and has been updated by Parliament on many occasions since then. The purpose of this first Act was to create the body now known as the General Medical Council (previously The General Council of Medical Education and Registration of the United Kingdom) "…so that Persons requiring Medical Aid should be enabled to distinguish qualified from unqualified Practitioners".

The Act created the position of Registrar of the GMC, still in existence today, whose duty is to keep up-to-date records of those registered to practise medicine and to make them publicly available.

In 1950 a further Medical Act introduced disciplinary boards and a right of appeal to the Council. It also introduced a compulsory year of internship for doctors after their university qualification, where doctors were only allowed to practise and prescribe drugs in NHS hospitals and under the supervision of a hospital consultant. They were temporarily registered by the GMC for that year, before moving to full registration if they successfully completed their training. Currently this internship has lengthened to 2 years known as Foundation year 1 and 2.

The Medical Act of 1983, together with a number of more recent amendments, the last being in 2010, provides the current statutory basis for the General Medical Council's functions which includes governance and responsibilities in relation to medical education and registration of doctors and also ensures that medical regulation changes reflect the changing needs of the society within which physicians

work. The Council is also bound by laws that implement a European directive on mutual recognition of professional qualifications from European Economic Area countries.

In essence therefore its role involves:

- setting the standards of *Good Medical Practice* it expects of doctors throughout their working lives;
- assuring the quality of undergraduate medical education in the UK and coordinates all stages of medical education;
- administering systems for the registration and licensing of doctors to control their entry to, and continuation in, medical practice in the UK and,
- dealing firmly and fairly with doctors whose fitness to practise is questioned.

The GMC regularly publishes guidance on all the above matters which is regularly mailed to all doctors or made available on their website.

GMC regulation also takes into account Common Law, the Data Protection Act 1998, the Human Rights Act 1998 and the Health and Social Care Act 2001 (England and Wales only).

7.1.2 The Common Law System

The judicial system in the United Kingdom has, through the common law system, developed rules which encompass the essential elements of medical professional responsibility. For those not familiar with the Common Law system, it has its source in decisions on cases made by judges. The doctrine of precedent is the main difference from codified law systems. A precedent is a legal case establishing a principle or rule that a court or other judicial body may utilize when deciding subsequent cases with similar issues or facts.

Common law developed in England and was influenced by the Norman conquest of England which introduced legal concepts from Norman law. In Scotland, Common Law developed from ancient Celtic Law. Common law was later inherited by the Commonwealth of Nations, and almost every former colony of the British Empire has adopted it.

Alongside this system of Law, there is a legislature that passes new laws and statutes. The relationships between statutes and judicial decisions can be complex.

7.1.3 Type of Enquiries

Within the judicial system in both English and Scots Law, cases involving professional medical responsibility are usually subject to a number of different enquiries or hearings, depending on the nature of the case in question.

A doctor may breach professional medical responsibility in relation to confidentiality issues, performance, incompetence and so on. In such circumstances redress is usually sought by the complainant through the civil courts and also come to the attention, directly or indirectly, of the GMC.

The GMC will also examine the issues involved and so the doctor may well be subjected to its disciplinary proceedings at some stage.

If a doctor has failed in his/her professional responsibility through commission or omission to the extent that the authorities feel that he may have committed a criminal act, then it is possible that he/she may be prosecuted and tried in a criminal court.

The coroner system of death investigation is another type of judicial process which examines why a person has died although it cannot apportion blame to any particular party. Such a hearing can, nevertheless, assess issues in relation to causation and whether medical malpractice may have been involved.

7.1.4 Recent Trends in the Number of Claims Made

The figures here are sourced from the latest National Health Service Litigation Report and Accounts published in (2010).

Over the 4 years up to and including 2009, the number of clinical negligence claims has risen by 8.7 % from 5,602 in 2005 to 6,038 in 2009. However, claims rose by 12.2 % between 2007 and 2009.

Payments made by the NHSLA in 2009 for damages for clinical negligence claimant and legal costs rose to £769.2 m, a 21 % increase on the 2008 amount of £633.3 m.

The highest numbers of clinical negligence claims are made for the specialties of surgery, obstetrics and gynaecology and for medicine. Damages for obstetrics and gynaecology claims account for more than any other specialty, more than £3.3 billion since the clinical negligence scheme for trusts (CNST) began in 1995.

7.2 Judicial and Extra-Judicial Institutions and Operative Roles

A doctor' professional responsibility may come into question in a number of ways and there are different courses of action which may be taken, some of which may overlap. There may be a situation where both a judicial and extrajudicial course of action is appropriate.

A doctor is required to set an example to the rest of society as a model of a caring, compassionate individual with special skills acquired through training, which allow him/her to deliver a high standard of care to patients. However, this

altruistic view—where doctors are placed on a pedestal—is unrealistic and it is not surprising that most doctors do not meet such high expectations.

It goes without saying that both the GMC and the judicial system will take into account in their deliberations and judgements, whether the issues in question are based on real expectations of a doctor's professional responsibility rather than a standard which can only be achieved by very few in the profession if by anyone.

If there is a case of alleged malpractice where the standard of care has fallen below that which is acceptable and the expected outcome for the patient has not been achieved, the doctor may be the subject of a complaint by the patient or an interested party such as a close member of their family and may be pursued through civil litigation in the High Court (Court of Justiciary in Scotland).

Once there has been settlement of the civil case the doctor may then be subject to examination by the GMC. The doctor is reported to the GMC and after the investigation he/she may be the subject of a hearing where he/she will either be exonerated or disciplined in some way. The most extreme punishment is erasure form the medical register which therefore does not allow them to practise, although the doctor can appeal against this decision.

Before the GMC can stop or limit a doctor's right to practise medicine, it needs evidence of impaired fitness to practise. This might be, for example, because they:

- have not kept their medical knowledge and skills up to date and are not competent;
- have taken advantage of their role as a doctor or have done something wrong;
- are too ill, or have not adequately managed a health problem, to work safely.

A warning can also be issued to a doctor where the doctor's fitness to practise is not impaired but there has been a significant departure from the principles set out in the GMC's guidance for doctors, *Good Medical Practice*. A warning will be disclosed to a doctor's employer and to any other enquirer during a 5 year period. A warning will not be appropriate where the concerns relate exclusively to a doctor's physical or mental health.

After a complaint is received about a doctor and preliminary enquiries have been carried out, the GMC decides whether to refer the doctor to a *Fitness to Practise Panel*. The GMC will consider both the seriousness of the allegations and the likelihood of being able to prove the case at a hearing. If the case examiners or the Investigation Committee are satisfied that there is a realistic prospect of establishing that the doctor's fitness to practise is impaired, the doctor will appear before a *Fitness to Practise Panel*. Sometimes, if the GMC believes it is necessary, the doctor will be asked to appear before an *Interim Orders Panel*, which has the power to suspend or impose conditions on the doctor's registration while questions about the doctor's fitness to practise are resolved.

The decisions in the adjudication process are made by medical and lay panelists appointed to sit on *Interim Orders Panels* and *Fitness to Practise Panels*. The panelists are independent, but are required to take account of the Council's policy and guidance.

Interim Orders Panels consider whether a doctor's registration should be restricted, either by suspension or by imposing conditions on their registration, while questions about the doctor's fitness to practise are resolved. This ensures that action can be taken to protect patients while enquiries are carried out into the doctor's fitness to practise. This Panel meets in private, unless the doctor requests a public hearing.

Fitness to Practise Panels hear evidence and decide whether a doctor's fitness to practise is impaired. These hearings are the final stage of the GMC procedures. If the Panel concludes that a doctor's fitness to practise is impaired it may:

- take no action;
- accept undertakings offered by the doctor provided the panel is satisfied that such undertakings protect patients and the wider public interest;
- place conditions on the doctor's registration;
- suspend the doctor's registration;
- erase the doctor's name from the Medical Register, so that they can no longer practise;
- if a panel concludes that the doctor's fitness to practise is not impaired, it may issue a warning to the doctor.

Fitness to Practise Panels meet in public, except when considering evidence relating to a doctor's health.

7.2.1 Doctors and Others Undertaking Assessment of Alleged Medical Negligence Cases

Those undertaking such assessments fall into a number of categories in the United Kingdom and will depend on the nature of the medical error and in particular in which aspect of healthcare and specialism it occurs.

If the patient is living, then the assessment would normally be made by a health care professional within the relevant specialty. For example if a mistake has been made in Obstetrics and Gynaecology then a specialist from that specialty will be used. It goes without saying that the specialist must have no conflict of interest in the case i.e., not work within the same health care facility or region (depending on circumstances), not be well acquainted with the doctor in question or the patient. In small fields of practice it is sometimes difficult to be entirely unfamiliar with the doctor being assessed and occasionally where necessary, a recognised specialist from abroad is employed. The engagement of the specialists to make such an assessment will be through advocates, acting on behalf of either the plaintiff or the claimant. In the case of the plaintiff, it could well be solicitors acting for the NHS or through the medical insurance societies. For the claimant, it is through solicitors and there are many firms which specialise in medical negligence claims.

Where death has occurred, then the initial assessment will be made by the pathologist carrying out the autopsy, usually a forensic pathologist, and could also be an anatomical pathologist. There would also, depending on the complexity of the case, be further assessment as in the living patient, by healthcare specialists within the relevant area of specialism concerned. Cases will be dealt with in terms of representation as above and additionally, the case will be subject to an independent Coroner's enquiry in the form of an inquest. In such hearings no direct blame will be attached to any individual, although the evidence from such a hearing may well be used in civil proceedings at a later stage.

In the initial stages of any possible action, other health professionals are also used either directly or indirectly as advisors working in medical insurance agencies. Their role is both to act as first point of contact and discuss the concerns of the health professional and to advise on what course of action should be taken, as well as arrange representation by solicitors in civil and criminal court hearings as well as coroners courts and other hearings such as the GMC and tribunals.

The GMC, in relation to its various hearings, employs both specialist and non-specialist doctors and other health professionals and lay panelists to adjudicate. All panelists undergo regular training by the GMC to assess their suitability for such work and to ensure that they are up to date with procedures.

7.2.2 The Judicial System Procedures

One of the most commonly used definitions of *negligence* is that it is a failure to act with the prudence that a reasonable person would exercise under the same circumstances. In order to claim damages it is necessary to also show that the negligent person owed a duty of care to the injured person and that the injury was directly attributed to the lack of care. These general rules have been considerably modified in regards to claims for clinical damages where it is necessary to show that there has been a failure by the doctor to treat and care for a patient with a reasonable degree of skill and care.

The duty of care in a clinical context is usually not a difficult problem for a lawyer. Doctors almost always owe their patient or somebody that they are looking after a duty of care. If a doctor is careless or lacked necessary skills then there may a liability for them or their employer or insurer to pay compensation if someone is injured as a result of their unacceptable behaviour.

One of the most difficult questions in medical negligence law is how to judge a doctor's *competence* and whether or not it has fallen to an unacceptable level which has caused injury to a patient. The case of Bolam v Friern Hospital Management Committee (1957) attempted to resolve these issues by measuring the standard of a doctor's care against that of other doctors. If a significant number of other doctors would have acted in the same way when faced with the same circumstances then a doctor will not be found to be negligent.

The definition in Bolam v Friern Hospital Management Committee (1957) (the Bolam Test) did however, cause some consternation and was slightly modified by the case of "Bolitho-v-City and Hackney Health Authority (1997)" where it was held that even if a method of treatment was supported by a body of the medical profession that method of treatment must still stand up to logical analysis if it was to be used as part of the defence.

The final element in UK medical negligence law for a successful claim for compensation requires the claimant to *prove that he has suffered injury* as a result of the inadequate care. This can be a difficult proposition as the claimant was probably ill prior to the commencement of the treatment and expert medical advice must be produced to show that the claimant would have been in a better position had an alternative treatment been used.

The Limitation Act applies to these cases and in general terms a claim for compensation for personal injury must be settled or legal proceedings must have been issued in a court of law within 3 years of the event causing the injury. Failure to comply with this rule may mean that the opportunity to claim compensation may have been lost forever. The Limitation Act does provide certain exceptions to this rule as follows:

- the time does not start running until the age of 18 years;
- the limitation period does run until the injury was first discovered;
- mental incapacity of a potential claimant may mean that the time period never starts to run;
- judges have a rarely exercised discretion to override the time limits.

7.2.3 No-Fault Compensation

In the current tort system, liability for clinical negligence remains fault-based, despite several attempts at reform (Maclean 1988). It would be a radical change to a transition to an administrative or no-fault system for compensating medical injuries. A central tenet of such a proposal is that the system should make compensation decisions, and clinical guidelines that might bear on issues of causation or avoidability, would be likely to play a pivotal role. A no-fault system in specific defined circumstances was proposed by the consultation document *Making Amends* (Department of Health 2003) but subsequently rejected by the Chief Medical Officer Sir Liam Donaldson, because of the potential rise in claims that would be far higher than under the present system. To be affordable, compensation would need to be set at substantially lower levels.

7.2.4 Civil Procedure Rules 1998

The Civil Procedure Rules 1998 (CPR) have radically transformed the rules of court that govern clinical negligence actions and practice directions orchestrate clinical negligence claims and preaction protocols. The overriding objective of the CPR is the early, efficient and cost-effective resolution of claims (Foster 1998). The rules require the use of alternative methods to resolve disputes as a key component in keeping with the overriding objective. Experts from both sides are encouraged to confer and determine what areas can be agreed and whether there are any outstanding points at issue and how they can be resolved out of court.

7.3 Ascertainment Methodology

7.3.1 Living and Deceased Persons

The procedure for initiating claims for medical negligence is initiated by the person who feels that they have a claim, by consultation with a lawyer who specialises in medical malpractice. The advocate would initially advise the potential claimant as to whether or not in the first instance they may have a case to proceed to claim for compensation.

A substantial number of medical negligence claims that are assessed are complex and require quite extensive evaluation. A lawyer will in the first instance ascertain the nature of the complaint and then follow that up by seeking advice from an expert in the relevant clinical area. It would not be unusual where a complaint has been made against a hospital in relation to care of a patient, that there may be a several different health professionals involved and encompassing a number of different specialties. For example, a typical situation may be the case of an elderly person in a nursing home who is difficult to manage, has Alzheimer's disease, is immobile and develops pressure sores then dies of sepsis related to the sores. In such circumstances a number of healthcare workers, doctors, nurses and other staff may be accused of not caring adequately for such a patient by allowing sores to develop and not treating them appropriately.

The medical notes in the first instance will be sought and carefully examined to assess the adequacy of their documentation and the standard and type of care received, conclusions drawn from the history and clinical examination by the clinicians and other health staff. Medical records in themselves, not infrequently, present the assessor with a mass of detail, which is frequently long written in hand rather than typed with many entries being hardly legible. Furthermore, it is difficult to assess whether additions or corrections have been made to original entries without further expert examination.

Assessment reports will be requested from relevant experts employed by the claimant's lawyers and would include for example experienced consultant

physicians, radiologists and other health care specialists. The role of these specialists will be to evaluate the adequacy of the treatment the patient has had and whether or not the medical staff against which the complaint is being made, have acted reasonably and appropriately in the circumstances of the case.

A clinical examination in addition to examination of clinical records, by relevant medical experts representing both the claimant (plaintiff) and the defendant(s) may be necessary to assess the degree of harm that the plaintiff may have suffered.

When action is contemplated, the medical staff against which the complaint is made (defendant(s)) will be represented by their Hospital Authority Indemnity arrangements or by other Medical Indemnity providers such as the Medical Defence Union (or Medical Defence Union of Scotland) or the Medical Protection Society. The lawyers representing the defendants will engage their own equivalent experts to the plaintiff's.

In relation to deceased persons, such cases are reported to Her Majesty's Coroner who will then order a post-mortem examination of the body. This examination will be carried out by a pathologist who is experienced in carrying out coroner autopsies. The pathologist is obliged to be fully briefed of the circumstances surrounding the death and the concerns that the family may have. As with the living patient, all medical records should be made available, and wherever possible, relevant clinical staff, such as the physician who treated the patient should make themselves available to attend the autopsy or at least communicate with the pathologist to explain relevant aspects of the patient's treatment. On some occasions, the family of the deceased will request their own pathologist to be present at the autopsy and produce a report for them, independent to the report prepared for the coroner.

In such autopsies it is common practice to retain relevant samples from the body for further examination including for histology, microbiology and toxicology. In addition, further specialist examination may be required for example neuropathology or examination of the heart by a cardiac pathologist. Other categories of death whether or not a complaint has been made are best referred for further specialist opinion. These will include maternal and neonatal deaths.

7.4 Evaluation Methodology

7.4.1 Standard of Care, Causation and the Development of Clinical Guidelines

In evaluating a case where the adequacy of health care professionals is brought into question, the central issue will be what is the standard of care expected of the professional? In the United Kingdom, the standard of care expected of the medical profession and other health care professionals in relation to medical errors was defined by the Bolam test referred to above and restated here. The standard of care

in a negligence suit was defined in Bolam v Friern Hospital Management Committee (1957) as *the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill at the risk of being found negligent. It is…sufficient if he exercises the ordinary skill of an ordinary man exercising that particular art*, and was the standard by which medical negligence cases were judged. However, recently, the Bolitho case has resulted in a shift away from Bolam, with significant effects for all future negligence suits.

Negligence is concerned with compensating those who have suffered some kind of damage as a result of the actions or inactions of others. It is therefore part of tort law, except in exceptional circumstances where gross negligence is said to have occurred, in which case a criminal offence charge may also be available. DrAdomako was an anaesthetist in charge of a patient during an eye operation. During the operation an oxygen pipe became disconnected and the patient died. He failed to notice or respond to obvious signs of disconnection. The jury convicted him of gross negligence manslaughter. At his trial in 1990 the judge stated *you should only convict a doctor of causing death by negligence if you think he did something which no reasonably skilled doctor should have done*. In 1994 the Court of Appeal dismissed his appeal (Adomako 1994; Dyer 1994).

Three essential components need to be proven in a successful negligence claim:

- a duty of care existed between defendant and claimant;
- there was a breach in this duty of care by the defendant;
- this breach caused, or at least materially contributed to, the damages incurred to the claimant on a balance of probabilities.

7.4.2 Causation

Causation is an essential component to show of that there is a breach in the duty of care to cause negligent outcome. The test by which causation is determined is a question of law. There are traditionally two tests: the "but for" test and the doctrine of material contribution.

7.4.2.1 The "but for" Test

According to the "but for" test, but for the negligence of the defendant the claimant would not have suffered the injury. There are two limbs to the "but for" test: a question of historical fact—what actually did happen; and a question of hypothetical fact—what would have happened if the defendant had not been negligent. The negligence is a causative if there is a material difference in the two outcomes.

Consider the following example. A night watchman attended casualty one morning with a history of vomiting. The duty nurse summoned the doctor by

telephone but he refused to attend. The man left casualty but died a few hours later. It was found that the death was due to arsenical poisoning. There was no reasonable prospect of an effective antidote being delivered before death. The doctor was found to be negligent, but the man's death was inevitable and would have occurred even if he had received appropriate treatment. The claim failed because the claimant had failed to establish causation between his death and the doctor's negligence for not attending to him [see Barnet v Chelsea and Kensington Hospital Management Committee (1969) QB 428]. The question of causation in medical negligence can sometimes be difficult–one is considering the effect of a medical intervention on an underlying disease process which may be changing itself. The alleged injuries may be indistinguishable from the underlying condition. There may be several concurrent or consecutive agents contributing to the patient's condition of which only one is the defendant's alleged negligence.

7.4.2.2 The Doctrine of Material Contribution

There may be several factors responsible for an injury, including the defendant's fault; the injury may have occurred without the defendant's fault, and the defendant's fault by itself might not have been sufficient to cause injury. Where a breach of duty has caused or materially contributed to the injury complained of, the tortious factor may be considered the cause of the injury [see Bonnington Castings v Wardlaw (1956) AC 613; McGhee c National Coal Board (1972) 3 All ER 1008]. This test of causation provides some relaxation of the logical rigour imposed by the "but for" test. The doctrine of material contribution has evolved from cases involving negligent exposure to noxious agents such as industrial dusts. The courts have applied this test in situations involving discrete clinical events [see Bailey v Ministry of Defence and Portsmouth Hospitals NHS Trust (2008) EWCA Civ 883].

In the past UK courts approached the issue of medical negligence with an exaggerated level of deference to expert medical opinion. They did not want to choose between conflicting opinions, finding in the vast majority of cases for the defendant so long as he could show others in his position would have acted similarly. *Bolitho* reminded judges that the courts reserve the right to decide that even accepted medical practice may be negligent, and allowed them to scrutinize what constituted 'reasonable' in the *Bolam* test. There are significant indications that *Bolitho* is being applied, and the Human Rights Act 1998 will enforce an even higher standard than either *Bolam* or *Bolitho,* that of best or expected practice.

The development of *clinical guidelines*, by the *National Institute for Health and Clinical Excellence* (NICE) among others, will only serve to promote this higher standard being applied, as courts will rely less on expert testimony and more on these guidelines of best or expected practice to judge allegedly negligent doctors against (Samanta et al. 2003). Guidelines are consensus statements developed to assist clinicians in making decisions about treatment for specific conditions. They are systematically developed on the basis of evidence base practice (Hurwitz 2004), and aim to promote effectiveness and efficiency of healthcare delivery.

It has been argued that evidence-based practice could be used to develop a framework that ensures consistent access to services and quality of care across the country, an approach espoused by the Department of Health.

To promote the development and use of guidelines, the government created the National Institute for Health and Clinical Excellence (NICE). The Healthcare Commission (HC), The Healthcare Commission, Commission for Social Care Inspection and the Mental Health Act Commission ceased to exist on 31 March 2009 and their functions were taken over by the Care Quality Commission.

The Care Quality Commission, the new health and social care regulator for England was also created as part of this government agenda for quality and has a duty to monitor the implementation of clinical guidelines. Some, however, believe that guidelines might fetter clinical discretion and autonomy and define too inflexible or unrealistic standards for clinical practice (Black 1998). Discretion lies at the heart of clinical judgment and has to take into account a number of competing influences relevant to individual patient circumstances and clinical care. It has been argued, therefore, that guidelines should not constitute a legal standard that is applied rigidly in every case. The precise role of guidelines in determining the legal standard of care is uncertain and there appears to be no empirical data on their actual or perceived use in medical litigation in the UK.

The GMC and Royal Colleges have concurred that good practice should be measured against established guidelines and have stressed the importance of robust mechanisms to identify and maintain high standards in medical care. The GMC has emphasised that in order to promote the required standards of professional practice, there must be effective quality assurance and clear professional accountability. To ensure good practice, doctors must remain responsible for their own performance and conduct and should share responsibility for the quality of care provided by their team.

The findings of the Bristol Inquiry (2001), involving the management of children receiving heart surgery, shook public confidence and called into question standards within the NHS. The fifth report of the Shipman Inquiry (2004) (this inquiry investigated the activities of the general practitioner and serial killer Harold Shipman) highlighted that it is not sufficient for guidance to be implicit in the context and circumstances of clinical practice. The lack of explicit standards may result in inconsistent and widely varying decisions, as well as tragic consequences for patients and their families.

The NHS Reform and Healthcare Professions Act 2002 introduced a further layer of regulatory control over healthcare quality. This Act established the Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence), a body that represents patients and the public in circumstances in which a professional regulatory body is perceived to have been overly lenient in the exercise of its regulatory functions. In the context of professional regulation, established guidelines might help define the expected standard of practice as well as raising the expectation of the community that good practice hinges on following established guidelines were clinically appropriate.

7.5 The Future

The NHS Redress Bill, which received royal assent in November 2006, created powers to set up a an NHS Redress Scheme to provide swift resolution to claims without the need to go to court; it would largely eradicate the need for lawyers for claims under £20,000, saving an estimated £7.6 million in legal costs in the first year (Hughes 2009). Secondary aims include establishment of a more open and fair culture in the NHS to ensure that lessons are learned from mistakes. Its origins come from the Chief Medical Officer's report, "Making Amends", released in 2003. However, the bill has been unworkable in England to date. While the Welsh and Scottish governments are speeding up plans to set up something similar to the Redress Scheme—Wales by next year and Scotland (date uncertain) probably going a step further with a no-fault compensation scheme similar to that in New Zealand—it appears that the Department of Health has not yet produced the necessary secondary legislation to make the reformation.

Many groups—including some NGOs and the august distinguished Parliamentary Health Select Committee—are concerned, disappointed even, criticising the Department of Health for dragging its heels over implementing the scheme. One charity, Action against Medical Accidents (AvMA) is especially critical of these delays. The Patient's Association, an organisation that advocates passionately on a range of issues for the public and has done successfully for many years, has consistently argued for better openness and transparency on matters of quality and safety The patient's association (2011).

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Chapter 8
Medical Responsibility and Liability in France

Eric Baccino

Abstract The first section of this chapter introduces the issue of medical liability in France, while the second one examines the epidemiological data within the same context. The third section looks at juridical procedures in penal jurisdictions, civil jurisdictions and administrative jurisdictions. Subsequently, non-juridical procedures intervening in medical responsibility are examined, looking at the Council of the Order of Medical Doctors and the Commission régionale de conciliation et d'indemnisation des accidents medicaux (CRCI). The sixth section of this chapter examines the nomination of experts in cases of medical responsibility, while the seventh deals with expert examination of living persons and cadavers. The penultimate section looks at the evaluation criteria for medical error/inobservances in France. This chapter concludes with present and future prospects concerning the issue of medical responsibility in France.

Contents

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8.1 Introduction

When we speak of medical responsibility, we imply responsibility deriving from an action carried out by a doctor, be it diagnosis, prevention of further impairment or injury or some kind of treatment.

When the doctor works in a public healthcare structure (a hospital), medical responsibility, apart from exceptional cases, is included in the responsibility of that structure which, as well as being obliged to protect its professional healthcare workers, must also take on responsibility for defects of equipment and of anything else its staff uses, particularly blood and haematic products.

For doctors who work in private healthcare structures (clinics), the fields of responsibility are separate, and it may happen that a doctor employed by a clinic enters into conflict with some part of that private structure (for instance, when a nurse, employed by the clinic and working in the operating theatre under the responsibility of a doctor, makes a mistake).

8.2 Epidemiological Data

Epidemiological data are extremely imprecise, for several reasons. The courts have no centralised accounting for complaints about medical responsibility. However, it is common knowledge that, for every 100 complaints received by courts, less than 2 % result in a condemnation. As regards insurance companies, data are of course confidential.

In France today, there are two types of insurance for doctors: the first, *Mutuelle assurance vie des professions de santé; mutual life insurance for healthcare professionals* (MAVPS) insures more than 120,000 doctors, mostly belonging to the private sector; the second, *Société Hospitalière d'Assurances Mutuelles* (SHAM) insures most public and private healthcare structures.

In France, in the course of their professional lives, the medical responsibility of one doctor out of two will be questioned, but the number of cases settled out of court, and numbers of court cases or even indictments per year, are unknown.

For doctors working in the private sector, insurance companies have developed the concept of "*sinistralité*", which consists of asking doctors to report any incidents which might involve their responsibility to their insurance company. There are about such 2,500 reports each year, or more than one report every 100 doctors, with a mean annual increase of 2–4 %.

The epidemiological importance of the raw data does not accurately reflect the interest of the matter. The qualitative and symbolic aspect is extremely important.

Many doctors feel a true sense of paranoia as regards court cases, due to a lack of substantiality of epidemiological data and perhaps also of those who make their living by them (lawyers, insurance companies and jurists).

The greatest risk lies in whether the quality of the doctor's relationship with patients is influenced or even altered by the fact of considering the medico-legal risk.

Due to their lack of knowledge of juridical terms and the functioning of the juridical system, doctors often do not discriminate between a penal indictment (extremely serious in France) and indictment before a *Commission Régionale de Conciliation et d'Indemnisation* (CRCI), a regional commission for settlements and estimation of damages, which has no punitive function.

From the viewpoint of doctors, therefore, it is necessary to differentiate clearly between charges which result in a penal court case (which are reported to the Order of Medical Doctors) and ones which aim at obtaining compensation for victims or those having rights to them (an administrative court for salaried doctors, a civil court for doctors in the private sector, and the CRCI for all).

8.3 Juridical Procedures

8.3.1 Penal Jurisdiction

In France, all doctors, in both public and private sectors, may be penally charged, a possibility applicable to everyone, as it is the concept of public order which is at issue. The Procurator may apply this power in person, but the intervention of a penal magistrate generally follows a report, made either to the police (in urban areas) or to the Gendarmerie (in rural areas), and transmitted to the Procurator.

The Procurator is a magistrate who does not pass judgements, but who has the power to decide whether to reject a report or not. If the report is rejected, the person who made it has no power of appeal. If it is accepted, both if it is an easy case (a rare event if a report is made against a doctor and the magistrate can decide on an immediate hearing [*comparution immédiate*] which will be assigned to another judge) or if it is a complex one (the usual situation), the procedure is

transmitted to the *juge d'instruction,* who has the task of discussing the dossier and demanding various types of expertise and examinations.

In France, the Procurator cannot pursue the simple possibility of a medical error, since she or he must determine whether a mistake has been made according to one of the articles of the Penal Code. The most frequently used articles are those referring to involuntary bodily harm (Arts. 221 and 222 of the Penal Code) or lack of assistance to a person in danger (Arts. 223 of the Penal Code).

A penal charge may involve fines, detention under surveillance, or even imprisonment (exceptional). Above all, this procedure is extremely distressing for doctors, because even though they are rarely condemned, the procedure itself gives rise to negative publicity in the media, which is extremely damaging from the viewpoint of a doctor's reputation. Fortunately, the great discretionary power of the Procurator as regards the opportunity of incrimination limits excesses in this particular sector.

The Procurators are all magistrates who went to a single national school, employed by the state, organised by the Ministry of Justice and apply a penal policy. It should be noted that penal courts also have the power to pronounce opinions, after expert advice, concerning the amount of compensation to be awarded to the plaintiff.

If the case involves a death, it is the Procurator who, in the great majority of cases, asks a medico-legal expert to carry out an autopsy. It is only after the conclusions of such an autopsy have been received that the dossier is sent to the *juge d'instruction,* if necessary.

In practice, in the case of a medical error made on a living or a deceased person, the doctors involved may examine the dossier itself, although in theory only the *juge d'instruction* has the right to appropriate medical documents and to transmit them, sealed (without examining them her/himself), to designated experts. In the case of medical errors, the Procurator almost always turns to medico-legal experts.

Instead, when the matter passes to the preliminary enquiry, the *juge d'instruction* calls upon expert doctors who may not be forensic specialists at all, but rather doctors specialised in the medical field in which the alleged error is best collocated. Medico-legal experts intervene as well as general medical doctors or specialist co-experts in evaluating bodily damage and causal links. This is particularly the case concerning medical error in living subjects.

8.3.2 Civil Jurisdictions

Civil jurisdictions concern doctors working in the private sector, both in their own surgeries and in clinics. Ever since 1835, the year when doctors first became liable to be charged and condemned for their professional work (the Giugne case), the principles applied have been the same, taken from the Mercier case of 10 June 1938, and more recently, by the law of 4 March 2002. These principles are the following:

- medical responsibility cannot be invoked unless an error and injury exist, and unless a causal link is established between the two;
- proof must be supplied by the patient, with some rare exceptions;
- in cases of cosmetic surgery and surgical prostheses, particularly dental, in which the doctor and above all the supplier of the material are obliged to produce positive results;
- when an iatrogenic infection arose within the setting of medical work carried out in a private structure (clinic);
- when an iatrogenic infection arose within the setting of a private doctor's surgery, the patient must supply proof of an error which caused the infection.

The definition of error, as stated in the law of 4 March 2002, is based on the principle of contractual responsibility, which obliges patients to pay their doctors and to follow their prescriptions. Doctors' obligations consist of providing the "most appropriate" treatment, in order to allow patients to benefit from a given therapy "the efficacy of which is recognised and which guarantees the best healthcare according to established medical knowledge". Preventive actions must not, according to medical knowledge, expose patients to risks which are disproportionate in relation to the anticipated benefit.

Doctors are not obliged to produce results but to act for their patients' benefit, at a certain moment in time, by providing treatment which "a good average doctor" would provide.

An error may be technical (e.g., damage to an organ after a surgical operation when there was no anatomical anomaly). Such technical errors may also be made at the moment of diagnosis (e.g., prescribing an X-ray of the skull when consensus opinion clearly recommends CT or NMR scans in certain cases of cranial trauma) or during post-operative check-ups or check-ups in general (e.g., a patient who falls from an operating table).

However, errors may also occur in a situation which is called lack of the "duty to humanity", i.e., lack of information or of patient's consent: that is, information given to patients must be clear, intelligible and honest, in the sense that patients must receive an explanation which can be understood. "Honest" means that patients must not be told only about the disadvantages of, for example, not being operated on, but above all they must have time to reflect. This information is of course indispensable for obtaining informed consent. Sick people, unless unconscious, must be able to give their consent. If they are unconscious, relatives previously designated must give their consent or, in their absence, someone close to the patient.

Clearly, these obligations do not exist in cases of urgency, particularly in life-threatening circumstances.

Even if patients have not consented, or if proof of consent had not been recorded by the doctor (this became a legal obligation for doctors after 4 March 2002), it is believed that if patients have no other choice than to be operated on (due to their state), then there is no bodily damage, or at most only partial damage,

which may be admitted according to the principle of the loss of the possibility of refusing medical care.

The theory of the loss of possibility is mainly applied in cases of lack of information, when patients are not informed of the possibility of refusing treatment or when they are not given a choice among various techniques, some of which are less dangerous than others. It is estimated that bodily harm is not linked exclusively to techniques, but to the fact that patients are not given the chance to choose the least dangerous treatment or to refuse to be operated on.

A recent sentence of 3 June 2010 (*Chambre civile de la Cour de Cassation)* goes completely against the above principles, and has given rise to much concern among French doctors, because it considers lack of information as an attempt to harm human dignity, even if there is no damage to health. Damage must exist, and it must be evaluated according to methods (which need not be discussed here).

In theory, the causal link must be direct, certain and exclusive. Doubt does not profit the victim. Accepted criteria are that the damage must be related to a clearly identified cause, that there is no intercurrent event explaining it, and above all that the patient's previous state did not predispose it excessively or exclusively. In the same way, both the physiopathology causing the damage and the relative error must be demonstrated. Too long an interval of time between cause and damage often means that causal links can no longer be ascertained.

As regards procedures, patients must turn to the court, and therefore require the services of a lawyer whom they will have to pay, or the state will have to pay, if such patients have the right to free legal aid (for those without sufficient means).

When the victim is a living person then the referring judge, generally the president of the court, names an expert who may be a medico-legal expert, but in most cases is an expert in bodily damage or a specialist in alleged medical error. The procedure is by cross-examination, that is, all parties must be present at all expert procedures and must share all information. The fee due to the expert must be paid by the patient, who will be reimbursed if she or he wins the case. Medico-legal experts are most frequently designated, alone or as co-experts, in the case of death.

8.3.3 Administrative Jurisdictions

These concern doctors who are salaried workers in hospitals. The principles involved are identical. The same goes for expert opinions, except that experts' reports are not sent directly to the parties in question, but to the presiding judge of the court, who later distributes copies to the parties. The method of remuneration is also slightly different (the losing party pays and there is no charge to be paid before beginning expert operations).

The administrative courts do not recognise shared responsibility or loss of possibility of choice. When an error is committed, all damages must be paid by the

party responsible. But as the amounts of damages are lower than those assigned by civil courts, in the end there is not much difference for the victim.

It should be noted that the administrative courts have no lists of experts, and that the experts working for such courts are chosen from the lists of juridical experts at the civil courts of appeal.

Until about 15 years ago, it was much more difficult to ask a public structure to pay compensation, rather than a private one. This is no longer the case, as the law of 4 March 2002 has rendered the principles uniform, as well as the term for prescription, which is 10 years for all trials for medical error.

The only great difference which remains is that doctors in the private sector are required to respond personally whenever an error is made, and are never covered by the structure for which they work (except in the case of iatrogenic infections inside private clinics), while doctors working for public hospitals are covered. The public structure defends such doctors and follows all procedures, and the hospital insurance company, if necessary, pays compensation.

The only exceptions (by definition, exceptional) are cases of error called "detached" from service, i.e., errors of particular seriousness, personal, without connections with the organisation of medical treatment, and penal in their nature (although not all penal errors can be so "detached" from service). Examples are: a doctor who refuses to come to a patient's assistance when he is on duty; a doctor who amputates a patient's right leg instead of the left one, etc.

8.4 Non-Juridical Procedures Intervening in Medical Responsibility

8.4.1 Council of the Order of Medical Doctors

Although the *Conseil de l'Ordre des Médecins* does not judge medical errors and above all has no function as regards compensation paid to victims, some of its 45 articles refer to errors which are also criminal errors: examples are lack of medical assistance and violation of professional secrecy.

Reports must be made to the *Conseil Départemental* (Departmental Council) which, in the case of a doctor in the private sector, must transmit it, although it may not agree with its substance, to the *Chambre Régionale Disciplinaire* (Regional Disciplinary Chamber). In the case of a hospital doctor, the complaint does not go to the above Chamber, unless the Departmental Council also decides to report the doctor (i.e., the Council plays the role of Procurator in deciding on the opportunity or otherwise of pursuing the case).

The Regional Chamber is the first disciplinary instance, and appeal to it is at the level of the Council of the Order, the Court of Cassation is at the level of the *Conseil d'Etat* (State Council) (as for administrative jurisdictions). It should be noted that civil and administrative jurisdictions also have three levels:

- first instance, appeal, and Court of Cassation;
- civil magistrates train at the *Ecole Nationale de la Magistrature* (ENM; there is only one in France, at Bordeaux), like penal magistrates. Magistrates in the administrative sector and those of the State Council train at administrative schools such as the ENA (*Ecole national d'administration)* or schools of political science.

8.4.2 Commission Régionale de Conciliation et D'Indemnisation des Accidents Medicaux

This is a great novelty for France (I believe it is the only one of its kind in the world), which came into being with the law of 4 March 2002.

Its essential aim is to compensate victims of therapeutic risk or medical error, as well as more serious iatrogenic infections, by means of national solidariety (the State).

Its other aims are to make justice accessible to all (the entire procedure is free of charge (including free legal aid if requested and authorised). It is rapid because, in theory, a decision must be reached no later than 6 months after the report has been received, including the time necessary for an expert opinion to be given, but current delays mean that waiting times are nearer 9–10 months. In any case, they are much shorter than civil or administrative cases, for which matters of responsibility often last 5 years or more).

The *Commission Nationale des Accidents Médicaux* (CNAM) created a list of experts. These experts are specialists (e.g., ophthalmologists, cardiologists) and experts in physical damage. Most of them have a university diploma in physical damage, which all specialist doctors must have (unofficially), having obtained a *Diplome inter universitaire* (DIU) as experts in medical accidents, courses organised nation-wide by the *Société Francaise de Médicine Légale,* involving a year's extra study.

A structure called *Office National d'Indemnisation des Accidents Médicaux* (ONIAM), subsidised by the state, has the task of making the system function and compensating plaintiffs. For financial reasons, compensation for medical risks is limited to the most serious cases, i.e.:

- cases in which partial permanent disability (IPP, AIPP, or Permanent Functional Disability) exceeds 25 % (corresponding at least to the loss of one eye, according to the estimation tables);
- cases in which a person is unable to work for a period of 6 months consecutively or discontinuously over a period of 12 months;
- cases in which the person was unable to undertake professional work;
- cases of particularly serious problems in living conditions, defined recently by a decree which specifies that such difficulties must impede daily life by 50 % or

more for a period of more than 6 months (partial temporary functional deficit, as initially defined by AREDOC for expertise carried out by insurance companies, but also accepted by most court experts and the CRCI).

When the patient has deposited all medical records with the CRCI, which acknowledges receipt, an expert opinion is sought and must be carried out rapidly, since the resulting expert report must be deposited no later than 3 months after the expert has been nominated.

Very often co-experts are chosen, who work with a medico-legal expert or specialist in physical damage and a specialised doctor [for example, if a case of "horse's tail syndrome" follows an operation for slipped disc hernia, the medico-legal expert is the person who actually carries out the examination, while a technical opinion is given by a co-expert neurosurgeon, or *sapiteur* (*expert in assessing damage*)].

In cases of death, the CRCI is the competent body. The CRCI expert opinions on deceased persons account for about 18 % of the total number. They are mainly entrusted to medico-legal doctors, whose role is to assess damage but also to determine how death occurred, in order to call a doctor competent in the relative medical speciality which caused the death (anaesthetist, surgeon, etc.) These experts are subject to cross-examination, but less strictly than juridical opinions.

As the resulting expert opinion sent to the Chairman of the CRCI is then sent on to the parties in question, when a commission is convened, those parties can criticise it. The commission is sometimes composed of representatives of healthcare professionals, insurance companies and universities, as well as of the representatives of the parties in question. The commission is not bound by the conclusions of the expert, and very often changes them. There is no possibility of appeal. Conversely, the commission may decide to request another expert opinion, or a new one.

The main difficulty with these expert opinions is determining the consequences of an involuntary medical error or therapeutic risk.

For this reason, the expert must eliminate everything which refers to the patient's preceding state, for which compensation will not be paid, and everything which refers to a medical error, which must be compensated by the insurance company of the doctor responsible.

A rough estimate shows that about one-third of cases are attributed to preceding states, one-third to medical error and one-third to an involuntary medical error. About 10–15 % of cases have multiple causes.

The State, through ONIAM, will only pay compensation for therapeutic risk. If therapeutic risk is considered to exist by the CRCI, ONIAM will pay compensation for it; if this does not coincide with the CRCI's decision and it is believed that a medical error has been made, it will turn to the insurance company of the doctor in question.

If the CRCI decides that a medical error was made, either the insurance company pays compensation and a trial is avoided, or, if the insurance company

refuses to pay compensation, ONIAM requests payment of compensation and, in this case too, turns to the doctor whose insurance company refused to pay.

About 6,000 expert opinions are sought every year, and about 1,200 people benefit each year from compensation paid for involuntary medical error. This procedure also avoids juridical expert opinions.

The CRCI are interesting for everyone (except lawyers), because they are rapid and free of charge, and their experts are competent. This last fact is due to the composition of the CRCI, which can call on experts or professors of Forensic Medicine who teach courses covering physical damage. Expert opinions are much more severely (and rightly) criticised when a magistrate is the only person who makes them. The only criticism which may be made about the CRCI is the lack of balance between the forces involved: the doctors are assisted by the doctors of their insurance company, lawyers, etc. The victims hardly ever receive any assistance.

It seems that (according to the lawyers) for the same error and the same injury, the sums paid in compensation assigned by the court are larger than those assigned by the CRCI, but this remains to be demonstrated.

8.5 Nomination of Experts

Although there are various lists of experts (CRCI experts and those of the juridical experts at the regional courts of appeal) or at the (nation-wide) Court of Cassation, there are no lists of experts for the administrative courts. All experts followed more or less the same training.

With medical specialisations, in general medicine or speciality, experts mainly followed specific training, i.e., a university diploma in assessment of physical injury, which lasts 1–2 years, the aim of which is to demonstrate knowledge of how to evaluate physical injury, to appreciate causal links, and to identify medical error. In the standard course for experts, the problem of error is faced, but not in great depth.

The DIU confers expertise in medical error on CRCI experts as the essential part of the teaching of analysis of medical error. Of these experts with diplomas, competent to estimate physical injury, some are mainly specialist experts (including forensic doctors), others are principally specialists, in their particular fields (rheumatology, cardiology, pneumology, etc.). Only a small percentage enters the highest and most complicated level, and involves experts with long experience.

As magistrates may enroll on the lists of experts those without university diplomas, and even choose experts not enrolled on any lists, occasions sometimes arise when expert opinions are given by excellent doctors, but very bad experts.

As regards doctors of forensic medicine, the situation has developed greatly since the beginning of 2011, when a reform attributed an overall budget to penal forensic medicine, by centralising all autopsy centres (only one per region) and

attributing to forensic medicine the function of clinical legal medicine (in general, one centre for each large hospital). All legal experts must have had training which corresponds at least to the understanding of legal medicine, or 2 years of training, and their role as public servants is to transport cadavers, carry out visual examinations, examine victims of violence, and undertake autopsies.

Some institutes are also competent in the fields of toxicology, anatomopathology and DNA testing: these services are invoiced, case by case, to the Ministry of Justice.

These institutes do not have the function of providing expert opinions, and many do not do so. However, autopsies can only be carried out by them, including those made for suspected medical error. The *legale* carries out an autopsy, and if it reveals the possibility of medical error, the expert nominated by the magistrate will use him to interpret the results.

Outside the field of penal forensic medicine deriving from the reform, in which the manager of the CHU assigned to the Head of the forensic medicine service the function of nominating doctors to carry out autopsies, other experts are chosen by the penal magistrate, penal for the *juge d'instruction,* administrative or civil, or the Chairman of the CRCI. The criteria are mainly chosen according to the expert field of specialisation and the level of satisfaction which that expert has already given, but some choices follow rules which are much less rational.

8.6 Expertise Regarding Medical Responsibility

8.6.1 Premise

There is a great difference between penal expertise and other kinds of expertise. Penal expertise does not involve cross-examination, whereas other kinds do. During penal expertise, only the person to be examined is present (a family member may be admitted, after verification of identity) and the report is sent solely to the *juge d'instruction.*

As regards access to the clinical documents, the *juge d'instruction* confiscates the patient's clinical record, whether the hospital in question is private or public, and seals it before sending it to the expert, who is the only person who can consult it and who must reseal it when sending back her or his report.

For all other kinds of expertise, juridical, civil, administrative or CRCI, the expert may have access to the dossier only if the patient, or those having the right or her/his representative, authorises it. The law of 4 March 2002 states that the expert is authorised to obtain the dossier from the hospital, even without the patient's agreement, but this is so contrary to French custom and tradition in this field that this disposition of the law, which was hastily written, is not applied.

For cases of cross-examination expertise, the person examined may be assisted by whomever she/he wishes:

- medical consultants paid directly by the patient;
- the medical consultants of the insurance companies, who insure the patient for third-party risk or legal assistance;
- the doctor who attended her or him;
- lawyers.

The doctor involved will also be present, assisted by the medical consultant of her/his insurance company for third-party risk and by a lawyer.

When the single nominated expert needs a specialist opinion, or that of a *sapiteur,* the choice of the latter varies greatly according to the type of procedure. In cases of a penal expert opinion, the expert must request the agreement of the *juge d'instruction* and propose a name, but it is the judge who chooses *sapiteurs,* nominates them, questions them, receives their replies, remunerates them and then transmits their responses to the expert, for the sake of completeness.

In administrative cases, *sapiteurs* are also proposed by the expert, but the chairman of the administrative court nominates them.

For other expert opinions, CRCI or civil court, *sapiteurs* are freely chosen by the expert, on condition that they are specialists from another field. The expert must only ensure that the Court has sufficient funds to pay the *sapiteurs*, if the plaintiff does not receive legal aid.

8.6.2 Phases of Expert Examination

The quality of an expert opinion obviously depends on the competence of the expert, any co-expert and/or *sapiteur,* but also on the quality of the documents obtained. Otherwise, the phases of the examination by the expert are always the same.

Information regarding the patient's previous state (medical antecedents): occupation or profession, leisure time hobbies and activities, in order to describe the situation which existed before the fact for which expert opinion is being sought.

Facts: indications, investigations, surgical operation report, pre- and post-operative surveillance, hospitalisation, report of any time spent in rehabilitation structures, report of the doctor following the patient at home, etc. In this regard, in cases of medical error, nurses' reports are essential in order to verify doctors' instructions, etc., and to understand the "climate" which existed between the family and the medical team. A complication or an act of negligence is often not recorded in the clinical record, but can be found in the nurses' records.

All X-rays must be examined. If there are no X-rays, the expert reports that she or he has only read the clinical record.

Documents recording the complaint made by the patient or those entitled to make a complaint if the patient died, are collected, and the expert passes to an examination of the clinical record. If documents are missing, in cases of penal

expert opinion, they must be requested from the parties, transmitted to the expert, and used exclusively by her or him. In cases of cross-examination (all other cases), documents must be transmitted to all parties, unless a lawyer has already done this.

When the expert has sufficient information and the patient is stabilised, even if no legal obligation exists, it is habitual for a discussion to take place in the presence of the parties, i.e., the patient, her or his family, and also lawyers. The expert is obliged to respond except, of course, in penal cases, or when the lawyer makes remarks to the *juge d'instruction,* who transmits them to the expert if she or he deems it necessary. When information is lacking or the discussion is too complicated, in most cases, the expert sends a pre-report to the parties, giving them a period of 1 month to make observations.

If the patient is not stabilised, a date for stabilisation is established. The expert must wait to be recontacted by the plaintiff, in both court and CRCI cases. The expert customarily makes an evaluation of the plaintiff's minimum injuries.

8.6.3 Access to Medical Documentation

In general, access to medical documentation is sufficient for a living plaintiff, since the law of 4 March 2002 obliges all doctors and healthcare structures to transmit medical documentation to patients or, in cases of death, to the persons having the right to receive them.

As regards deceased persons, France is a country which carries out very few autopsies (less than 10,000 per 550,000 deaths/year). The cause of death is thus often not known. This is almost always the case when there is nothing except a death certificate, which is almost always based on an external examination carried out by a doctor who is not a specialist in forensic medicine. This happens less often when the patient was hospitalised before death. The expert's conclusions are thus very often speculations as regards the existence of an error, but it is sometimes difficult to demonstrate that death was secondary to such an error.

It should be noted that there are two types of autopsies in France, medico-legal and medical. The latter is disappearing, due to the lack of anatomo-pathologists and the reluctance on the part of families towards the idea of an autopsy. At present, anatomo-pathologists mainly deal with autopsies on fetuses, and carry out hardly any on adults. The current trend, which is that followed in most large cities in France, is that medical autopsies are carried out by forensic doctors. These are generally, but not everywhere, done by two doctors. Toxicological and anatomo-pathological samples are systematically taken, but are not as systematically analysed, because magistrates make their decisions case by case. In addition, as the period for which seals must be legally applied is not established nation-wide, losses occasionally occur; so that by the time a case reaches the court, the relevant anatomo-pathological and toxicological samples are no longer available.

Exhumation is possible, upon a judge's request, but rarely supplies proof of medical error.

8.7 How is Medical Error Evaluated?

We have seen that, according to jurisdiction, there are laws (penal) or principles (civil or administrative courts), and even principles and laws (obligation of information for CRCI and TGI).

In addition, at the moment when certain events took place, an expert must know what normal conduct is in a given situation, above all if that situation is simple (e.g., any general practitioner will diagnose diabetes when faced with a polyuro-polydypsic syndrome in a patient who has lost 15 kg in a month after an attack of bronchitis).

In complicated cases requiring specialists, there are also documents issued by consensus meetings of experts and, recently in France, recommendations by such experts published by the *Haute Autorité de Santé* (higher authority of health, HAS). These "recommendations" are in fact obligations, since the experts consider that they represent data supported by scientific knowledge, and judges also base their decisions on them. The *Societé Francaise d'Anesthésie et Réanimation* is particularly active in this field.

Determination of error, i.e., an act not conforming to these recommendations admitted by everyone, is sometimes evident, sometimes more complicated, and experts must then refer to literature sources or recommendations published by HAS and scientific associations. Sometimes the involved doctor argues her or his non-voluntary respect for procedures in a particular case, and such argumentation, if presented well and in a logical way, may be considered.

There are also cases in which the majority of doctors would have acted in a certain way, but where the minor choice is not excluded; in this case, the error is not taken into consideration.

It is sometimes very difficult to differentiate between sequels which derive from error and those which derived from a preceding state, even from an involuntary medical error.

Let us take as an example: a person of 75, operated for inflammation of cholecystis, who shows a sub-phrenic abscess during the post-operative period, the discovery and diagnosis of which were missed, and that the patient died as a result of a second operation, this time for the abscess. In trying to ascertain the cause of death, what depended on the patient's preceding state or disease (cholecystitis in an elderly person), on error (in not checking the patient thoroughly and the consequent delay in complete diagnosis), or on therapeutic risk (two operations in a short interval of time on an elderly person)?

This is made even more complicated by the fact that some jurisdictions refuse partial imputability (penal but also administrative courts) while others, such as the CRCI, ask that the responsibility for any cause (error, preceding state or risk) should be quantified.

As regards deceased patients, the regulations to determine error are the same, but most of the damage is not ascertained by the expert (except for temporary

functional deficits, DFT) and the suffering undergone by the patient), since the person has died.

It should be noted that, since 2009 in France, there is a new name "DINTILHAC nomenclature", which allows far more detailed analysis of damage for living persons. It includes temporary damage: that is, before stabilisation, time off work, temporary total impairment and temporary partial impairment or TFD (divided into four stages: stage I 10 %, stage II 25 %, stage III 50 %, stage IV 75 %), which are applied even to patients who do not work, to treatment, and temporary aesthetic damage (PET).

After stabilisation, there may be permanent functional deficits (DFP; previously known as IPP or AIPP), permanent aesthetic damage (PEOP), suffering undergone, agreed compensation, professional damage, sexual damage and future expenses.

The reform has complicated the expert's task, but it makes expert opinion more complete and reproducible.

8.8 Conclusions and Prospects

France made a great step forward in creating the CRCI, which certainly allows therapeutic risk to be compensated. However, they have had a secondary effect, due to the need to evaluate medical error during the course of the expert's work, i.e., a not inconsiderable number of juridical expert opinions can be avoided.

There is total uniformisation of expertise: all experts have more or less the same training and follow the same criteria in assessing damage, and thanks to the DINTHILAC reform, they have been extended to everyone and the steps in the expert's procedure are increasingly more uniform.

We are moving towards a unification of tariffs: those of the insurance companies, or of AREDOC, are the most frequently used (compulsory for insurance claims and CRCI), and are also used for specifically penal expert opinions.

In practice, some experts use the tariffs of the *Société Francaise de Médicine Légale*. The SFML and AREDOC have also recently produced a common tariff for assessing suffering undergone.

Weak points persist: for the victims of medical error who died as a result of the low number of autopsies carried out in France (the legal medical reform mentioned earlier may lead to an increase in their numbers), but this is mainly because doctors have not understood that if one of their patients dies of a possible medical error, it is entirely in their own interests to propose that an autopsy should be carried out. In juridical and above all penal procedures, it is not being declared guilty which frightens doctors, but the fact of being accused. Doctors are rarely imprisoned for medical error, but their reputations can easily be ruined by the mass media.

It is therefore in the interests of everyone—for a family to grieve, for justice to seek truth—but also for doctors to ensure that, if they believe it is needed, an autopsy can produce results which enable problems to be solved rapidly.

In my opinion, in France, the most important step which still remains to be taken in the next few years is for alleged medical error to be examined and ascertained by expert opinion after autopsy.

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Chapter 9
Medical Responsibility and Liability in Spain

María Castellano Arroyo and Ricardo de Ángel Yágüez

Abstract The first section of the chapter gives an overview of the judicial and normative situation of medical liability in Spain, including an analysis of extra-judicial institutions and operative roles. It defines the diverse cases of mala praxis from the point of view of doctors and healthcare professionals acting as "free professionals" and those who are functionally dependent upon a private healthcare institution, also discussing cases in which the healthcare institution itself acts defendant. This section also discusses out-of-court settlements and criminal medical liability, providing some statistical data concerning claims of medical liability. The second section of the chapter focuses on the ascertainment methodology in living persons and cadavers, expert ascertainment in professional liability and clinical information obtained before and after a potentially liable act. The third section deals with the evaluation criteria for living patients and cadavers. This chapter ends with a discussion of future perspectives and the possible reforms that may occur in Spain concerning medical liability.

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9.1 Judicial and Normative Overview and Judicial and Extra-Judicial Institutions and Operative Roles

9.1.1 Introductory Note on the Terminology

In Spain we usually talk about "healthcare liability" ("responsabilidad sanitaria"), or "medical-healthcare liability" ("medico-sanitaria"), when we refer to both individual liability—either a doctor or other healthcare professional—and the liability of a public or private healthcare institution. In turn, the liability of a healthcare institution is covered from two perspectives: liability for healthcare defects outside of the professional activity of a doctor or other health professional (for example, "organisational defects") and liability for healthcare per se (one could say "professional"), but without the conduct resulting in harm to the patient being attributed to a specific professional (these are the so-called cases of "anonymous fault"). "Healthcare liability" would also be considered in the case of the liability of a healthcare insurance company for the harm caused to a patient as a result of the acts of a doctor (or other healthcare professional, such as a midwife), included on the insurance company's "lists".

On the other hand, we often talk about "medical liability" ("responsabilidad médica") (more commonly "doctor's liability") ("responsabilidad del médico") when *mala praxis* is attributed by the Court to a Medical professional, i.e. apart from any possible liability of the healthcare institution where the doctor performed the act which eventually led to their liability.

9.1.2 The Complex Regime of Healthcare Liability in Spain

We here refer to the claims where a plaintiff only seeks remedy or compensation for the harm allegedly suffered. In other words, we shall not analyse possible criminal claims. However, by way of illustration, it must be noted that in Spain, as a general rule, when a criminal complaint is made against a doctor or other healthcare professional, the criminal court (if it finds that an offence has been committed and the corresponding sentence is imposed) decides on the civil liability which may be incurred by the professional acting as the defendant. This means that it decides on the compensation to be paid to the victim.

As such, our analysis is limited to (a) civil claims (those made against a healthcare professional who acts as a "liberal professional" or within the framework of a private institution) and (b) the administrative or contentious-administrative (similar to judicial review) claims (where the harm is produced within the scope of action of a healthcare authority or "public health"). The administrative claim (b.1) is that which is formulated extra-judicially against the titleholder entity of the corresponding healthcare centre (e.g. the State or Government of an Autonomous Region). The contentious-administrative claim (b.2) is within the judicial ambit. This is made when the public body has entirely or partially rejected the victim's prior extra-judicial claim. Hence, the Court is asked whether the allegedly liable public body correctly decided the prior administrative claim; if not, the Court decides on the liability and, if applicable, on the quantum of the compensation.

9.1.3 Mala Praxis is Attributed to a Doctor or Other Healthcare Professional Acting as "Free Professionals"

The starting point should be the most "traditional" case, i.e. where *mala praxis* is attributed to a doctor or other healthcare professional acting as "free professionals" (the classic case of a "private consultation"). This hypothesis is similar to the case of the healthcare professional acting in a private healthcare institution, without the doctor having any functional dependence on the institution (a classic case of a private clinic).

Under these circumstances, the claim is made before the civil jurisdiction.

In this type of claim, the doctor's civil liability is governed by the so-called *principle of fault.* In other words, the doctor only incurs liability if there has been *fault* by the doctor. And the doctor's fault is not presumed, but rather must be proven by the plaintiff. This is the result of the constant case law which declares that the doctor's obligation is not one of results, but of means. In other words, the doctor is not bound to achieve the patient's cure, but only to treat them with the skill and diligence required by *lex artis*. However, this reasoning is not followed in judgements on cases of so-called "satisfactory Medicine", as in the case of aesthetic surgery, infertility surgery, certain acts of odontology, etc. which state in

these cases that the doctor has promised a *result.* All of this is in contrast to so-called "Curative medicine". But this case law orientation has been highly criticised and in recent years has become uncommon.

It is increasingly common for the Courts to define the *lex artis* according to "protocols", i.e. professional action guidelines (particularly in the case of surgery). For example, in a recent judgment (judicial review) in a case where the gynaecologist maintained the vaginal birth formula, despite the fact that the protocol from a gynaecology and obstetrics scientific association indicated that a caesarean was more appropriate.

However, notwithstanding the general principle that the doctor's fault is not presumed and that there is no reversal of the burden of proof, in recent decades, the civil case law has been using "mitigation" criteria of the burden of proof corresponding to the plaintiff (e.g. using legal concepts of "virtual fault", "res ipsa loquitur" or disproportionate harm or result").

On this last criteria, the Supreme Court Judgment (civil) of 18 December 2009 (death as a result of a late ambulance transfer between two hospitals) stated:

> The disproportionate harm referred to in many decisions from this Chamber is not a binding criteria, but rather a result generated in the sphere of action of the defendant that normally only occurs as a result of negligent conduct. It simply obliges the medical professional to prove the circumstances in which it occurred by the principle of facility and probative proximity. As such the absence or omission of explanation may lead to an accusation, creating and leading to a conclusion of negligence.

Some of those claims are due to diagnostic errors. And the Courts tend to reject such claims, considering that the diagnosis is a question of subjective appreciation or of "criteria". Claims are admitted for diagnostic errors in the case of serious or obvious error, and where the doctor decided not to include another more specialised professional (recently a case where the doctor diagnosed hypoglycaemia in the case of a cerebral ischemic infarction).

The doctor is acquitted where there is no proof of fault or when the causal link is not proven between the professional actions and the harm which is claimed. However, in relation to the causal link, the Courts increasingly use the criteria of "qualified probability", i.e. "more probable than not" (for example in the cause of a cardiac arrest and that of a cerebral injury during birth).

If the doctor has acted in a private healthcare institution "independently" and without the personnel dependant on the institution, the latter will be acquitted.

9.1.4 Mala Praxis is Attributed to a Doctor, or Other Healthcare Professional, Who Acts in a Private Healthcare Institution

Another case is that of attributing *mala praxis* to a doctor, or other healthcare professional, who acts in a private healthcare institution, and is functionally dependant on the institution.

In this case, the competent jurisdiction to hear the claim is civil. It is very common that, together with the doctor, a claim is made against the healthcare institution or one of its employees (for example, a nurse or the head of the blood supply service).

As regards the doctor, the criterion of attributing liability is also a fault by the professional. Neither in this case is the doctor's fault presumed (the plaintiff must prove it), although the Courts apply the aforementioned reasoning of "mitigation" of the burden of proof.

That stated above in relation to proving the causal link is also applicable.

9.1.5 The Defendant is a Healthcare Centre

However, the situation is different as regards the defendant healthcare centre (we are still referring to a private centre). For many years, the civil courts have tended to attribute liability to the healthcare institution (even though the doctor's fault is not proven), on the basis of an Article (previous 28, now 148 of the General Consumer and User Defence Act, currently Act of 16-11-2007).

This liability of the healthcare institution is strict liability. This is why in many cases judgment is entered against the healthcare establishment, but the doctor is acquitted. Judgment can also be entered against the healthcare institution when it creates in the patient the appearance that the doctors acting in the establishment form part of the institution's structure (the concept of "apparent dependence").

9.1.6 Events Occurring in the Framework of Healthcare Provided by a Public Authority

The legal and jurisdictional framework changes radically in claims for *mala praxis* by a doctor (or other healthcare professional, or even a non-healthcare worker) and the events occurring in the framework of healthcare provided by a public authority. The judicial experience and statistics show that this type of claim has exponentially increased recently, and it looks as though it will continue to increase in the future as a result of the widening radius of healthcare practised by the public administration.

1. The victim of the harm can only make their claim against the corresponding public administration; i.e. they cannot make the claim against the doctor. As stated above, an administrative claim must be made to the corresponding public administration. If it entirely or partially rejects the claim, the interested party can go to the courts (judicial review, *contencioso-administrativa* in Spain) to challenge the administrative decision rejecting their claim.

The judicial claim must be made before the contentious-administrative jurisdiction, i.e. not the civil jurisdiction. This has been the situation since 1999, as

previously it was common for civil claims to be made jointly against a healthcare authority and a doctor. Equally, by way of example, there were frequent joint civil claims against a health authority and a supplier of clinical material.

The same happens when the injured party *also* opts to sue the health authority's civil liability insurance company. But it is not rare for the injured party to make a claim (civil) *exclusively* against the Authority's insurance company. The judgment on 11 February 2011 declared the civil jurisdiction competent in this last case, when the victim exercises the "direct action" against the civil liability insurance company on the basis of Article 76 of the Insurance Contract Act, and does not sue the Administration in whose installations the harm occurred.

2. The liability of the public healthcare authority is practically strict liability; it can be stated that it is *strict*, *albeit not absolute*, *liability*. There are only three circumstances where the Authority's liability is excluded: force majeure, "the legal duty to sacrifice" charged to the patient and the concept known as *state of the art*. This concept of state of the art has frequently been applied, for example, in cases of contagion of HIV, hepatitis C and B.

All of this has been the result of an Act of 26 November 1992, which was substantially reformed in 1999.

When the Administration pays compensation to the injured party, it can make a claim against the doctor or healthcare professional responsible, but only if the latter has acted intentionally or with serious fault.

9.1.7 Out-of-Court Settlement of the Claims

In Spain, there is no "institutional" formula for out-of-court settlement of the claims for medical or healthcare liability.

There have been attempts to establish an arbitration system when the defendant is a doctor and/or private healthcare institution. But these attempts have failed.

In other words, unless there is a prior agreement between the parties (transaction), the claims have to be settled through the courts. However, the consumption arbitration system allows a private healthcare centre to undertake, to submit, and to arbitrate all claims that may arise; but in practice, this possibility has had no significant consequences.

The amicable conflict solutions (transaction) are not very common, particularly due to the resistance of the doctor's or healthcare institution's civil liability insurance companies. This means that judicial claims are very common, as shown by the court statistics.

9.1.8 General Considerations

1. Many of the claims (civil or judicial review) are upheld as the Court considers that the doctor, or healthcare establishment, did not give the patient sufficient

information (so-called "informed consent"), even though the doctor's acts were otherwise absolutely in line with *lex artis*.

The Judgment (civil) of 4 March 2011 said on the matter:

> The effects which derive due to a lack of information are specially related to the type of intervention: necessary or welfare, voluntary or satisfactive, taking into account the clear differences that this Chamber's case law has introduced relating to the information which must be provided to the patient, more rigorous in the latter than in the former, given the need to avoid silencing the exceptional risks the knowledge of which could lead the patient to withdraw from an unnecessary intervention or one more relatively necessary. Other factors are also related: foreseeable risks, independently of their probability, or percentage of cases, and risks unknown by medical science at the time of the intervention; the suffering and personal conditions of the patient; foreseeable and frequent complications or adverse results which may occur, whether permanent or temporary, including post-operative; significant therapeutic alternatives; contraindications; characteristics of the intervention or of its substantial aspects; need for the intervention, with very specific special features in the cases of prenatal diagnosis.

And Judgment (civil) of 20 January 2011 stated:

> The information which is provided to the patient before the operation and the correlative consent from the patient is an essential premise and element of lex artis for the performance the medical activity, and is particularly important in non-necessary medical interventions, where the patient is freer to choose to reject it in view of its unnecessary nature or its lack of urgency, and because the relativity of the necessity could in some cases give rise to a silencing of the exceptional risks, aimed at avoiding the patients withdrawal from the intervention.
> As such, the information must be provided with sufficient time and dedication and binds both the doctor responsible for the patient, in this case the surgeon, and the professionals assisting the patient during the recovery process, as one more of those who form part of the medical or recovery action, so that the patient can take the best decision in the interests of his/her health. In addition, to do so in a comprehensible manner that is in line with their needs, so as to allow them to take charge or assess the possible consequences which may derive from the intervention on their particular state and, as a result, to choose, reject or delay a certain therapy due to its risks and even attend a different specialist or centre.

2. As regards the causal link ("causation in law"), the Courts generally adopt the theory of adequate cause.

However, since the beginning of the twenty-first century, it is increasingly common to apply the theory of objective accusation, "transferred" to civil jurisdiction from its source in the criminal doctrine. In other words, theoretically the theory of causation in fact is applied, but the doctor is acquitted in any of the circumstances which exclude said objective accusation; for example, the "general risk to life"; the intentional or clearly negligent actions from a third party or the acts of the victims themselves.

Sometimes, the Court rejects the claim based on *too remote* causes. Of importance on this matter is the judgment (civil) of 14 February 2006.

The plaintiff had an intrauterine pregnancy that caused her pain and blood loss, for the evacuation of which scraping was advisable. The scraping was performed

on the plaintiff by one of the co-defendant doctors, Mr. Hugo. The appeal court found it proven that the scraping performed by Mr. Hugo had been completely incorrect; parts of the pregnancy remained behind inside the uterus of the plaintiff. Days after the scraping, various anomalies were noticed in the patient, and the other co-defendant doctor, Mr. Manuel, performed another operation consisting in the extirpation of a segment of the left Fallopian tube, with the functional loss of said organ. The Trial Court also declared it proven that the professional action of Mr. Manuel had been incorrect, i.e. in the same way as it had understood the performance of Mr. Hugo.

The Appeal Court found the two co-defendants jointly and severally liable. The Supreme Court upheld the cassation appeal from Mr. Hugo, stating:

> These facts, which lead the trial court to consider (from the angle of the quaestio facti or issue of fact within the competence of the trial court) the conduct of the appealing doctor as relevant cause from the strictly physical point of view, insofar as his performance can be considered conditio sine qua non [essential condition] for the production of the harmful result (the extirpation of the left tube with the consequences of limiting the patient's procreation possibilities), are not however compatible from the strict liability perspective, which is necessary in order to legally establish the causal relationship, with recognition of the legally relevant causal link between the violation of the lex artis, which is attributed to him (performance of an incomplete scraping not duly detected) and the harmful result which has just been referred to, given that the course of the events shows that between said conduct and the result there was performance by other doctors who were not part of the appellant's intervention, one of which, at least, is directly relevant from the causal point of view for the production of the harmful result.
>
> With this, it is clear that the objective imputation to the appellant (or attribution of the result, quaestio iuris [legal question] revisable on cassation within the scope of Article 1902 of the Civil Code cited as violated) of the consequences of the total extirpation of the left tube performed by another doctor who performed an inaccurate laparoscopic assessment supported by the echography in the patient's clinic records—when it does not derive from the facts declared proven that participating in this echography assessment and evidence was the appellant, who had performed the scraping previously—means, without other reason than it was before in time and are steps in the course of the events which led to the result, a return to conduct before other; in this case, the appealing doctor who performed the scraping, at the time the performance of which, without any later intervention on the patient, the final result which occurred could not reasonably be expected, directly related to an error in the subsequent diagnosis and, as such, immediately cancelling the causal link with the subsequent negligence of another doctor.
>
> This backwards movement is not acceptable in the work to integrate the causal link from the legal point of view, which must maintain a degree of reasonable proximity, acceptable in legal terms, and in accordance with the rules of experience over the possibility of envisaging the consequences, at least when the imputation is by way of fault (Articles 1105 and 1107 CC), between the negligent conduct or conducts to which the liability is connected and the harmful result produced—which breaks down when there is more specific and determining subsequent conduct—without which the possible negligence noted in the agent's conduct lacks the necessary relevance in order to give rise to the existence of civil liability.

3. On the matter of medical liability (which also occurs in the liability of a lawyer), the Spanish Courts frequently apply the doctrine of "loss of opportunity" (in French, "perte d'une chance").

The case of French case law is *classic*: a woman suffered womb haemorrhages. The consulted doctor did not diagnose a cancer, despite the quite clear clinical data. When the patient finally consulted a specialist, it was too late: the womb cancer had reached its final stage and the patient died. It could not be said that the first doctor had killed the patient. She may even have died even if she had been treated on time. If it is considered that the harm is death, it could not be said that the doctor's fault was a condition *sine qua non* of the death. But if it is noted that the patient lost an opportunity to survive, the doctor's fault made her *lose those opportunities.*

The civil case law applied this doctrine in a first judgment on 10 October 1998. The nurse's actions made it impossible to perform a retransplant operation of a worker's hand who had suffered an amputation. The Supreme Court decided against the nurse, but with lower compensation than it would have ordered in the case of liability for the loss of the hand, with the Court considering that it was unknown whether the hypothetical retransplant operation would have been successful had it been performed.

The *loss of opportunity* has also been applied by the contentious-administrative (judicial review) Courts, for example in the Judgment on 23 September 2010, which stated:

> This depriving of expectations, in our case law called "lost opportunity", is based on the fact that it is sufficient with certain possibility that the medical action could have avoided the harm, although it cannot be affirmed with certainty that compensation may be ordered for all of the harm suffered, while it is enough in order to acknowledge the compensation of an amount that approximately takes into account the loss of the possibilities of being cured which the patient suffered as a result of that late diagnosis of the illness since, although the uncertainty of the results is inherent in Medical practice (a circumstance which explains the non-existence of a right to be cured), citizens must have a guarantee on the part of public health services that they are going to at least be treated with diligence and the application of the resources and instruments that medical science has made available to the Health Authorities.

9.1.9 Criminal Medical Liability

Criminal medical liability is not often claimed in Spain. There are various reasons for this: the burden of proof rests with the patient and it is often very difficult to prove the specific event from which the damage derived, and the specific individual author of the conduct. Team medicine tends to dilute the actions towards a welfare community, which hinders the criminal requirement of pointing with certainty to the author of the reprehensible conduct and to the conduct that has caused the harm.

The Spanish Criminal Code classifies a series of actions performed intentionally, or recklessly. In the event that there is "professional recklessness", the professional's disqualification from practice will be added to the custodial sentence for the duration that is indicated. This conduct is:

- homicide due to professional recklessness, which carries with it a prison sentence of between 1 and 4 years and special disqualification from practicing the profession for a period of 3–6 years;
- inducement to suicide;
- euthanasia;
- abortion due to professional recklessness, carrying with it a prison sentence of between 3 and 5 months or a fine of 6–10 months, and special disqualification from practicing the profession for a period of 1–3 years;
- injuries due to professional recklessness, carrying with it various sentences according to whether there occurred the loss or rendering useless of a main limb, a non-main limb, an organ or one of the senses; sterility or impotency; a serious or nonserious deformity; or a serious or nonserious somatic or mental illness or mental reduction;
- harm to the foetus due to professional recklessness, carrying with it a prison sentence of between 3 and 5 months and special disqualification from practicing the profession for a period of 6 months–2 years;
- genetic manipulation;
- omission of the duty to save, refusing health assistance and/or abandonment of the healthcare services, punished equally with custodial sentences and disqualification from practicing the profession;
- supposition of birth or alteration of paternity, state or condition of the minor;
- against public health;
- revelation of secrets, professional secret;
- falsifying certificates;
- falsehood in expert evidence.

In these cases, a complaint is made to the Court of Instruction which will then conduct the investigation phase of the proceedings, collecting all of the evidence: (1) Testimonies/declarations, (2) Expert reports, both from the official expert (Forensic Doctor), and from other specialists who act on request from a part of the judge if deemed necessary.

The result of this investigation phase leads to the judge filing the case or charging and processing the author(s) of the events. The case will be tried by another court, called the Criminal, before which the whole case will be reproduced (declarations, testimonies, ratification and defence of expert evidence, etc.); this trial allows for experts to be compared in contradiction, and for the parties' lawyers to examine-in-chief and cross-examine, as the Public Prosecutor and the Judge are also able to do. It is this criminal judge who will make the judgment to acquit or convict. An appeal can be made to the Provincial Court and—if applicable—to the Supreme Court.

These criminal proceedings have the specific feature, whereby the civil liability insurance company is directly civilly liable to the victim. This rule is frequently applied, as it is common (general) that the doctor has contracted civil liability insurance. The public and private healthcare centres are also usually insured.

9.1.10 Statistical Data

1. In Spain, we do not have reliable and up-to-date statistics on claims for medical professional liability. The figures offered by the Public Prosecutors' annual report are partial, only contain criminal proceedings and are not representative of the reality. It is impossible to know about the civil and judicial review proceedings, as it would require examining all of the judgments from the different jurisdictional bodies. The Patients Ombudsman (*Defensor del paciente*), an unofficial body, which receives complaints from citizens, in 2010 registered 12,162 cases, which are 675 cases less than in 2009. Of these, 554 of the cases were mortal, which are 32 cases less than in 2009. Based on the available indicators, one could come to the conclusion that the number of complaints has levelled. Spain is different compared to the other countries in our ambit, in that the number of complaints is much higher. Most of the complaints against doctors are started in the criminal jurisdiction. This is due more than anything else to a procedural strategy, as it is easier to obtain the necessary documentation in the criminal jurisdiction so as to later approach the civil or judicial review jurisdiction; but it is clear that Spanish doctors suffer more pain and suffering than in other countries.

   However, we offer some figures by way of an outline.

   Thus, Fig. 9.1 shows the growing evolution over the years, with the increase in claims starting in 1988.

   Grouping the claims by speciality, in first place comes family/general medicine, followed in second place by traumatology and gynaecology, in third place general surgery, in fourth place ophthalmology, in fifth place specialised surgery and then Accident and Emergency.

2. Place where the claims are made

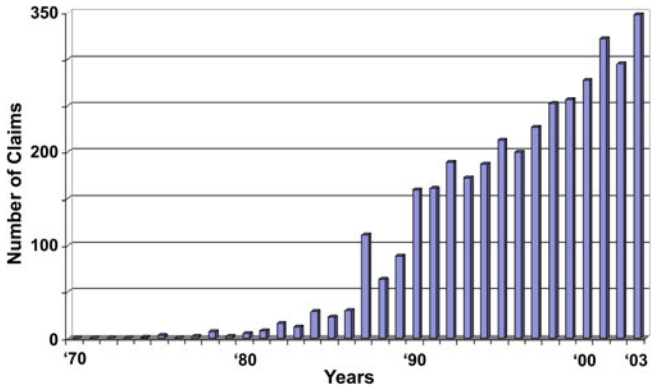

Fig. 9.1 Claims rate over the past years

As regards the centres where the claim is made, 83 % of the cases refer to the Public Health System and 17 % to private centres. In the public centres, the distribution of the liability was attributed to the doctors in 47.4 % of the cases, in 30 % of the cases to the centre and the remaining 22.6 % was attributed to auxiliary personnel (nursing, nursing assistants, etc.).

3. Reasons which could explain the increase in the claims

   (a) Changes to the doctor–patient relationship. The movement away from individualised medicine towards hierarchical medicine, where the patient loses the perspective of a direct relationship with their doctor.
   (b) Change in the paradigm regulating this relationship. The movement away from Medicine guided by the principle of beneficiary towards medicine guided by the principle of autonomy, in which the informed consent becomes the centrepiece of the relationship.
   (c) Growing recognition and protection of the rights of the patients and the relegation of the doctor, at times, to a mere dispenser of services. On the other hand, the medical act has become banal at the same time as it has become more interventionist, with the patients confusing the right to healthcare with the right to be cured.
   (d) Materialism of society. The economic interest in the claim cannot be overlooked, in addition to the wide media coverage when doctors are being convicted.

The increase in claims in Spain is attributed to the following factors:

4. Judicial decisions

(a) Criminal area
Regarding the time which passes between the claim and the proceedings in the criminal jurisdiction, most cases are decided in the first 5 years, with some lasting longer (Fig. 9.2).
The acquittal rate in criminal proceedings is 95 %, and as such the professional is only convicted in the remaining 5 %.

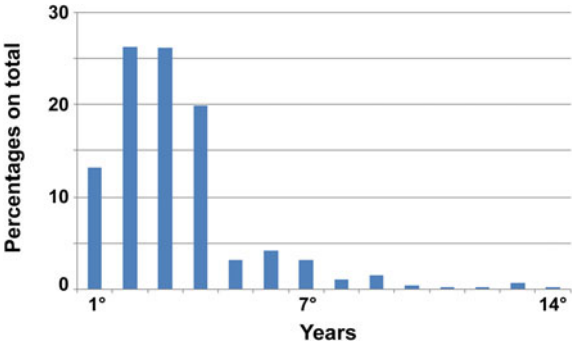

Fig. 9.2 Delay claim starting of Penal procedure

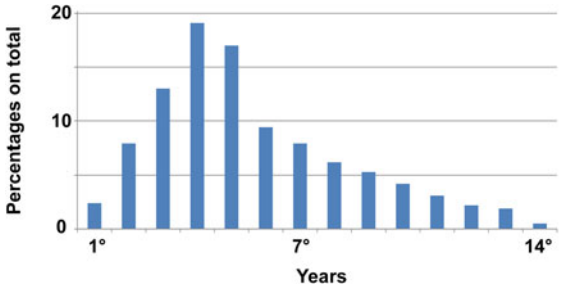

Fig. 9.3 Time in civil claims between the medical act and claim

(b) Civil ambit
The duration in civil proceedings is much longer, as shown in Fig. 9.3. The number of decisions in favour of the medical professional amount to 75 % of the cases, while the remaining 25 % would be judgments against the medical professional.

Currently, the judicial review jurisdiction (*contencioso-administrativa*) has received most of the claims when care was provided in public centres. In this case, as the Administration is liable, the judges are more inclined to accept the harm and associate it with the care received, with compensation being the most frequent result, although the case law is changing as indicated elsewhere in this chapter.

9.2 Ascertainment Methodology

9.2.1 Cases Calling for Expert Ascertainment in Professional Liability

As Gisbert and Fiori have stated, medical liability is understood as *the duty of the physician to respond, repair or satisfy the damage that has been caused to a third party, either by having committed an illegal act, or for having abstained from executing what is compulsory by civil or moral law.*

The cases of medical liability lawsuits are quite varied and occur in all specialities, although with diverse frequency and seriousness.

In order to present the lawsuit, it is necessary to have suffered damage or loss. When the patient is living, then he is the one who suffers the damage. In normal conditions, it will be the patient who files the claim; but when the patient is a minor or has his mental capacities affected, it will be his family members who represent him in the lawsuit. In the case where the patient has died, it will be his family members or "rightful claimant" who may sue as injured parties.

Both in the case of a living patient and in that of a cadaver, the expert's report must clarify:

1. the damage that the patient has suffered, taking into account the sequelae;
2. the events, medical conduct or circumstances that originated the damage;

3. cause-effect relationship between the event-medical conduct-circumstances and the resulting damage;
4. other information of interest (evaluation of the moral and financial damage, etc.).

Although the reasons for suing are diverse, the most frequent are produced by:

1. failure in the duty to assist (not providing assistance or providing it late);
2. diagnostic delays, most frequent in the cases of cancer;
3. diagnostic errors in cardiac, abdominal, cerebral pathologies and others;
4. nosocomial infections (hospitals);
5. hospital contagion;
6. surgical interventions:
   (a) inter-operatory accidents or post-operatory complications;
   (b) deficient evaluation of the patient (pre-anaesthetic examination);
   (c) no prior preparation of anticoagulated patients;
7. foetal damage for defect in monitoring pregnancy and assistance in childbirth;
8. lack of diagnosis of chromosomopathies or foetal malformations;
9. suicide of patients in treatment or with prior request for assistance.

In Spain, the Law of Civil Procedure is the one that regulates the expert's activities in its Articles 335 to 348. According to this text, the aim and the purpose of the expert's opinion has to do with the need for scientific, artistic, technical or practical knowledge in order to evaluate relevant facts or circumstances in the matter, or acquire certainty about them.

With regard to the expert it states:

The experts must possess the official title that corresponds to the subject of the opinion and to its nature. In medical subjects, the necessary title is Bachelor's Degree in Medicine, for which we can say that the Spanish law does not require the specialist title in order to act as a medical expert.

Regarding the form in which the experts are designated, we can differentiate among:

- the doctor who is summoned by the Judge as witness expert. This is a disputed figure included in the Spanish Law of Civil Procedure and appears in the new Law of Civil Procedure in its Article 370, which we reproduce literally for your information:

> (1) Once the general questions are answered, the witness shall be examined by the party which proposed him, and if he has been proposed by both parties, the questions formulated by the claimant shall be asked first. (2) The witness shall respond by himself, verbally, and shall not use a draft of responses. When the question refers to accounts, books or documents, he shall be allowed to examine these before answering. (3) In each of his responses, the witness shall express the reason for his statements. (4) When the witness has scientific, technical, artistic or practical knowledge of the matters referred to in the facts of the questioning, the court shall admit the statements added by the witness to his answers on the facts due to this knowledge…

This figure of the witness expert coincides with the doctors who provided the patient with some type of assistance; they are summoned to put on the record that this assistance was given, as well as information upon it. However, the lawyers usually take advantage of the presence of the doctors to ask not only what they observed, but also the scientific interpretations of this information. That is, it deals with concealed expert testimony, since these doctors (witness-experts) do not receive any economic compensation, as do the expert witnesses.

- The doctor who is proposed as party-appointed expert. The plaintiff (patient or family members who file the claim) can propose him, or else the doctor on whom the civil claim is being filed, or he can even be proposed by the institution, hospital or clinic that is being sued.
- The doctor proposed as judicial expert. In this case, it is the Judge who proposes the expert witness with the parties accepting the proposal. The choice of the doctor can be made by random selection or by following the order of the list of medical experts provided by the Medical Association of each province, since the Law states that in the month of January of each year, the Association will provide the Judges with the list of member doctors who are willing to act as experts.

The request for an expert can also be made to the Royal Academy, Medical Association, Consulting Council or other institution. The usual procedure is for them to discuss and evaluate the opinion in a collegiate manner, although only one or more of their members were speakers at the trial, the signature of the expert opinion is usually that of the Chairman or person responsible for the Institution. Nevertheless, attendance at the trial is done by the person signing the expert opinion and, where applicable, the member of the Institution who acted as speaker.

In the event that the expert must examine a place, object or person in order to comply with the purposes of the requested opinion, the parties and their defenders can be present during the performance of the action, provided it does not hamper the expert's work and the accuracy and impartiality of the opinion; this presence must be decided or denied by the court, and in the affirmative case, it will be communicated to the expert who must be the one in charge of calling the parties at least 48 h in advance so they may witness his actions.

In the trial or in the prior hearing, the experts will adjust their actions to what the court admits, which corresponds, in practice, to all that is not impertinent or unnecessary. In general, the parties or their defenders can request:

1. the complete divulgement of the opinion, when this requires the realisation of other operations, complementary to the provided written document;
2. explanation of the opinion or of some of its points, whose significance is not considered to be sufficiently expressive for the purposes of the evidence;
3. answers to questions and objections on method, premises, conclusions and other aspects of the opinion;
4. answers to requests for further details of the opinion in relation to other connected points, in case it could be carried out in the same act and for the purpose,

in any case, of knowing the expert's opinion on the possibility and usefulness of further details, as well as the period needed to carry it out;
5. critique of the opinion being dealt with by the expert of the opposing party.

The court can also ask questions of the experts and require from them explanations on the subject of the opinion, but it cannot request that it be broadened unless the expert was designated by the court.

With respect to the Expert Opinion, the Law states:

> The opinion will be provided in writing and Article 348 states that "The Court shall evaluate the expert opinions in accordance with the rules of sound criticism". The criticism must, in our opinion, include an evaluation of the expert actions, putting them in relation to the documents evaluated in the opinion by the expert. The sound criticism must also evaluate the scientific reasoning on the content of the expert opinion and further details provided in interrogation and their rigor; the recognition of the conclusions that must be derived rigorously from the content of the report. However, the court has full freedom to appraise the expert opinion or report.

In Spain, the Forensic Doctors are the official experts, at the service of the Judicial System. They carry out their work in the Legal Medicine Institute of each province and are civil servants of the Ministry of Justice. They are selected by competitive examinations and only a degree in Medicine and the demonstration, through an exam, of their scientific knowledge typical of Legal Medicine are required.

On the other hand, there is the title of specialist in Legal and Forensic Medicine. This title qualifies a person for the free exercise of Legal Medicine (expert activity). Frequently, the specialist takes the exam in order to become a Forensic Doctor and in this way an official expert at the service of the Ministry of Justice.

9.2.2 Ascertainment Methodology

The medical expert designated to prepare the expert report relies on:

- Prior clinical information.
- Subsequent clinical information.
  - Interview and patient examination.
  - Complementary diagnostic tests that the expert may consider necessary.
  - In deceased patients, he/she can have either the clinical autopsy report (from the hospital) or the medico-legal autopsy report (from the Legal Medicine Institute).

9.2.2.1 Clinical Information Prior to the Events

- Patient's clinical history

This documentation is basic and the more completely it is filled out, the more useful it is.

The Law 41/2002 on patient autonomy, rights and obligations in regard to documentation and clinical information defines the compulsory documents in the clinical history of the patient. Some of them are of the administrative-statistical type, but the majority are of the medical type and are prepared in order to provide medical care; in case of claims, these documents are elementary in the medico-legal investigation. The Law 41/2002 distinguishes the possibility of access to the patient's Clinical History "… judicial, epidemiological, public health, investigation or teaching purposes", having in these cases to comply with the Organic Law 15/1999 on the Protection of Personal Information.

The most important are:

- the admission authorisation. This consent from the patient is essential, having to be signed by his/her legal representative, in case the patient is not in a psychophysical condition to do so;
- emergency Room Assistance Sheet or Emergency Room Report. This document is filled out when the patient has requested care in the Emergency Room; it includes the reason for the consultation, the result of the examination and the tests requested, the clinical opinion, the diagnosis, and as a result, the decision to request inter-consultation or collaboration of the specialist (according to the pathology), to start treatment and to send the patient home or to indicate admission to the hospital. If the death of the patient occurs at home (generally for acute pathologies such as myocardial infarction, cerebral haemorrhages and others), this Emergency Room Report will be fundamental in checking whether it indicates the proper diagnostic tests, whether the results were interpreted correctly and if the medical decision was in keeping with the appropriate Guidelines of Good Practice or protocols, where they exist;
- anamnesis Sheet and physical examination. This is elementary for quality medical care and a prior step for diagnostic and therapeutic accuracy; therefore, its omission or insufficient completion would indicate inadequate medical conduct;
- evolution Sheet. This document is generated for hospitalised patients. In it are recorded the daily changes of the patient's condition, his response to the treatment, the indicated tests and their results and the clinical evaluation of the patient's evolution until he is released;
- the Medical Orders Sheet. The decisions that the doctors attending the patient make according to his evolution are noted on this sheet. Each decision (medical order), request for tests, prescription, etc., must be recorded, including the identification of the professional who orders them;
- the Inter-consultation Sheet. On this sheet, the actions of other specialists who may visit the patient at the request of the doctor responsible for him/her are recorded; this occurs when pathologies other than that for which he/she is admitted appear in a certain department. It is an important document, because when the medico-legal evaluation of the case is performed all of the

professional actions, along with their quality, diligence, opportunity and effectiveness are taken into account;
- the Reports of Complementary Examinations. This refers to diagnostic tests whose results are interpreted and reported by the specialists making them: imaging, neurophysiological, psychological tests, etc;
- pre-operatory Examination Sheet. This document is filled out in case there is surgery. The pre-operatory examination is done by the anaesthetist; there is a protocol for it and the patient is classified with respect to the ASA index or risk level of the patient. It is very important in view of the information that must be given to the patient and the assumption of the risks by him;
- anaesthesia Report. It includes all the information of the physiopathological state of the patient during anaesthesia and surgery. A very important document in lawsuits for intra-operatory death or anaesthetic accidents;
- operating Room Report. The nature of the surgery, all the incidents related to the technique and the specific findings in the patient in question are recorded in this report; it is, therefore, a personalised document that is usually illustrated with simple drawings showing what was done in the surgical field: sutures, drains, etc. This sheet is essential for the analysis of medical conduct when operatory or post-operatory complications arise;
- post-surgical Evolution Sheet. This includes the monitoring of the patient with respect to his general condition and to the specific surgery that was performed. It is also very important when one has to analyse the healthcare quality in this phase (detection of appearance of complications, early and correct action to head them off, etc.);
- pathological Anatomy Report. In the case that these studies are requested;
- pregnancy Monitoring Sheet. Very important in the cases of pregnancy. In Spain, the monitoring is done by the Family Doctor and the Midwife. The pregnant woman visits the gynaecologist in the initial examination, in the 20th week and at the end of the pregnancy. It is a very important document as it includes the visits, the record of vital signs, incidents in the woman, evolution of the foetus (measurements, weight, cardiac record, etc.), results of screening of chromosomopathies and malformations, etc;
- report of Record or Childbirth Assistance. When everything is normal, the assistance is provided by the midwife; when there are complications, she is the one to inform the gynaecologist. This system can cause medical-legal problems, since when the Doctor arrives, damage to the foetus may have already occurred, for which reason subsequent liability can be required from him. A good record of the evolution of the childbirth will clarify what was the problem, when it was detected and at which moment each professional intervened;
- informed Consent Documents. These documents are compulsory by law (Law 41/2002). Although, as a general rule, the consent will be verbal in the daily relationship, *it must be written for surgical interventions, for the diagnostic procedures and invasive therapeutics, and in general, for the application of procedures that signify risks and inconvenience of manifest and foreseeable negative repercussion on the patient's health.*

Liability can be recognised when the patient has not been informed and the informed consent form has not been filled out. It can also occur when the consent document exists but is insufficiently filled out, leaving sections blank such as the explanation of personalised risks according to the personal and professional characteristics of the patient, or when it does not clarify all the doubts in this regard. The objective of this document is for the patient to have all the necessary and sufficient information in order to be able to freely choose or reject a treatment or a diagnostic test.

- evolution and Nursing Care Planning Sheet. All the incidents related to the vital signs, administering of medication, request for care, and any decision that must be made outside the normal course of events are recorded on this document. Frequently detailed notes are found that are of interest in these nursing sheets;
- the therapeutic application of nursing. In this document, the administration of medicine, dose, time and incidents are recorded. Also noted is if medication considered as "rescue" has been administered, which is what is prescribed as prevention in case symptoms appear in hours outside the usual working day, especially of an analgesic type;
- graph of vital signs. This also corresponds to the nursing staff and is done with the frequency that the doctor indicates;
- clinical Release Report. This is issued when the patient is released medically and goes home or to another centre. It summarises the hospitalisation period, and although it is brief and specific, it should be a complete document that includes the cause of the hospitalisation with the precise diagnoses, the treatments administered, the evolution, the state of the patient at release and the treatment he must follow with the indicated examinations that he has to have in the future and whether the family doctor should carry out the monitoring;
- autopsy Report. This Report will only exist when the result has been the death of the patient. The autopsy can be a Clinical Autopsy or Forensic or Medico-legal Autopsy. The clinical autopsy is done in the Pathological Anatomy Department of the Hospital where the death took place and requires the authorisation of the family members. The forensic autopsy is done in the Legal Medicine Institute of the province where the patient died; this is ordered by the Judge and occurs when the family has presented their claim before the Court immediately after the death, so that the intention of the claim and the immediate judicial intervention are already known;
- consultation Sheet, where the visits to the external consultations or to the Healthcare Centre are recorded. Currently, these medical consultations are adapted to complex computer programs which note, greatly synthesised, the reason for the visit, the tests requested and the results, the diagnoses of the patient, as well as the prescribed treatments. In some sections, the computer program offers some rigid options to which the specific case must be adapted, and this could lead to inaccuracies between the reality of the patient and what is noted.

With respect to these documents, the Law 41/2002 states "…The filling out of the clinical history in the aspects related to the direct care of the patient will be the responsibility of the professionals who intervene in such care". Thus, it directly establishes a legal duty (besides an ethical-deontological duty) to fill in this documentation according to *lex artis* and medical good practices, with justified motive when the claim is for the omission or improper filling out that leads to injury or damage to the patient.

- Personal testimonies

This information can be provided by the persons present at important moments in relation to the case. Therefore, the family members who accompanied the patient and witnessed his condition, reactions, request for attention, calls for the nurse, etc., as well as the nursing staff could provide interesting information.

Frequently, this information is provided to the medical expert by the Court itself, as judicial documentation obtained in the instruction or investigation phase in order to assess the claim.

9.2.2.2 Clinical Information Subsequent to the Claim

- Interview and patient examination

The medical expert, once he knows all the prior clinical information, can interview and examine the patient. This medical act permits him to:

– check the condition of the patient at that time;
– verify that his/her clinical state corresponds to what is shown in the prior documentation, except for the evolution that has continued afterwards;
– relate the patient's current state of health with the claimed fact and the events and medical actions included in the history; this will help him to establish and support the cause and effect relationship;
– in the case that sequelae have remained, he can record them, describe their nature, location, importance and the limitations of an anatomical as well as functional, mechanical nature and so forth, to which they may lead;
– when the sequelae are of a psychiatric nature, the examination can include psychodiagnostic and psychometric tests;
– when the patient has died, the practice of the autopsy can be proposed in the cases in which this examination had not been performed.

- Complementary diagnostic tests that the expert may consider necessary

The expert can be limited to evaluating the diagnostic tests provided in the clinical history or else request new tests in order to update the patient's condition at the time of the medico-legal evaluation. In this section, any type of tests, blood analyses, imaging, electrophysiological, neurophysiological, psychodiagnostic tests, etc., can be requested.

This is the general ascertainment procedure of the expert when there is a claim for medical liability. Methodologically, he proceeds in a similar manner in the case of a live patient or with a cadaver, although with some important differences which merit clarification.

9.2.2.3 Ascertainment Methodology in Living Patient

The majority of the ascertainment methodology is similar in living patients and in cadavers, since, as we have indicated, it is based on clinical documentation that has been provided and on the information provided by persons who were witnesses of the facts.

The most important difference is that when the patient is living the expert can count on the former's own testimony, when he/she is in a psychophysical condition that allows it.

Furthermore, with the living subject it is possible to conduct the clinical examination and complementary tests that permit a precise understanding of the current state of the patient, show the damages and demonstrate that these have been the consequence of the claimed events, medical conduct or circumstances.

9.2.2.4 Ascertainment Methodology in Cadavers

In the healthcare process that produces the death of the patient, it is usual that this death is presented as a damaging result of the medical action. Therefore, it can be said that the medical expert, at the commencement of his expert work, already knows the result.

However, through the study of the clinical documentation and the testimonies collected (provided by the Court in the proceedings, or else obtained by the expert in the interview with family members of the patient), the medical expert must confirm or reject that the death was a consequence of inadequate medical care or of a chain of events that ended in such a serious effect that caused the death of the patient.

A peculiarity of the ascertainment in a cadaver is the possibility of having the autopsy data from the cadaver of the patient when it has been performed.

The Autopsy Report, when it is performed, is a fundamental document in order to understand the physiopathological mechanism of the death, its immediate cause, its basic cause and other circumstances of interest. This information will indicate to us with certainty if the death had a direct causal relation with the medical care received.

The autopsy could be performed under two modalities.

- Clinical Autopsy. This is done in the Hospital where the patient dies, in the Pathological Anatomy Department, and is authorised by the family. This autopsy is complete and detailed and is complemented by histological analyses

that are conducted in the same Department. The final Report is attached to the clinical history of the deceased and a copy is given to the family. This document is usually added to the claim. Royal Decree 2330/1982, of 18th June, developing the Act of 21 June 1980 regulating Clinical Autopsies.

- Medico-legal or Forensic Autopsy. This is one of the most important acts of the forensic doctor's activity. It is regulated by the Criminal Procedure Act in Articles 343, 349, 353, 459 and 785. It orders that in violent deaths or when criminal activity is suspected, even when the external examination may seem to show the cause of death, there will be an autopsy on the corpse by the forensic doctors, or, if applicable, by those designated by the Judge, who afterwards must precisely describe the said operation, which shall report on the cause of death and the circumstances. The autopsies are performed in public premises designated for such a purpose, the Legal Medicine Institute of each province, dependant on the Ministry for Justice in each Autonomous Region. Royal Decree 286/1996 of 1st March passed the Regulations of the Legal Medicine Institute, with the autopsies being performed in the Pathology Service of said Institute.

The Ministry of Justice Order 28654, of 8 November 1996, passed the rules for preparing and sending objective analysis samples by the Toxicology Institute. The Toxicology and Forensic Science Institute is a body dependant on the Ministry of Justice and has three seats in Spain: Madrid, Barcelona and Seville. This is where all of the complementary analysis and tests are performed by the toxicological, anatomopathological and genetics laboratory, which are requested by the Forensic doctors to resolve *judicial deaths* (violent or where criminal activity is suspected).

The European regulations are based on some previous resolutions, both from the Council of Europe and from the United Nations. It is important to note recommendation number (99)3 of the Council of Ministers of the Member States for the methodological harmonisation of the medico-legal autopsies, which was passed by the Council of Ministers on 2nd February 1999. It insists on the independence of the experts, indicating the phases which must be covered:

- inspection of the place where the events occurred. Clearly differentiated from that which may be performed by the police. In malpractice, it is sometimes possible to visit the operating theatre, check the material used, the type of medicines, etc;
- later external and internal examination, recommending the opening of the three cavities and a careful examination of the neck. In cases of malpractice, when there has been prior surgical treatment, it is important to review in detail the external incisions, types of drainage, sutures, etc. and afterwards review, from plans, the surgical action to the tissue, organ or viscera intervened upon;
- sample-taking for complementary analysis.

The recommendation also deals with the way in which the autopsy report must be prepared in order that it can be understood even by people without medical

knowledge. It advises that the statement be composed in a logical manner, so that the report takes on the appearance of a well-reasoned essay.

The Judge orders it and it is performed in those cases in which, after the death, the family states to the doctors and/or to the Court its intention to file a claim. This circumstance means that the responsible Doctor does not sign the Death Certificate, for which reason the judicial investigation that starts with the performance of the forensic autopsy is put into operation.

In these cases, this autopsy is also performed completely and in detail, and is accompanied by anatomopathological, toxicological studies, etc. As a result, the corresponding Report is issued, which is sent to the Court and from which a copy is provided to the family.

The family of the deceased can propose, and the Judge usually accepts, that a party-appointed doctor-expert be present and participate in the autopsy. This expert is usually the same one who undertakes the expert's report of malpractice, when clinical elements are found that support it and the family decides to go forward with the claim.

When the autopsy is not performed, we are faced with an important fault in information. In practice, this occurs because the responsible doctor (in the hospital) or the family doctor signs the Death Certificate after the death of the patient, in which the immediate and fundamental cause of death appears; with this document, the inhumation or cremation of the cadaver is authorised. The information recorded in the Death Certificate could be considered as sufficient for knowing the causes of death. However, the reality shows that often these causes of death are not verified with the precision and accuracy necessary for them to be assessed, from the medico-legal perspective, as infallible and sufficient.

When the autopsy of the patient has not been performed after his death and a certain amount of time has transpired (weeks, months), in the situation where the family of the patient decides to file a claim, it can ask the Judge to exhume the cadaver and to have the autopsy performed. If the Judge accepts the evidence, this autopsy is always the medico-legal one and it is performed in the Legal Medicine Institute, by the Forensic Doctors and/or by the medical expert that the claiming family proposes to perform the autopsy. This doctor-expert is usually the same one in charge of the expert's report on the existence or non-existence of medical malpractice.

The situation that we just commented on is justified depending on various factors: (a) The time transpired is important, since the cadaveric phenomena can invalidate the findings corresponding to the pathology that the patient suffered, as well as the consequences of the treatment administered and other circumstances of the possible malpractice. (b) The findings that, hypothetically, we want to investigate are also determining factors in the opportunity of performing the autopsy. For example, if a therapeutic error is looked for regarding a dosage of medicine, the post-mortem time is important, because a valid toxicological analysis might not be possible; if we look for a surgical treatment evidenced by incisions, sutures, prostheses or the oversight of a foreign body, etc., then it is possible that the autopsy can provide important evidence to clarify the facts, although time may

work against this. (c) Other circumstances will also be determining factors in considering whether the autopsy performed at a time after death can be useful; these will be determined in each case (place of burial, meteorology of the season, etc.…).

When the autopsy of the patient has not been performed, and the exhumation is not indicated for the reasons listed above, it is very difficult, on occasion, to establish with certainty the mechanism of death and its relation with the claimed facts.

9.3 Evaluation Criteriology

9.3.1 Evaluation Criteria in Living Patients

In the previous phases, the expert has studied the clinical documentation and the data extracted from his actions, as mentioned above, from which he deduces in the specific case:

- medical conduct and care provided;
- clinical response of the patient to this care;
- damage suffered.

With these data, the expert proposes his Hypothesis. When this Hypothesis is affirmative, it means that the medical expert has identified the possible acts/omissions or circumstances in the care that were the origin of the malpractice.

This is the expert's evaluation phase, in which the medical expert compares the medical and care actions, presumably inadequate (imprudent, negligent…), with the Criteria of good medical practice that will serve as a reference point. In this way, he can conclude whether the professional conduct was according to lex artis and good medical practice or if, on the contrary, the claim is justified, because the improper conduct that led to the damage has been identified in a clear causal relation.

The evaluation criteria of the medical expert are as follows:

- bibliography according to the case. The classical texts and the updated bibliographic revisions provide the expert with the scientific information to which the medical care provided must be adapted. The expert's own knowledge, his training and his professional experience are also important here;
- action Guides. These can be found in the form of published books. In Spain, some medical specialities have prepared these texts in order to homogenise medical assistance, especially that of trainee doctors (medical residents) or those with little professional experience. Thus, the Family and Community Medicine Resident's Book is a very useful text, because its content extends to all general pathology and it recommends the diagnostic tests that must be requested in each

case, the treatment and the criteria for sending the patient to the hospital or to a specialised consultation;

- healthcare System Protocols, prepared by the Health Departments of the Autonomous Regions. These usually refer to the care procedure "by processes" which must be followed. They intend to standardise and systematise the care. They regulate the frequency or periodicity of the visits, tests that must be conducted or requested, the healthcare personnel who conduct them (doctor, nurse, midwife, etc.). Since the contentious-administrative avenue is the most frequent for claims in Spain (against the hospital and, financially, against the health administration), in the situation when the health administration itself (Health Department of the Autonomous Region) has published its own Protocols for care and in the case where this protocol has not been carried out, the medical expert can find that there is sufficient and necessary evidence to prove malpractice;
- care Protocols of the Scientific Societies. In Spain, there are numerous Scientific Societies that have prepared action protocols for certain interventions. These are the results of discussion and rigorous scientific consensus, for which reason they offer a guarantee for the doctors and for the patients, insofar as conduct which adapts to the protocol is appropriate for good medical practice;
- protocols of specific actions, adapted to the circumstances of a medical speciality, of a health centre, or an inter-professional or multidisciplinary group (for example: Protocol of preparation for surgery of the anticoagulated patient, prepared by the Coagulopathies Group of the Haematology Society, etc.). These have a more localised application and at times are adapted to economic adjustments or budget cutbacks (the contracts-program of the hospital Departments…).

When the medical expert finds that there is an Action Protocol in the pathological process which is the motive of his expert ascertainment, he makes a comparison of what was done in the case under study and what should be done, according to what is indicated in the Protocol. The conclusion can, therefore, be definitive and convincing, as it is supported by rigorous scientific criteria and backed by the consensus that is behind the Protocols.

9.3.2 Evaluation Criteria in Cadavers

As in the case of the living patient, also in the prior phases, and after studying the clinical documentation and his own actions, the expert must establish at what moment of the care and as a consequence of what actions the damage that ended in the death of the patient could have originated.

Nevertheless, everything that was said for the living patient in reference to the Protocols is applicable to the cadaver.

The only thing to add is the practice of the autopsy when it has been performed. In this case, the common Autopsy Protocol in Europe is applicable for medico-legal autopsies and for clinical autopsies.

There are no other criteria or protocols in Spain applicable to cadavers as regards the procedure to follow in the expert evaluation.

9.3.3 Evaluation of the Sequelae

In the expert report on malpractice, the parties or the Judge can direct to the expert a general request to "pronounce on whether or not malpractice existed" (not very usual), or else specific requests to which he/she must respond, in his/her turn, specifically. These can be several questions on medical aspects or administrative and managerial functioning of the centre that progressively enter into the elements of liability: professional conduct or actions, their consequences, causal relation, etc., which would finalise the expert's report.

However, in many cases, the expert is asked to assess the damage.

When the result of the malpractice has been death, the Judge himself can establish the worth of the person with general criteria: age, profession, activity, persons in his charge, etc.

When the patient has survived, an assessment of the sequelae is made, according to the following criteria: (Royal Decree on civil liability and insurance in the circulation of motor vehicles).

Type of sequelae: The indicated scale, although it was made for compensations for traffic accidents, in Spain is applied in other areas, since the purpose is the same, namely, to discern the damage suffered by a person as the result of a determined event; it does not matter whether this event was a traffic accident, a work accident or healthcare assistance. This scale is very useful for these purposes, since in its TABLE VI it goes over all the possible sequelae that may affect a person. It is evaluated in points, considering the psychophysical integrity of the normal person as 100 % and equivalent to 100 points. If the patient's specific sequela does not appear, the assessment can be made by analogy with others of similar anatomical or functional effects.

9.4 Future Perspectives

It is not foreseeable how the subject of medical liability will evolve in the future in Spain.

Currently, some Autonomous Regions have an instance court for attending to medical liability claims, which is the first to receive and study the claim. In this court, malpractice and institutional liability can be observed and recognised, which leads to the study of a compensation agreement, with which the case ends.

When the pre-trial agreement is rejected, the claimant or filing party usually commences the judicial channel.

Currently, the most frequent claim channel, the contentious-administrative (against the administration, financially responsible for the public centres and hospitals), and occasionally, the civil channel, allow the proceedings to terminate in an abnormal way, that is to say, without trial, when the following is produced during the process:

- proposal of arrangement, by the judge, in which an agreement is established on the compensation that is to be offered, after recognising the damage produced;
- opinion of the State Council or of the Consultive Council of the Autonomous Region.

Different professional associations such as the professional Medical Associations and the Bar Associations have proposed the possibility of arbitration courts. They would be utilised prior to taking the case to court.

These arbitration courts would hear the parties, study the expert reports provided by the parties, and propose a solution, either of justified rejection of the intention of compensation, or else a proposal for recognition of the damage and its evaluation. In this way, the injured party could gain numerous advantages:

- greater speed;
- the reduction of costs, suffering, disappointments, etc;
- the justice administration would be relieved of numerous cases, focusing on those that merit attention for their complexity or seriousness.

In our opinion, European harmonisation could take effect with the proposal of these arbitration courts. It would be the professional Medical Associations and Bar Associations that would take on the responsibility of proposing regulations that would be of common application to all the countries of the European Union.

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Chapter 10
Medical Responsibility and Liability in Portugal

Vera Lúcia Raposo and Duarte Nuno Vieira

Abstract The first section of this chapter provides a brief introduction to the civil and criminal categories of medical responsibility in Portugal, while the second section is concerned with the epidemiological data for cases of medical malpractice in the same context. The core part of the chapter contains a judicial and normative overview of both civil medical responsibility, with particular emphasis on the presumption of guilt and the obligation of means/obligation of means/results—and criminal medical responsibility—focusing on the criminal categorisation of medical acts and medical interventions without the patient's consent. The fourth and fifth sections of the chapter deal with ascertainment methodology and the role of the Medical Legal Council, respectively. This chapter ends with a conclusion on the current and future situation of the Portuguese system of medical malpractice.

Contents

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10.1 Introduction

Under the Portuguese juridical system medical professionals may be charged with malpractice at three different levels, even simultaneously: at the level of civil law, criminal law and/or at the disciplinary level.

Civil responsibility takes place when the injured patient files a lawsuit claiming patrimonial and non-patrimonial damages derived from a tort committed by a medical professional. If the doctor operates as a public servant in a public hospital the legal action may be brought against the State exclusively, or the State and the doctor together, and more rarely solely the doctor, under the statute of extra-contractual liability of the State (Law no. 67/2007, of 31st December) (Cascao 2004; Dias 1996; Dias and Monteiro 1984; Nunes 2005; Pedro 2008; Pereira 2007; Reys 2008; Rodrigues 2000; Sousa 2011, 1996).

Criminal responsibility operates when a criminal offence is committed against the body, health or life of a person by a medical professional, in the course of a medical act (*latu sensu*), and it is a more severe one since it can ultimately impose upon the professional a sentence of imprisonment (Dias and Monteiro 1984; Andrade 1999a; Fidalgo 2008).

In addition to this, we can also have a disciplinary responsibility, which can be of a professional nature (handled by the Portuguese National Medical Association—"Ordem dos Médicos"—supported namely by the Deontological Code), an administrative nature (if the doctor is a public servant in a hospital belonging to the public healthcare service) or can be derived from labour law (when the doctor works in the private sector). Disciplinary responsibility is resolved extra-judicially, among the referred entities; however, the final decision can be reviewed by a judicial court (Nunes 2011).

10.2 Epidemiological Data

In Portugal, as in many other countries, it is impossible to know the real figures concerning cases of medical malpractice. Official claim figures are not available, and even if they were, they would not reflect reality, since many victims of malpractice do not file claims, while many non-victims do.

Moreover, there is no reliable data concerning the total amount paid in compensation within the context of medical malpractice, or about the number of civil and criminal convictions. The only information that exists is isolated data from occasional investigations into medical malpractice, the official data of the cases

being examined by the Portuguese Medico-Legal Council (CML) (described below), and data regarding the public health sector compiled in a very recent report presented by the Portuguese General Inspection of Health Services (IGAS), which analyses inquiries made to public hospitals about their activities in the years 2008, 2009 and in the first semester of 2010.

This study concluded that, during the period in question: (1) 2/3 of public sector institutions were the object of complaints; (2) the compensations paid exceeded 26 million Euros; (3) only 60 % of those hospitals had protocols in place to prevent medical mistakes; (4) no more than 1/3 of health institutions had computer systems designed to alert professionals to risks arising during medical assistance; (5) very few institutions and barely 1/6 of individual health professionals had professional liability insurance.

The IGAS report also identified the most frequent medical faults (infections, accidental lacerations, negative reactions to blood transfusions, birth traumas provoking lesions to the newborn; mistakes in patient identification and/or the medical act to be performed; complications resulting from anaesthesia; objects left in the human body following surgery; falls from beds and stretchers, and errors in the prescription of medication) and also the most problematic areas of practice (surgery, orthopaedics, obstetrics and internal medicine).

The data from isolated studies and from the CML have also shown that the medical specialities most frequently involved are internal medicine, surgery, obstetrics and orthopaedics, and that the health professionals in question usually have more than 10 years' experience, have various occupations or are overworked. In most cases, legal claims arise from defective communication with patients and/or their families and from failures in assistance, though legal processes resulting from carelessness in filling out clinical records, reports and prescriptions are also common. Curiously, most situations of alleged medical malpractice do not arise from complex interventions, but tend to involve small technical medical-surgical procedures.

In Portugal, as elsewhere, the number of lawsuits involving alleged medical malpractice has steadily increased over the years. The reasons for this increase include: (1) consumer enfranchisement; (2) an emergent "compensation culture" encouraged by a growing personal-injury "industry"; (3) a loss of confidence in and respect for medical and other healthcare professions; (4) disenchantment with the inevitable inability of modern medicine to keep pace with public expectations, particularly its failure to measure up to the healthcare professionals depicted in televisions shows; (5) a lack of rapport and communication with patients and families; (6) the decline in physician–patient relationship due to excessive specialisation, and (7) careless remarks made by one physician about another.

10.3 Judicial and Normative Overview

In order for the doctor to be held accountable for medical malpractice the court has to verify certain requisites that vary according to the type of responsibility under discussion.

A condemnation under civil responsibility demands an illicit and culpable act, which causes injuries to someone, while criminal responsibility requires the commission of an act (or the omission, since an offense may also be the product of a negative behaviour/non-performance) that constitutes a type of offense which is performed, additionally, in a guilty manner (negligence or malice). While criminal responsibility never dispenses with the requirement of guilt, civil law sometimes admits an objective responsibility; however, regarding medical malpractice, civil responsibility is always a subjective one.

In both cases it is also necessary that a causal relation intercedes between the act committed and the actual result.

In Portugal the dominant theory of causal relation is the theory of the adequate cause, according to which

> it must only be considered as the cause of damage in the circumstances where, with regard to the *experience rules* and the particular situation in which the agent was inserted (keeping in mind what was known or knowable by him/her under the circumstances), it is revealed as fit, suitable or appropriate to produce that damage. However, for a fact to be considered an adequate cause of the damage suffered by someone else there is also the requirement that such damage constitute a normal, typical and predictable consequence, therefore, it is demanded that the judge puts himself in the concrete situation of the agent to issue the decision, taking into account the circumstances that the agent knew or those a regular person, in the same situation, should know (Supreme Court, decision from January 15th, 2002).

It is not always easy to define a medical fault, although the violation of *leges artis* is a decisive criterion in this situation. *leges artis* basically defines the kind of behaviour that can be expected from a regularly diligent doctor, in other words, the "*bonus pater familiae*" standard applied to this particular issue in the form of "average practitioner" (Reys 2008). Nevertheless, sometimes it is not obvious how an average doctor in a certain situation would behave.

Medical malpractice is usually due to some unreasonable behaviour on the part of the defendant. But occasionally the medical fault results from instruments used. Even in this case the responsibility still belongs to the health professional, since he has a duty of care and diligence when handling instruments. Consequently, if he concludes that the material is not in an appropriate condition, his duty is to alert the institution. Indeed, this is a perfect example of solidary responsibility both from the practitioner and the institution, for the reason that they should mutually take care of the quality and safety of the instruments used, unless such knowledge was not expected of him/her:

> The defendant, owner and administrator of the private hospital where the petitioner was submitted to a surgical intervention, is responsible for the negligent conduct of a nurse in its service who brought to the operating room, at the request of the second defendant (the doctor performing the intervention) an auxiliary lamp whose valve was not technically adequate to be used during the operation and which consequently caused a third degree burn in the left lower quadrant of the petitioner's abdomen. However, we cannot criticise or blame the second defendant for the use of the referred lamp or for not having refused it, or for the injuries that were derived from it, because a regularly alert and diligent surgeon would not have held the supposition that the hospital had a lamp that, while illuminating the operative

field, could cause in this area a third degree burn trauma on the patient to be used in the surgical room (Supreme Court, decision from April 27th, 2004).

Diagnostic errors are likewise widespread medical faults, especially when the patient presents generic symptoms, or in the emergency department. These mistakes frequently result from the omission of complementary means of diagnosis. The Lisbon Court of Appeal, in a decision of April 20th, 2006, ordered two doctors to pay compensation to the plaintiff who went to the emergency department twice with severe abdominal pain, but was never submitted to complementary means of diagnosis and, consequently, was not diagnosed correctly and was sent home on both occasions. The court concluded that doctors violated a subjective right of the plaintiff and had therefore committed an illicit and guilty act, since in the particular circumstances they could and should have acted in a different way, which is understood as a clear sign of legal guilt.

The medical fault in a process of clinical diagnosis may simply result from the fact of not having requested from another doctor the necessary expert opinion. In a decision from November 5th, 1997 the Supreme Court analysed an accusation of manslaughter regarding a pregnant woman, who died of sepsis because of the loss and putrefaction of her foetus, but the situation was not detected and she ended up dying of an internal infection. The doctor was not convicted by the Court of Appeal or by the Supreme Court, but several times it was alleged that the omission of complementary diagnostic methods and the refusal to ask the intervention of another doctor represented a medical fault.

10.3.1 Civil Medical Responsibility

Civil responsibility follows the general rules of civil law (Magalhães and Vieira 2010b; Vieira 2008b). The Civil Code does not have any particular regulation for medical malpractice, which is often argued as a deficiency of our system.

Portuguese jurisprudence is still divided regarding the grounding of medical responsibility: a contract between the doctor (Dias 1996; Dias and Monteiro 1984; Rodrigues 2000; Sousa 1996; Gaspar 1978) and the patient or the violation of the patient's personal rights (Gaspar 1978)?

This is not a purely theoretical question, since the legal regimes of these two responsibilities are quite different. Actually, contractual responsibility is much more beneficial for the offended patient and, in contrast, much harder on the doctor. The controversy still exists among judges and law professors in favour of each one of these two kinds of civil responsibility, while some even advocate the conjunction of both responsibilities, which leaves to the offended choice of the rules that best suit his interests and thus permit him the best of both regimes (Dias and Monteiro 1984; Sousa 2011; Monteiro 2003). This has been the approach taken by several of our courts, even the Superior Court, which even recently confirmed the enforcement of both responsibilities simultaneously:

> [T]he offended can benefit from a double protection (contractual and extra-contractual responsibility) since the illicit fact represents, at the same time, both a violation of a contract and a non-contractual illicit (decision from October 7th, 2010).

10.3.1.1 Presumption of Guilt

One of the most characteristic aspects of contractual responsibility is the presumption of guilt: instead of the patient having to prove that the doctor committed an illicit and guilty act which caused him harm, the enforcement of this presumption implies that the patient only has to demonstrate the commission of an illicit act, so that thereafter guilt is presumed.

This has been a very problematic feature for medical malpractice because some argue that imposing on the doctor the burden of displaying that he/she did not act with guilt presupposes a "diabolic proof", since it would force him/her to demonstrate that he/she has not violated any of the several rules that govern medical practice. On the other hand some others contest that the presumption of guilt finds its justification in the fact that it is easier for the doctor to dispel this presumption than it is for the patient to demonstrate guilt on the part of the doctor, not only because he/she is the one keeping the medical records, but also because he/she possesses technical expertise that the patient lacks, especially keeping in mind that not all patients can afford to pay a medical expert in order to confute the doctor's allegations and that "silent pacts" still rule among the medical profession.

Presumptions of guilt are typical of obligations of result. But no matter what the nature of the obligation is, they also arise as a consequence derived from certain facts of life, especially from harmful errors committed by the doctor.

> [A] harmful mistake—i.e. an incontestable violation according to state-of-the art medical science while making a diagnosis or a treatment—is sufficient to indicate, through judicial presumption or prima facie evidence, the negligence of the doctor (Lisbon Court of Appeal, decision from April 24th, 2007).

In this decision the court concluded that the defendants made a harmful mistake by not initiating immediately an endotracheal intubation directly after the cardio-respiratory failure of the patient, and instead decided to administer drugs and to perform an external cardiac massage, while a basic rule of aesthesia is that in the case of a not immediately reversible cardiac arrest the proper measure is an endotracheal intubation.

Portuguese courts have occasionally invoked *prima facie* evidence (Sousa 2011), a deductive technique that allows the assumption of medical negligence when

> common experience reveals that in the normal course of things certain accidents could not happen, except because of a cause revealing gross incompetence and lack of care (Lisbon Court of Appeal, decision from September 11th, 2007).

Furthermore, presumptions of guilt are also applicable when using dangerous procedures or instruments (Pedro 2008), as stated by article 493, no. 2 of the Civil Code. Nonetheless, this norm does not define what is considered dangerous to this effect. Therefore, it is for the doctrine and the jurisprudence to clarify the concept and grant it some content. In its decision from March 1st, 2005 the Supreme Administrative Court qualified as an exceptionally dangerous activity a blood transfusion that resulted in the person becoming infected with HIV. Surgical interventions involving the opening of the abdomen were also qualified as a dangerous activity by the Supreme Court, in a decision from December 9th, 2008.

Nevertheless, Portuguese jurisprudence currently tends to impose on the doctor the presumption of guilt, regardless of the kind of obligation (Pereira 2004, 2007; Almeida 1996) (of mere means or of an actual result) present:

> Whether we accept that the doctor is bound to an obligation of results or to an obligation of means, the defendant is always under the burden of proving that he acted with the diligence demanded for good practice, if he wants to be exempted from responsibility (Lisbon Court of Appeal, decision of March 9th, 2010),

which concluded with the conviction of a dentist who was ordered to pay damages to the amount of 30,000 Euros to the plaintiff as compensation.

However, and despite many arguing that it is easier for the doctor to remove the assumption of guilt since he is the one that has mastery over the rules of the *métier*, the fact is that we are dealing with an extremely difficult demonstration. In relation to a case involving aesthetic surgery for breast augmentation, where the plaintiff suffered damages due to an encapsulation taking place, which is very common in aesthetic surgery, the court established the presumption of guilt. During the trial it was demonstrated that encapsulation is a risk that may occur in 8 % of the procedures involving this kind of intervention as a result of the technique itself. Nonetheless, the court was not satisfied with the demonstration of the level of risk in any intervention of this kind and ordered the doctor to clarify that it was not because of any faulty behaviour on his part that the surgery came under this 8 % of risk (Supreme Court, decision of December 17th, 2009).

10.3.1.2 Obligation of Means/Results

The presumption of guilt is usually associated with obligations of result, the failure of which allows for the presumption that the failure occurred because of the agent's behaviour and, consequently, that he is the one with the burden of demonstrating otherwise (Dias and Monteiro 1984; Sousa 1996).

Nevertheless, medical services are traditionally considered as a simple obligation of means, in other words, as an obligation to conform to the best medical practices existing at the moment and to develop the required level of care, but not as a duty to actually treat or cure the person, since this is an outcome that largely depends on several other circumstances, unrelated to the doctor, his knowledge or his performance, but with the human body and its imponderable vicissitudes.

But once in a while we came across a decision stating that specialist doctors are bound to an obligation of results. The most decisive and explicit declaration on this matter was issued at the end of last year, when the Supreme Court very controversially stated that:

> Usually, the doctor's obligation is one of result (or of pure diligence) and it therefore rests on the offended to demonstrate in a court of law that the conduct (action or omission) of the person liable was not in conformity with the rules of behaviour liable, in theory, to produce the desired result. On the contrary, when it comes to a specialist (for instance, an obstetrician) upon which rests the specific burden of adopting the adequate technique, the inversion of the burden of proof is understandable, since it is an obligation of result—and the doctor should be civilly held accountable on the basis of the simple finding that the proposed aim was not achieved (proof of failure), which is based on a presumption of ethical-juridical censurability (decision of October 7th, 2010).

The fact is that some medical acts were always qualified as an obligation of result due to their simplicity and the level of development achieved in the particular technique, and Portuguese courts have been considering that some medical acts configure obligations of such a kind.

Aesthetic interventions are included in these particular medical acts, since their aim is not to save lives or to cure, but solely to mitigate the suffering of the patient. In all the other modalities of medical interventions the patient faces the alternative between the risk of failure, on one hand, and the inertia and the consequent degradation of his health condition, on the other hand. Differently, in a purely aesthetic intervention (this note excludes reconstructive surgery from the safeguard we are going to do, therefore reconstruction is still a mere obligation of means) the only acceptable outcome is to achieve the intended result, because otherwise it is not worth taking such a risk. After exposing these juridical considerations the Supreme Court, in its decision from December 17th, 2009, concluded that

> [i]f it's not an obligation of result, with the doctor committing himself absolutely to the desired aesthetic improvement (accorded between the two of them), it is certainly an obligation of almost-result because it is an obligation where the result matters, both for the plaintiff and for the defendant (…) the inexistence of a result or an entirely unsuitable result are evidences of a failure by the doctor-debtor.

Likewise, whenever the doctor takes on, with regard to the patient, the commitment of achieving a certain goal, he is concomitantly accepting an obligation of result:

> The doctor assumes an obligation of results when, after instructing the patient about the disease affecting the latter (Dupuytren's contracture), the adequate surgical technique and the inherent risks, he informs him that it is a simple surgical intervention capable of repairing the finger and therefore eliminating the contraction (Supreme Court, decision from December 17th, 2002).

The fabrication of proteases is also considered an obligation of result because of the level of perfection that the technique has achieved by now, although its application to the organism is in contrast an obligation of means, since the doctor never knows how the human body will react.

Laboratorial exams are qualified as an obligation of result as well, due to the level of specialisation this technique has accomplished. Thus, the margin of error is practically null and if the anatomo-pathologist doctor

> provides the client with a scientifically incorrect result we have to conclude that he acted in a guilty way, given that this result can only be due to a mistaken analysis (Supreme Court, decision of March 4th, 2008).

The same is true for surgeries so undemanding that they encompass a minimal margin of error, for instance the removal of sebaceous cysts or of appendicitis. A *contrario sensu*, in surgeries more subject to risk and to unpredictability, the obligation cannot be but one of means, such as in internal medicine, cardiology, neurology and gastroenterology. Following this reasoning, the Lisbon Court of Appeal (in a decision of October 23rd, 2007), considered that a tubal ligation was an obligation of means, because it has been demonstrated that even if applying the more developed and adequate techniques the risk margin of failure was 0.2–0.4 %.

The intrinsic difficulty of the intervention also dictates the range of facts that each party has to prove. In more intricate surgical interventions the doctor is only required to establish the complex nature of the intervention, and it lies with the patient to demonstrate that *leges artis* have been violated and, afterwards, that this violation was an adequate cause of the lesion, i.e. the demonstration of the causal relation. Contrarily, in routine and simple interventions the patient has to ascertain the simplicity of the intervention and subsequently the doctor needs to demonstrate that the failure is not the product of his negligence. Whereas in the first hypothesis the most difficult proof falls upon the injured patient, in the second hypothesis it falls upon the doctor.

The obligation of result was also upheld in a decision from the Lisbon Court of Appeal of May 22nd, 2007. Primarily, because the case concerned an ophthalmologist and thus a specialist doctor as such, he was therefore obliged to demonstrate that the failure did not originate from his malpractice. Furthermore, because the defendant should have presented the ultrasounds whose existence he invoked, showing the sanguineous eye of the patient. However, the ultrasounds were never presented (perhaps because they were not even performed). From this omission the Court of Appeal derived an inversion of the burden of proof, based on article 244, no. 2 of the Civil Code, according to which:

> There is also a reversal of the burden of proof when the opposing party has improperly made it impossible to the encumbered to prove the facts, without prejudicing the sanctions that the law of procedure especially enforces in cases of disobedience or false statements.

Therefore, there is an inversion of the rules of burden of proof each time the doctor makes the presentation of evidence by the patient difficult in an intentional or even negligent way. This happens, for instance, when the doctor conceals the patient's clinical file or destroys the compress used to treat the patient, which is necessary in order to clarify a particular fact.

10.3.2 Criminal Medical Responsibility

Unlike the Civil Code, the Criminal Code includes specific norms pertaining to the criminal responsibility of health professionals, for it comprises norms that predict offenses which can only be perpetrated by medical professionals: false medical certificate (article 260 of the Criminal Code); undue change of exams or obituary (article 283, number 1(b) of the Criminal Code); refusal of medical treatment (article 284 of the Criminal Code). Apart from those offenses that only can be committed by particular persons, doctors may also commit crimes not specific to the medical profession, such as manslaughter or battery.

The two main lines that conform criminal medical responsibility in Portugal, deriving from our Criminal Code, are the following: primarily, the assumption that medical acts (in the strict sense of the concept) are not criminal offenses subsequently justified by the patient's consent or by the therapeutic aim; secondly, that every medical intervention requires the patient's consent, even if refusal may lead to his/her death (Magalhães et al. 2010a).

10.3.2.1 The Criminal Categorisation of Medical Acts

The Portuguese Criminal Code contains a very particular norm, as far as one knows without correspondence in comparative law: the explicit declaration that the medical act (providing it respects certain legal requisites) is not legally considered a criminal offense subsequently justified by the patient's consent or by the therapeutic benefit that it carries with it (article 150, number 1 of the Criminal Code) (Andrade 1999a).

In order to escape from a criminal qualification the action must fulfil certain requisites demanded by article 150/1:

1. to be performed by a person qualified for it (a doctor, a nurse);
2. with a therapeutic aim (though the law only mentions the therapeutic purpose, the doctrine encompasses a large understanding of this expression and also includes in it aims of diagnosis and prevention, which is not excluded by the prohibition of analogy since this principle only applies to the *malen partem* analogy and in this case we are using an analogy which will benefit the accused): this condition excludes interventions where the patient is not the direct beneficiary, as for instance pure experimentation, clinical trials, voluntary sterilisations, sex changes and organ donations. The actions referred to are not necessarily criminal offenses, because although initially considered as such, they are eventually justified by consent, which operates in a similar way to an exculpatory cause;
3. in respect to *leges artis*;
4. with a medical indication: this requirement rules out treatments not yet medically validated or which follow methods excluded from institutionalised medicine. This is the case for naturalistic processes or homeopathic practices,

though not law. 45/2003, of the 22nd August, refers the juridical regulation of alternative medicines to this norm of the Criminal Code.

Whenever the medical act respects all of these requirements it cannot be qualified as a criminal offense. The failure to achieve the pursued aim is not synonymous with malpractice, much less with a crime. What is relevant is the fulfilment of the conditions legally required, not the result in itself.

In order to hold the doctor accountable for a criminal offence it is not necessary that the patient suffers effective damage. The mere fact of acting against *leges artis*—and therefore provoking a serious danger to the body, health or life of the patient—is sufficient for a criminal condemnation for medical malpractice. If the damage actually takes place then the offense in question will be a different one, specifically the one corresponding to the particular injury in question.

Likewise, the commission of a medical act without the patient's consent constitutes a criminal offense, even if the patient did not suffer any injury to their body, health or life, which underlines the value of patient self-determination.

10.3.2.2 Medical Interventions Without the Patient's Consent

Article 156 of the Criminal Code punishes arbitrary medical interventions (Andrade 1999b), i.e. performed without the patient's consent. The legal interest protected by this norm is neither life nor physical integrity, but self-determination in decisions about our body and our life. Any intervention not grounded on the patient's consent, even if medically indicated, is considered in the Portuguese criminal system as a violation of self-determination and human dignity (Nunes 2011; Pereira 2004; ERS 2009; Oliveira and Pereira 2006; Oliveira 2005).

Nonetheless, this core rule suffers from two kinds of limitation. The first one derives from the existence of a legal authorisation that enables the doctor to act independently of any consent (promotion of public interests by the imposition of mandatory inoculations; forced feeding of prisoners and other persons in the custody of the State). The second limitation to the basic principle contained in article 156, no. 1, results from no. 2 and it is called presumed consent.

The juridical figure of presumed consent provides the doctor with a legal basis to intervene on two occasions: (1) if the consent cannot be obtained in the moment but, on the other hand, the intervention cannot be postponed, since otherwise the person's life or health will be at risk; (2) or when the consent was given to a particular intervention, in the course of which other steps revealed themselves to be necessary. These hypotheses are only admitted when it is plausible to assume that the patient would not oppose the intervention. The criterion for carrying out this evaluation is not an objective one, based on the best interests of the patient according to common sense, but a subjective criterion grounded on his effective wishes, as foolish and temerarious they may be.

Finally, it is noted that the consent demanded by article 156 of the Criminal Code (and also relevant in the context of civil law) is a free and enlightened

consent (article.157 of the Criminal Code). Therefore, if the consent was actually given, but without all the necessary knowledge for it to be an enlightened decision, the consent does not have any value.

10.3.3 Judicial and Extra Judicial Institutions and Operative Roles

Medical responsibility is significantly increasing in Portugal. A couple of years ago few cases arrived at a judicial proceeding and only a small part of them were concluded with a decision against the health care practitioner. Conversely, nowadays patients present several complaints against health professionals and the number of convictions has substantially increased. In fact, in recent judicial decisions we can even detect an increase in the level of severity and exigency used in the evaluation of the practitioners' behaviour.

Judicial institutions—in other words, judicial courts—are the main protagonists in dealing with conflicts of medical responsibility, since in Portugal we lack extra-judicial institutions to resolve these types of conflicts, though their existence has already been discussed. However, we do have some other organisms and legitimate institutions that monitor the activity of health professionals and health institutions, and which even have the power to sanction some behaviour with administrative measures.

Both Civil and criminal responsibility are mechanisms available to any person who believes that they have suffered damages in body or health, or when a relative of theirs has died because of a medical negligence.

In Portugal, most of the judicial complaints follow the civil path solely because it is still rooted in the belief that a criminal conviction of a doctor is difficult to obtain, mainly because of the rules governing the burden of proof. Whenever both responsibilities are being actuated they are decided in parallel by the same court (Rodrigues 2000).

Civil responsibility is handled exclusively in courts. Although the parties can make an agreement between themselves to put an end to the judicial civil procedure (this possibility is excluded in criminal proceedings), the Portuguese juridical system does not offer any mechanism to resolve the litigation outside of the judicial system.

Not all civil proceedings are handled in civil courts, but only those related to the private practice of medicine. Diversely, acts performed by doctors acting as public servants in a public hospital are submitted to an administrative court. Consequently, although the medical behaviour is evaluated according to regular civil law rules, afterwards the ascription of legal responsibility between the Institution (in other words, the State) and the concrete agent is dictated by Law no. 67/2007, of 31st December, which determinates the legal regime of State responsibility (Quadros 2011; Moniz 2003; Cadilha 2008; Sousa and Matos 2008).

The State is exclusively responsible every time the act in question is committed with ordinary fault (article 7, no. 1, Law no. 67/2007). On the contrary, if the act is committed with grievous fault or with malice—that is, intentionally—we have a case of joint liability (article 8, no. 1 and no. 2 of Law no. 67/2007), although the State has a right of subrogation against the offender (article 8, no. 3 of Law no. 67/2007). However, if the agent has surpassed the limits of the tasks legally attributed to him, he will be the only one to be held responsible (a *contrario sensu* from article 7, no. 1 and article 8, no. 2, of Law no. 67/2007).

Instead of a fault of the concrete agent we can have a fault of the institution itself, which is called "*faute de service*" under the influence of the French doctrine.

Article 7, no. 3, of Law no. 67/2007 expressly hosts the idea of "faute de service" (Cadilha 2008) for situations where the damages are not the result of a determined performance of a particular person, or when it is not possible to demonstrate that a personal action or omission in its origin thus represented an abnormal running of service.

In no. 4 the abnormal running of service is defined, where it is construed as abnormal when the surrounding circumstances and the average standards of results provide, as a reasonable expectation, for the avoidance of the damages that occurred. For instance, leaving a patient out of his bed, in a cold garage, waiting in an ambulance in order to be transferred to another hospital, for the simple reason that the current hospital did not have a specialised professional to take care of him, was considered by the Supreme Administrative Court as a "*faute de service*" (decision from June 17th, 1997).

Criminal disputes are also handled exclusively in a court of law, after the presentation of a criminal complaint in the 6 months following the knowledge of the occurrence of the offense by the injured person or by his/her personal representative (in case of minors or incompetent persons). Diversely, in so-called public crimes, criminal procedure is opened by the Public Prosecutor, in the fulfilment of his professional duties, independently of a criminal complaint or even against the will of the persons involved. The difference in the nature of the crime lies in the character of the subjacent legal interest: if it concerns almost exclusively the offended person then it is a private crime or a semi-public crime, but if it is closely connected with the community interests then it is a public crime (for instance, an involuntary manslaughter committed by a doctor).

10.4 Ascertainment Methodology

If a health professional commits wilful or gross negligence, which results in damage or injury to a patient entrusted to his care, he, like anyone else, should be liable for the harm he inflicts. A Bachelor, Master or Doctorate degree in medicine, or a specific specialisation in a medical area, is not a passport for impunity. However, medical error, which involves a large circumstantial component, is not

the same as negligence, which reflects incompetence in medical practice. A negative outcome alone is not sufficient to indicate professional negligence. There is always a degree of uncertainty in any medical intervention, even when the appropriate treatment has been given in the correct way.

Thus, as previously stated, when a normally reasonable and prudent health professional makes a mistake in a particular case that is, to all intents and purposes, identical to others dealt with in the past, having acted in accordance with standard professional conduct, employing a procedure that an averagely competent, prudent and responsible colleague with the same academic and professional qualifications would have used on that date in similar circumstances, this cannot be considered as constituting guilt. In other words, the doctor is required to display the degree of care and competence that might reasonably be expected of a professional in the same general line of practice with the same qualifications acting under similar circumstances.

This means that an expert investigation carried out in a situation of alleged medical malpractice will attempt, first of all, to establish if the actions of the doctor in question were consistent with the reasonable and ordinary care, skill, and diligence that physicians or surgeons, in the same neighbourhood, in the same general line of practice and in the same or similar circumstances, ordinarily have and exercise in like cases.

Judicial proceedings regarding medical responsibility demand a level of medical expertise that the judge lacks. The medical expert is responsible for providing the judge with the most complete technical information about the facts, for explaining the pathology in question and for clarifying obscure topics. Nevertheless, the expert is not an adviser of the judge, but a translator of the medical knowledge that is relevant to decide the case (Sousa 2011).

Therefore, the following aspects should be systematically checked in an analysis of alleged situations of medical malpractice:

1. that there existed a healthcare provider-patient relationship;
2. that the healthcare provider had a duty to the plaintiff;
3. that there was a dereliction or breach of that duty;
4. that there was a violation of the applicable standard of care;
5. that the dereliction of duty resulted in damage to the patient and that the patient was, in fact, damaged;
6. that there was a causal connection between the violation of the standard of care and the harm suffered, or (in fatal cases) the cause of death;
7. the temporary and permanent economic and noneconomic damages suffered by the patient, taking into account injuries and sequelae (in civil law);
8. the gravity of the damages suffered, taking into account the injuries and sequelae suffered (in criminal law);
9. the cause and circumstances of death (in fatal cases);
10. other information of interest.

From Point 3 onwards, the intervention of a medical expert is essential, and from Point 6, a medico-legal expert.

Medical experts—forensic medical experts or doctors from different medical specialties—are expected to evaluate the medical error, according to the criterion of the "reasonable medical doctor" (in other words, the one who acts according to *leges artis*), evaluate the harm caused to the patient and evaluate the causal relation.

The judge is not a passive receptor of the expert's opinion. He has the power to autonomously evaluate the expert evidence, because *iudex peritus peritorum*, i.e. the judge is the expert of the experts.

In Portugal, forensic medicine services are concentrated in a single National Institute of Legal Medicine (INML), with headquarters in Coimbra, three delegations (in Lisbon, Coimbra and Porto) and a network of 31 medico-legal offices spread around the country. These are located in central hospitals, and are answerable to one of the INML delegations, in accordance with geographic area. In principle, any medico-legal expert assessment requested by a magistrate should be addressed to the INML, which will decide who shall carry it out (i.e. the expert is not appointed directly by the magistrate). It should be pointed out that by "medico-legal expert investigation" we mean the assessment and quantification of damages suffered by the victim (a clinical forensic investigation for a bodily damage assessment), with a view to applying a particular criminal penalty or granting compensation, or the performance of a forensic autopsy in order to determine the cause of death and whether this was in fact connected to the alleged medical malpractice. Therefore, a medical expertise (rather than medico-legal) expertise is required to gauge whether the doctor's conduct in the case in question was consistent with the reasonable and ordinary care, skill, and diligence that physicians or surgeons, in the same neighbourhood, in the same general line of practice and in the same or similar circumstances, ordinarily have and exercise in like cases. This assessment may (and should) be carried out by one or more specialists in the field(s). In reality, any doctor who has the same or superior qualifications to the doctor in question may be appointed to investigate the first phase of the aspects listed above, as Portuguese law permits anyone with a degree in medicine to be called to attend as a medical expert. In these cases, the usual procedure is that the court will ask the National Medical Association ("Ordem dos Médicos") to indicate a doctor or doctors in the speciality or specialities concerned to be appointed as expert witnesses. These will then proceed to analyse the case and issue a written opinion or make statements in court. There is no official list of medical experts, as they are appointed on a case-by-case basis, following indications provided by the National Medical Association.

If, however, an autopsy or bodily damage assessment is required (i.e. a medico-legal expert investigation in forensic pathology or clinical forensic examination), this will have to be done by the INML, as mentioned above. It is also possible for the parties involved (victim and health professional or their insurers) to appoint private experts to represent them in these investigations (which may therefore take the form of collegial expertise) or request their own investigations from private experts (with the exception of autopsies). These experts representing the parties in the official investigations undertaken by the INML have to be previously approved by the court.

Medico-legal expert investigations take place after the launch of the legal proceedings brought by patients or their legal representatives (in the case of minors, mental patients or mortal victims, for example).

The medical forensic expert who will examine these cases has access to all of the clinical data included in the legal process, and may also request further information deemed relevant to the case. In the case of expert investigations ordered by the court, experts from the INML have direct access to all relevant clinical information, which they may request directly from hospitals, private doctors, clinical departments of insurance companies or any other institution involved in the situation under examination. These bodies are then obliged to send a copy of the requested documents to the INML within 15 working days under penalty of legal sanctions.

It should also be pointed out that the forensic medical experts from the INML have, by law, total autonomy to order any complementary tests deemed scientifically justifiable for an accurate understanding of the situation, without having to seek prior approval from the court.

The parties involved and the court may of course also request further clarification from the INML concerning the investigation being conducted, or may seek the answers to concrete questions about any aspect of the medico-legal investigation (about the methods used, complementary tests, scientific interpretation, conclusions etc.) or even about merely scientific aspects. The court has full freedom to appraise the experts' opinion or reports.

During the course of the investigation and subsequent preparation of the report, the medical expert must consider all prior clinical information (clinical history, hospital records, etc.), as well as opinions and testimonies issued by private experts, and should interview and examine the patient and undertake any complementary diagnostic tests deemed necessary. If required, colleagues from that specific line of practice may also be heard (these may be contacted directly by the INML or may even work for it, as there are INML careers not only in forensic medicine but also in hospital medicine involving various medical specialities).

Medico-legal expert investigations in clinical and forensic pathology, and the respective complementary tests, are always charged (even when ordered by the court) in accordance with an officially-approved price list. The cost of the expert investigation will be subsequently included as a legal expense, and will be paid to the court at the end by the losing party.

During the interviews and expert examination of living patients, the medical legal expert is obliged to follow protocols approved by the INML, which clearly stipulate the various procedures to be followed and the items to be considered in the expert report, in accordance with the area of law involved (criminal or civil law). These procedural protocols are published in the Portuguese Journal of Bodily Damage. The expert report must also be drawn-up using an officially approved computerised model.

The same occurs with investigations involving the death of the patient. In fact, protocols are also defined for medico-legal autopsies, and once again, the legal-medical expert has total freedom to request any complementary tests deemed

pertinent; there also exists a computerised template for the official report, enforcing compliance with the officially approved model that is in force.

The decision regarding whether or not to carry out a medico-legal autopsy is the exclusive responsibility of the magistrates of the Department of Justice (though this is legally required in cases of violent death or death from unknown causes). Experience shows that, whenever the possibility of medical malpractice is raised (usually by the family), the department of justice will order a medico-legal autopsy.

10.5 The Medico-Legal Council

Under the Portuguese medico-legal system, there exists a consultancy body of the INML known as the Medico-Legal Council (CML) (Vieira 2008a). The main functions of this body are to provide technical and scientific consultancy services, pronouncing upon technical and scientific aspects of the expert investigation that is being carried out. Today, over 95 % of cases covered involve claims of medical malpractice. The CML is made up of representatives of the regional disciplinary councils of each of the regional sections of the National Medical Association, professors of public universities from various medical areas (surgery, internal medicine, obstetrics, neurology, medical ethics, etc.) and professors of law (criminal and civil), as well as specialists of recognised merit and the directors of the INML Delegations. It is presided over by the President of the INML.

Whenever doubts are raised in a trial involving medical malpractice (if, for example, divergent scientific opinions have been presented by different experts), the CML may be called to intervene, issuing an opinion that is often considered by the courts to be final. In fact, revisions of the technical-scientific report presented by the Forensic Council are not allowed (article 6, no. 4 of Law-Decree no. 131/2007). Nevertheless, the parties to the suit may request another medical examination, invoking the reasons why they disagree with the first one, or the tribunal itself can order it (article 589 from the Code of Civil Proceeding). The requirement of a proper justification is oriented to exclude purely dilatory requests of a second medical expertise and, therefore, to grant that this mechanism is only used when the first examination led to some questions to be resolved concerning the facts under investigation.

To avoid inundating the CML with requests, only the Minister of Justice, Supreme Council of Magistrates, the General Prosecutor or the President of the INML may request an opinion of the CML (in the last case, when the opinion has been requested directly of the INML and the president considers that it is of sufficient importance to be referred to the CML). In 2010, the average response time of the CML to requests for technical-scientific opinions was around 60 days.

The CML meets every 2 months and the opinions it issues are charged to the court, in accordance with an officially published price list; the amount, which reverts to the expert issuing the opinion, is considered a legal expense, to be paid by the person that loses the lawsuit.

10.6 Conclusions

In a general overview, the main aspect that needs to be pointed out in the Portuguese system of medical malpractice is the huge increase in this class of litigation. Though still very far away from the reality of other European countries (and most certainly from the United States), not only has the volume of complaints amplified during the last couple of years, but also the number of convictions has suffered an enormous increase. In other words, juridical decisions have become more punitive with regard to doctors, sometimes too punitive.

However, more decisions do not necessarily correspond to better decisions. Actually, the Portuguese model still reveals some important weaknesses. Primarily, judges have not reached a consensus on relevant issues of medical malpractice (namely, the contractual or non-contractual nature of civil medical liability) so that the outcome of a judicial process becomes quite unpredictable. Besides, the majority of judicial agents (lawyers, judges, the Public Defendant) are not aware of all the particularities of medical liability and of the medical profession, which means that they do not ask the correct questions to the forensic expert, or understand the exact relevance of his answer. Additionally, forensic exams are sometimes performed by private doctors who cannot be considered forensic experts; therefore, the results of some exams lead to legitimate doubts. On the other hand, the "corporative spirit" still exists among medical professionals, which makes it very difficult for the patient to gather the necessary evidence to present his case in court.

Despite all these weaknesses the Portuguese model is showing a tendency towards improvement, as the increase of the number of lawsuits will certainly draw attention to these issues. Therefore, it is likely that the newly acquired relevance of this topic will provide an incentive to correct past mistakes and will enable doctors and lawyers to begin using a common language, understandable to both.

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Chapter 11
Medical Responsibility and Liability in Italy

Pietrantonio Ricci, Francesco Ausania and Paolo Arbarello

Abstract The first section of the chapter discusses, from the Italian perspective, both the physician's responsibility as a 'contractual liability' and the liability for defects in health care outside of the professional activity of a doctor or other healthcare professional. The second section concerns epidemiological data, focusing on the increase in professional liability cases in Italy and errors in the diagnostic, prognostic, or therapeutic phases. The third section provides an overview of the normative and judicial situation in Italy in terms of criminal and civil medical responsibility, while the fourth section deals with 'Nomofilattica' and professional medical liability. The fifth section outlines the methods of ascertainment as well as the evaluation criteria in living persons and cadavers. The chapter ends with a discussion on the future perspectives of medical liability within the Italian context.

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11.1 Introduction

In the Italian legal system, responsibility is identified with the obligation to answer for the consequences resulting from an unlawful conduct.

In this regard, it considers two types of legal responsibilities: civil and penal.

In civil matters the claim for compensation belongs to the patient as part of a transaction contract under article 1218 of the Civil Code.

11.1.1 The Physician's Responsibility as "Contractual Liability"

The physician's responsibility, as "contractual liability", bases its *ratio* on the inadequacy of the health service.

The claim for compensation manifests its effects in the configuration of the physician's responsibility as the "debtor" who did not perform his contractual obligation properly.

11.1.2 Liability for Healthcare Defects Outside the Professional Activity of a Doctor or Other Health Professional

The Italian Civil Code, however, also provides a different form of liability ex art. 2043. This defines, in fact, the "tort" where the claim is derived from an unlawful

act for which there is, regardless of the nature of the event, a claim for unfair damage.

In the context of criminal cases, we can speak of responsibility where there is existence of a crime.

The constitutive elements of the crime, in addition to an active player (one who commits it) and the debtor (one who is disturbed or offended) are: the psychological element, the fact, and the conduct.

By analyzing the psychological element, mentioned in art. 43 of the Penal Code, it is possible to identify three types of situations: misconduct, culpability, and manslaughter.

11.2 Epidemiological Data

11.2.1 Increase in Professional Liability Cases in Italy

The extreme complexity of the criminal justice system has contributed to an increase in professional liability cases in Italy.

It is certainly not the only cause. The increased awareness on the part of citizens about the right to health protection, the pressure of the media, the "predatory" attitude by many work practitioners (lawyers, consultants) have contributed to the evolution of the means of diagnosis and treatment, and the resultant increase in complications.

To this we must add the birth and development of organizations representing the interests of consumers and an increased attention to professional liability.

Furthermore, a bicameral parliamentary commission for the study of professional liability was also established, with investigative powers and trainers involved in all cases in which an alleged case of "malpractice" is claimed.

This also causes problems for the coroner when handling such cases, or the consultant/expert (as well as the prosecutors and judges) who can be subjected to undue interference that may cause an alteration in the serenity of the proceedings. Added to this is the fact that, in parallel with investigations and criminal proceedings, legal proceedings may be launched for damages in civil courts.

This now happens so routinely that we can talk of "penal blackmail" in the use of indiscriminate presentations to the judicial authorities for all cases where a death occurs after a medical service has been performed, at all levels and in all settings.

Statistical data are not available regarding the prevalence of the phenomenon, because such information has not been analyzed.

An attempt at continuous and credible monitoring was conducted a few years ago by gruppo interdisciplinare di studio danno iatrogeno (GISDI), a working group developed within the società italiana di medicina legale e delle assicurazioni (SIMLA) framework. However, the data, especially with regard to the scope of

penal law, are not reliable. Other sources are represented by federazione nazionale degli ordini dei medici chirurghi e degli odontoiatri (FNOMCeO) and associations for the protection of consumer rights as Active Citizens. A very reliable data source may be represented by associazione nazionale fra le imprese assicuratrici (ANIA), the association of insurance companies, but such data have never been revealed in their entirety or are otherwise not easily obtainable due to company policy. In any case, the phenomenon is growing, with a negative reflection on the budget of the National Health Service and the Regional Health Services.

This results in problems in the private insurance sector, with the gradual increase in insurance premiums for healthcare facilities and individual professionals, as well as the gradual withdrawal of many companies from the market of medical liability.

Over-compensation and *over-deterrence* have both given rise to a series of regional legislative initiatives of particular interest.

Among these, we should mention the law of the Veneto region of July 31st, 2009 n. 15 (Extra-judicial rules on the management of healthcare litigation), whose constitutionality was upheld by the constitutional court Judgment n. 178 of May 14th, 2010.

Finally, the decision n. 11584/2010 of the IV Criminal Division of the Ordinary Court of Milan should be reported due to the severity of the alleged offenses and the severity of sentences imposed on defendant physicians.

They were physicians working in a private organization in Milan practicing unnecessary and harmful operations only for profit and more precisely to justify the so-called DRG.

For the same event there is another ongoing trial against the same defendants, in which case the crime is murder for the death of patients after surgery.

11.2.2 Mistake in the Diagnostic, Prognostic or Therapeutic Phases and Percentage of Mistakes According to the "Court of the Patient" and Data GISDI

The physician's responsibility is identified in the mistake during the diagnostic, prognostic, or therapeutic phases. The diagnostic error is when the doctor fails to reach a correct diagnosis of the disease that afflicts the assisted person (wrong collection of anamnestic data, misidentification or underestimation of a symptom, an objective examination performed incorrectly, an error in the execution or interpretation of imaging and/or laboratory studies).

A diagnostic delay results in a delay of treatment. A mistake in the prognostic phase is when the doctor reaches a conclusion that is then proved to be unfounded, which affects further therapeutic orientations, thus causing harm (the prognosis is "recklessly" in favor of inertia or failure of therapy, unfavorable prognosis). A mistake in the therapeutic phase is when the doctor makes a mistake either during

the choice of the therapy or at the time of its execution. These mistakes frequently depend upon previous diagnostic mistakes and they can be distinguished either as a medical mistake or as a surgical therapy mistake.

Examples of the former type of mistake are the choice of an inappropriate or ineffective medication, its incongruous route of administration or its inadequate dosage, the lack of consideration of drug contraindications, side effects, and iatrogenic effects that were neither expected nor avoided. Among surgical mistakes, it is possible to identify a mistake during the operatory phase consisting in an error of judgment of inoperability and/or a reference to intervention, in the selection or execution of the anesthesia and/or in the calculation of the risks related to it, in the instruments used during the procedure, and an error in the postoperative phase consisting of mistakes or negligence or postoperative care.

In Italy, the Parliamentary Committee that inquires into both errors in the field of health and causes of regional health deficit last year estimated that around 250 events of malpractice occurred, 170 of which resulted in a fatal outcome.

The estimation is arrived at by the use of a rough guide, since the ordinary judge is in the end called upon to pronounce on the physician's responsibility. According to the "Court of the Patient" the percentage of mistakes was distributed as follows: 16.5 % Orthopedics, 13 % Oncology, 10.8 % Obstetrics, and 10.6 % Surgery.

However, the most frequent mistakes are those committed in the operating room (32 %), followed by the wards (28 %), as well as emergency departments (22 %).

In clinics, however, the percentage recorded is 18 %.

The GISDI, Observatory on forensic medical *malpractice*, funded by ministero dell'università e della ricerca scientifica e tecnologica (MURST) (currently (MIUR) ministero dell'istruzione, dell'università, della ricerca) and affiliated with the SIMLA, showed that, out of 1,564 cases reported, the specialties with the highest number of reported cases were Obstetrics and Gynecology (121 cases), General Surgery (82 cases), Orthopedics and Traumatology (68 cases), the ER (57 cases), Oncology (35 cases).

Also from the same source, the specialties recognized as responsible (in the expert's assessment) were Obstetrics and Gynecology (55 cases), General Surgery (40 cases), Orthopedics and Traumatology (39 cases), Oncology (24 cases), and Emergency Department (20 cases).

11.3 Normative and Judicial Overview

11.3.1 Criminal Medical Responsibility

The physician must respond in front of a criminal court with regard to his willful misconduct, his negligent conduct, the committal of manslaughter in relation to his conduct, which has resulted in personal injury or the death of the patient.

The following matters constitute willful responsibility: voluntary and conscious transgressions concerning facts of a criminal nature, commission or omission, and fines that are of different nature.

The offense is defined as *intentional* by art. 43 of c. p. and the following cases fall into it: interventions without consent (even if the issue is controversial both in doctrine and in jurisprudence), the revelation of secrecy, failure of medical report, wrongful death, ideological falsehood committed by public officials in a public act, ideological falsehood committed by public officials in certificates, omission of mandatory reporting, illegal prescription of drugs, nepotism, and embezzlement.

The crime, instead, must be defined as *culpable*, or against the intention, according to the dictates of the III paragraph of art. 43 c. p.

Within that both a generic and a specific fault can be distinguished.

The general fault is characterized by the presence of negligence, carelessness, and inexperience.

Negligence consists in the omission of the care required by common rules and practice observed by the majority of physicians.

Imprudence consists in the absence of prevision of possible harmful consequences of interventions.

Inexperience consists in ignorance regarding how to perform what another doctor of the same professional level would properly execute in the same clinical case.

Specific fault lies in the violation or nonapplication of rules that the doctor is required to know and observe. Such rules can be represented by real laws or by rules drawn up by a public authority or hierarchy also aimed at regulating and governing the execution of certain activities or the good performance of the work ("regulations, orders and disciplines").

The crime must be called *manslaughter, or beyond the intention*, according to the second paragraph of art. 43 c. p. when the physician's action comes from a conscious detrimental desire, but is reflected in an unwanted surplus in effect.

This particular case of the subjective element seems to be safeguarded by the Supreme Court, which has until now rejected any interpretation made against physicians (Court of *Assise* of Florence, October 18th, 1990), making it a nearly impossible hypothesis (Cass. Pen., Section IV, June 24th, 2008, n. 37077; Cass. Pen., Section IV, January 16th, 2008, n. 11335; Cass. Pen., Section I, July 11th, 2002, n. 26646).

To access compensation in relation to civil appeal one must inquire, through one's own lawyer, to the Civil Court, located where the event is presumed to have taken place.

There are only two ways: the summons and the complaint.

The injured person, having brought a damage claim for compensation, must necessarily take his request to the court.

The criminal trial, on the other hand, sponsored by the Public Prosecutor who represents the prosecution, is established with the knowledge of *notitia criminis*.

The procedures that inform the prosecutor of *notitia criminis* are the complaint and the lawsuit.

The former is distinguished from the latter, because it presents to the Public Prosecutor a crime or a violation for which the law provides for a punishment "at all costs", and so ignores the will of the person harmed by the offense.

The lawsuit, instead, is represented in full by the willingness of the victim, who desires that the guilty person be punished (for example, personal injury pursuant to art. 582 c. p.).

If the person harmed by the offense decides to discontinue criminal proceedings against the offender, he can do so by extinguishing every action of a punitive nature.

In a criminal trial, the victim may claim compensation for damages by activating the civil action in court, but this has to be done by the lawyer who will represent him.

11.3.2 Civil Medical Responsibility

As mentioned above, other than a penal liability, a civil liability is also taken into consideration by the Italian system.

The doctor is obliged to compensate the damage caused to his client in all cases where there is a discernible fault.

It is distinguished from a professional liability tort (art. 2043 c. c.) and a contract (art. 1210 c. c.). In summary, contractual liability is in the presence of a pre-established type of relationship and this contractual liability obeys the general principle of *neminem laedere*.

The assumption of liability is the existence of a compensable damage. The assessment of civil liability is intended to shift the cost of damage from the person who has unjustly suffered to the subject who is held responsible. No doubt has ever arisen in cases where the doctor acted as a totally autonomous and independent practitioner, who is obligated in this case to respect a contractual relationship.

Initially, the relationship between the physician employee of a health facility (public or private) and patient was setup by law in contractual terms, on the grounds that the only contractual relationship was that established between patient and healthcare facility.

Based on a note of the Supreme Court in 1999, the relationship between the patient and physician-employee of a health facility is considered to be outside the scope of contractual liability.

According to the landmark verdict (Supreme Court sent. n. 589 of January 22nd, 1999), the responsibility of the physician, acting as either an employee of the NHS or as a freelancer, is always contractual, since these roles essentially involve identical practices.

The physician and patient are united by a contractual relationship stemming from social contact.

According to the principle of contractual obligation, the physician agrees with the patient not to guarantee the result of healing, but rather to use the most

appropriate means that medical science makes available to achieve the result. In some areas of medicine, however, the two requirements coincide (e.g., in esthetic medicine).

When an unfavorable result occurs, it has to be proved that it is related to the professional conduct of the doctor. Under Italian law, in the event of contractual liability, the damage is a consequence of the failure, the limitation period is 10 years, the damages recoverable are those expected at the time when the debt was incurred, and there is a burden of proof.

In the case of extra-contractual liability, in which damage is the result of an illegal episode, the limitation period is 5 years, the damages recoverable are predictable or not, and the burden of proof is up to the victim.

As for the burden of proof in the case of contractual liability, it is borne by the debtor (in this case the doctor), who is required to prove that the alleged failure (according to the creditor, who has suffered some kind of damage) is due to reasons that are not attributable to him/her. Otherwise he/she is liable to pay damages.

In the case of tort the burden of proof is borne by the injured person, who is required to prove infringement, damage, and the existence of a causal relationship (art. 2697 c. c.).

The aim of the Italian civil law is to compensate the damage to the person and to restore the situation that existed before the damaging event. Therefore, the compensation must be in a specific form and when this is not possible (as in the case of personal injury) it must be in an equivalent form. In the context of civil liability, art. 2226 c. c. involves the anchoring of the physician's responsibility to malice or gross negligence, but only in cases of special difficulty. In "normal" cases the responsibility is extended to include mild negligence.

This approach is now more established and also operates upon the reversal of the 'burden of proof' (Cass. Sez. III Judgment n. 9085 of April 19th, 2006, Case n. 23918 of April 18th, 2006).

Regarding the causal link it is necessary to remember what is indicated by Cass. Section III, Case n. 7997 of April 18th, 2005.

It sets out the following principles:

1. the causal link is a structural element of the offense that runs between a behavior (the author of the act) and the event;
2. identification of the primary relationship between behavior and event, disregarding in the first instance any assessment of predictability;
3. the causal link between conduct and material event is one which has been generated by each prior behavior, or has even been contributed to, by the fact that the objective report should be considered the "cause" of the event itself;
4. legal causation is, conversely, the etiological report of the facts as they occurred in order to determine whether they fit the event or break the link with the fact of all previous causal antecedents;
5. assessment of legal causation must be made according to the criteria
    a. of scientific probability (where this appears exhaustive),
    b. of logic, if invoking the laws of scientific probability is not feasible.

The existence of the causal link between a medical procedure and the injury that must be proved by the injured person, permits the logical and chronological identification of the subjective element of the offense, namely the existence or not of the guilt of the agent that, in spite of a proven causal link, could be independently excluded according to criteria of predictability and avoidance.

The functional criteria of the determination of medical negligence are those

1. of a contractual nature;
2. whether or not there has occurred a worsening of the patient's condition;
3. assessment of the degree of guilt;
4. the proper performance of the burden of information and the existence of the subsequent consent of the patient.

In the next verdict (n. 975/2009) the principle of "more likely than not" was established, in terms of causation, by the membership of the Supreme Court.

In specific terms this means that the proof of a causal link between the conduct and alleged harm in criminal cases should be in terms of near certainty, while in civil cases it should be in terms of probability.

This has resulted in a further increase in claims so as to force a de facto legislature to enact a law on the so-called compulsory conciliation media, precisely in order to reduce the litigation in this area.

The D. Lgs. n. 28 of March 4th, 2010 that came into effect from March 1st, 2011 after a heated debate, which had a strong opposition on the part of the Italian Advocacy, is pending before the Constitutional Court owing to objections of unconstitutionality having been raised.

It is therefore impossible to evaluate the effectiveness of this new legislation.

The major reason for criticism of D. Lgs. n. 28/2010 is the principle according to which the experience of the mediation process is imposed as a condition of a claim's admissibility, with the inclusion of a specific system of sanctions.

Another interesting development is the national and regional legislation regarding clinical risk, which led to the publication of guidelines that have been developed with the dual aim of rationalizing the use of health resources and of directing medical choices.

Their acceptance cannot be unconditional and must be subjected to critical analysis and possibly limited.

However, they seem to be a useful tool not only for the forensic evaluation of cases of alleged medical liability, but could be a useful tool for collaboration with the forensic point of view for the prevention of litigation.

11.4 *Nomofilattica* and Professional Medical Liability

One peculiarity of the Italian legal system is the "nomofilattica function" or "nomofilachia", which is the duty to "ensure the exact observance and uniform interpretation of the law, the unity of the national objective law" that art. 65 of the Law on the Judiciary (R.D. 30 January 1941, n. 12) assigns to the Supreme Court.

Therefore, the jurisprudence of Cassation represents an essential reference point for the coroner as well as the magistrates involved in the various levels of courts in cases of medical professional liability.

Judgments of the Criminal Appeal, therefore, have repeatedly made reference to the criterion of beyond reasonable doubt, finally acknowledged in the decision of the United Sections Criminal no. 30328 of 2002 (commonly known as a Franzese ruling, its name being derived from that of the accused doctor).

Following this ruling other judgments of the Supreme Court have confirmed this principle (Cass. Pen. n. 32494/2004, Cass. Pen. Section IV, Judgment March 11th, 2009, n. 10819, among many others).

The Supreme Court has also addressed other recurring problems within the area of medical professional liability, indicating the fault lines of interpretation such as, for example, in the case of medical responsibility of a team (the principle of the error and clear the principle of custody Cass. Pen. Section IV sentence July 12th, 2006, n. 33619) and the relation between failure/lack of informed consent and involuntary manslaughter. In this context, the verdict that has effectively established the principle that the lawfulness of the medical act involves the consent of the entitled person is the Massimo ruling, named after the condemned surgeon in the case.

In this sentence (Cass. Pen, Section V, April 21st, 1992, n. 5963) a doctor was convicted of manslaughter for the first time in Italy.

From this verdict others have resulted, which are well known and have been commented upon (the cases, always taking their names from the doctors charged, of Barese, Cicarelli, Firenzani, Volterrani, Caneschi, Huscer, Ruocco, and Giulini). There is a very strong debate among both lawyers and legal doctors about the value that should be given to consensus in the field of penal liability.

The decision cited above of Giulini on December 18th, 2008 is particularly important, because the United Sections have dismissed the relevance of the criminal conduct of the physician who performs surgical treatment on a patient which is different to the one for which informed consent has been given, in the case where the surgery, performed according to protocols and *leges artis*, is successfully concluded and from which an appreciable improvement in the patient's health condition is derived, also in relation to any conceivable alternatives and without indications contrary from the same patient.

The ruling calls for legislative intervention, introducing into the Penal Code the crime of arbitrary medical treatment.

However, there were no legislative responses.

In the Parliament a number of draft laws lie in this area and these include, among the DDL unified n. 153, "New rules of professional responsibility of the physician".

The recent decision n. 34521/10 of May 26th, 2010 known as the Huscher case, has introduced a further element of discussion in this area by even providing the potential for a mere possibility: "... the inevitable consequence in law is that he who violates in body and mind, without any justification, the person of the patient commits the typical fact of murder or an injury or even the crime of voluntary

manslaughter, if the doctor does not act with the therapeutic intentions and accepts the negative and potentially grave consequences (in this case the crime can even be punished as a possible fraud)...".

The ruling limits the validity of the unwritten consensus of exemption from liability in the event of surgical procedures that are not justified by the prevailing surgical and experimental practices, the former being unacceptable because they do not have a realistic chance of success or extension of survival.

In conclusion, the criterion of reasonable doubt must therefore be an essential tool of the medical examiner who shall, if the question can not be resolved, notify the client so that he/she can make informed assessments about the evidence acquired and their value for the purposes of the claim, which is placed below or above reasonable doubt.

It is a problem that occurs in all of the coroner's activities, whether in civil or social security, but in a penal context it is of the utmost importance in all of the services and those relating to crime victims, both those concerning the eligibility of the authors and application of security measures.

11.5 Methods of Ascertainment and Evaluation Criteria

Once the medical mistake is identified it is essential to ensure the existence of a causal link between mistake and the damage sustained by the patient (personal injury or death) in accordance with the requirements of art. 40, 41 and 45 c. p. First of all, it is appropriate to recall the main theories of causation which dominate the landscape of legal scholarship.

Many theories of causation in law contain the assumption that an event is preceded by a complex of antecedents, including those necessary for the identification of the one attributable to the person, that is *the human action responsible for the fact*. The solution of the problem is conceptualized in two ways: either assign an equal value to all the antecedents, which are in this way equal with respect to the law (*criterion equivalence*), or attribute to them a decisive value in the production of an event (*criterion of prevalence*).

- **Theory of equivalence or *condicio sine qua non*:** this theory identifies the cause with the totality of the antecedents, each of which is necessary when the event occurs. The causality is permissible as long as it is made prior to any condition necessary to represent the occurrence of harmful consequences to the person. The theory of equivalence, although it is an exact natural term, has the disadvantage of leveling-off all prior advances, without distinguishing between causes, concurrent causes, conditions, and opportunities or including in the causal circumstances any kind completely unrelated to those human factors on which criminal liability should be based.
- **Theory of prevalence:** the theories that are based on this theory are those which seek to identify the real cause of the condition and opportunity by differentiating

between qualitative and quantitative criteria, identifying among the various antecedents of a fact the one that has exercised the decisive role.

- **Theory of adequate causation or *id quod plerumque accidit*:** in this theory there is an assumption that human behavior is considered to be caused only by those effects that at the time could be considered likely and not by those of an extraordinary, exceptional, or atypical nature. The theory excessively restricts the field of criminal liability, as it excludes the causal connection between the fact and the consequences when the latter, although depending on the fact, were presented as quite exceptional cases and highly atypical at the time they had to be implemented.
- **Theory of human causalness:** according to this theory any human behavior would be considered as a cause, without which the event would not have occurred, provided that the latter is not due to the intervention of exceptional factors, which cannot be eliminated, because of the inability of the human agent to govern the etiologic course of his conduct, through his/her cognitive and volitional powers. Man is responsible for something when the basis of the chain of events is his free action, free will, so that there *is a choice*.
- **Theory of causality according to subsumption under the laws of science:** according to this theory any event prior to the event can be considered the sole cause of the event, because the etiological connection is adequately supported by scientific laws. This theory perfects the conditional one, in the sense of the counterfactual impress of the opinion based on scientific laws. Such laws are in fact possible to verify if, the action or omission of the agent being removed, the event would not have occurred (assuming causality) or if the event itself would have occurred anyway (causation excluded).

The Italian legal system has taken art. 40 and 41 c. p. *the theory of the condicio sine qua non.*

According to art. 40 c. p., the relevant penal conduct can be by commission (the consequence of an action) or by omission (the result of a failure).

In Italian law this article serves as the glue between the action or omission and the event, by identifying the realization of the second consequence from the first.

The assessment is based on the study of the human conduct of the physician and it requires knowledge of the cause as the etiological factor necessary and sufficient in itself for the implementation of a harmful event.

We talk about concurrent cause pursuant to art. 41 c. p., if they are able to alter the causal connexion, causing failure by influencing, contributing, or even erasing the correlation between the act or omission and the realization of the event.

In the presence of a study of a cause or multiple causes, the etiological reconstruction of the medical conduct remains a very complex study, where, beyond an obvious behavioral deficiency, an accurate analysis of clinical data should be carried out with the most careful contextual comparison of scientific data. The forensic investigation should be based on cogent analysis of the real problem, according to an appropriate methodological rigor.

The methodology of the study is focused on demonstrating the causal relationship between material action (or its omission) and its legally relevant harmful consequences.

In the criminal investigation the assessment of evaluation of medical conduct starts first with an epicritic diagnosis, both on the living and on the corpse. When a cause of death or injury has been identified it is then possible to evaluate the appropriateness of the healthcare conduct in relation to general standards of conduct expected by the international scientific literature (guidelines, consensus conferences), evaluating their application in this case (age and sex of the patient, concomitant diseases, etc.).

Any violation of the rightful rules must then be placed in causal connection with the injury or death of the patient.

To meet this last step, the coroner can and must rely on expert advice (gynecological, orthopedic, surgical, etc.). In fact, the investigation conducted by the coroner in the reconstruction of criminal etiology must satisfy the principle, according to which a criminal sentence must be issued beyond a reasonable doubt (533 c. p. p.).

In the Italian legal system the judgment of penal responsibility of the physician is up to the judiciary, who may use a technical advisor in the case of prosecution or an expert in the case of judging judiciary.

The consultant or expert are not necessarily required to be specialists in forensic medicine, nor is the use of a panel of specialists in various fields mandatory in the case of particularly complex problems, despite the indication in the code of medical ethics (art. 62 C.D. of 2006).

Until the 1970s, the legal guidelines were based on a "special favor" toward the medical profession, whereas in the next decade there was greater severity towards the work of medical practitioners, with the development of so-called defensive medicine in analogy to that observed in other countries.

A new orientation of the judiciary has recently appeared, according to which the penalty of incorrect medical professional conduct is subject to the attainment of the certainty of the case on the evidence of guilt "beyond a reasonable doubt".

This expression is included in art. 366 c. p. p. (as amended by L. February 20th, 2006, n. 46, art. 5).

This term is contained in art. 66 of the Statute of the International Criminal Court (Rome, July 17th, 1998), ratified by L. n. 232 of July 12th, 1999.

In the context of criminal liability, such medical criteria have to be used both in providing technical advice on guilt and technical advice on the causal link.

To the consultant/expert are not granted, if not at the preliminary stage of his analysis, possibilistic perspectives of low or medium probability, but findings and conclusions which then allow the judge to rely on them for the purpose of "procedural certainty".

In forensic practice, the application of these methodological rules is complex, although unitary; in most cases, the real opportunity to recognize and prove—not hypothesize or assume—a real responsibility on the part of the healthcare conduct

is small because, in many cases, it can be extremely difficult to distinguish culpable conduct from an excusable error.

In civil law the assessment follows the same pattern of investigation. The main difference with respect to the criminal investigation is that there is a "weaker" causal link, subject to the criterion of "more likely than not" and the quantification of biological damage.

The Italian Republic recognizes and guarantees the inviolable human rights (Article 2 of the Italian Constitutional Charter). Included within this scope is the right to health protection, which is defined as a fundamental right of the individual and collective interest (Art. 32 Italian Constitution). Having said that, we can appreciate how the compensation of the damages to the person becomes, in view of the Italian legal system, both an individual and social interest to be protected from all hurt and to receive reparation in case of injury.

In the past, pecuniary damage, in the vast field of personal injury, was distinguished from non-pecuniary damage. As part of this distinction, the traditional interpretation of Article 2059 of the Civil Code defined the non-pecuniary damage as a mere pecuniary damage. Therefore, the impairment of the health of the subject did not receive any sustenance. The first Court to sanction the refundable nature of the biological damage was the court of Genoa (the judgment of October 20th, 1975, GI 1976, I, 2443, and December 15th, 1974, FI 1976, I, 1997).

The real change came with the decision of the Constitutional Court 184/1986, where good health was recognized as a fundamental right of the individual. From this decision emerged the concept of the refundable nature of good health, regardless of the subject's ability to work to produce income. The combined interpretation of this sentence with art. 2043 of the Civil Code led to the concept of biological damage. Later, with the introduction of the "twin judgments" (Civil Court of Cassation., Section III, May 7th-31st, 2003 n 8827 and 8828) of 2003, article 2059 of the Civil Code was given a new interpretation. In the area of non-pecuniary damage, regarding any and all damages which are not susceptible to economic evaluation, existential damage was included. This type of damage was better defined in the historic judgment of the Constitutional Court (November 7th, 2003, No. 233), in which it was stated that the categories of harm that fell into 2059 cc were subjective moral damage, biological damage and the damage caused by the injury in existential terms.

A number of judgments of the Court of Cassation followed on the ontological value of non-pecuniary damage.

However, doubts persisted about what should be meant by the category of existential damage; also, it was not clear whether this figure, if any, could be combined with the biological damage (defined as a breach of the right to health, ex art. 32 of the Constitution) and non-pecuniary damage (defined as transient psychological disturbance).

In 2008 the Court of Appeal (Civil Court of Cassation, ON, December 11th, 2008, No. 26972, 26973, 26974, 26975) argued that non-pecuniary damage, pursuant to art. 2059 cc, cannot be divided into various asset damages, but must be considered as essentially unique.

The subcategories of existential and moral damage have been abandoned, because only the verification of the injury of the inviolable rights of the person is necessary. In addition, the interpreter must follow article 2059 of the Civil Code with inviolable constitutional rights, which are not intended as *an numerus* clauses: protection is not restricted to cases of inviolable rights of the person expressly authorized by the Constitution in this historical moment, but, by virtue of the opening of article 2 of the Constitution to an evolutionary process.

These judgments deny the existence of autonomous existential damage and moral damage, while acknowledging the existence within the biological damage of "existential" prejudices concerning relational aspects of life.

The main focus of forensic evaluation is therefore the biological damage. The cardinal principle in the assessment of biological damage is the globally accepted concept of health, as formulated by the World Health Organization as "a state of complete physical, mental and social well-being." Thus, it is clear from this definition that health is not understood exclusively in terms of absence of disease or infirmity. In fact, a new concept of health has emerged from the analysis of this definition, in terms of assessment of biological damage: the understanding of health as a balance of biological and psychological functions, integration into society and the moral aspect of the inner life. Therefore, the sense of well being, resulting from an optimal state of health is important in the regulation of human actions. In this scenario it is clear that the possible lack of individual well being leads to repercussions from the utilitarian point of view in the life of the individual to which it is inextricably linked.

The legal concept of biological damage means the damage as a breach of the right to health considered as a primary good. To this notion is added the medical profile, which considers the damage as the psychic and physical damage in itself. In the definitions given above it is clear that the assessment of the damage is beyond the ability to produce income (as was the case in the past), but refers to the person's physical or mental injury as such.

Concerning Italian law, it was necessary to transfer the universal concept of health to the quota of damages suffered by adapting to the rule of law, in order to make a qualitative and quantitative assessment of the overall damage to health. Therefore, in view of the Italian legal system, the biological damage is inevitably bound to the equipment and impairments of explicit functions in everyday life. Biological damage is described as physical and/or mental disability with the following characteristics:

1. is a given-event itself constituting the parameters under which other components are further damaged;
2. is refundable in any case, even when it does not affect the ability to produce income;
3. is evaluated in its entirety by considering the lifestyle of everyone (social, cultural, recreational);
4. is compensated using an egalitarian criterion, regardless of any circumstance or consequence.

To quantify and qualify the biological damage the coroner must determine: the nature and extent of injury, duration of the total temporary or partial disability, the degree of permanent disability (i.e., the impairment of the physical and mental integrity of the subject himself and its impact on their activities and social life). Therefore, in the evaluation of the biological damage the duration of disability (temporary or permanent), considering the activities of the individual both potential and actual (leisure, social life, etc.), must be taken into account. Temporary disability means the suspension of all activities of the entity during the period of illness and convalescence, considered as full or partial, depending on the degree of inactivity of the individual himself. Instead, permanent disability is defined as the result from the stabilization of the disease in the aftermath or of the chronicity of said disease in psychophysical terms. In case of multiple impairments, the degree of disability does not correspond to the sum of individual percentages, but it is assessed based on the overall decrease in production capacity. Forms and coefficients of personal injury are those factors that are thought to refer to the individual's physical, psychological sphere (biological damage), and other factors that give an economic value to man, because directly productive of income or potentially profitable, since they allow large expressions of personality (*Puccini: the assessment of biological damage*).

Therefore, biological damage is compensable in the current system according to the definition of Article 32 of the Constitution (which protects the right to health) and Article 2043 of Italian Civil Code (which governs the tort liability). In fact, it states that any damage, albeit willful, negligent, or unlawful must be compensated by the person who has caused it. Compensation tends to restore the balance sheet of the injured, restoring the economic situation that existed before the unlawful act that caused the damage. The liquidated damages will be governed by Article 2058 of Italian Civil Code and can happen in two ways: in *specific form*, through the return, the replacement or repair of the damaged thing, or its equivalent. In the case of personal injury monetary compensation is used, which is based on the assessment of liability and the amount of damages. Therefore, the compensation must take into account both the economic loss suffered from loss of income and the restoration for damage to health (art. 1223 cc).

For liquidation purposes the disabilities are expressed in percentage points and evaluated with reference to the existence of a tabular date. The tables refer to the impairment of organs and/or equipment. Recently, the national legislature has introduced innovations in this field, inserting D.L. n. 70 of March 28th, 2000 and the "micro-permanent" law of 57/2001, which is the biological consequence of a permanent nature valued in a range between 1 and 9 %. The rates over 9 % are defined as macro-permanent. Tables have been developed in order to know the translation of monetary tables of damage, including the most famous of the Court of Milan that was introduced in the 1990s and is still up-to-date. Recently the Supreme Court (Civil Court of Cassation, Section III June 12th, 2011, n.12408) established the principle that the liquidation of non-pecuniary damage to the person from physical to mental damage requires the adoption of the Tables on the

merits of the Court of Milan by all judges as the only yardstick to be taken into account throughout the national territory.

Within non-pecuniary damage moral damage is added, which is regarded as unjust disturbance of mood, of an impermanent nature, affecting the inner sphere of the injured. This damage does not have tabular references and is assessed on an equitable basis by the judge.

11.6 Future Perspectives

Italian forensic medicine has attempted, on several occasions, both through its scientific society and through the contribution of its teachers, to indicate a methodology-evaluation of professional liability established according to the modern principles of the Consensus Conference and the publication of shared guidelines. However, these efforts have still not been successfully accepted by all.

It should be added that there is not yet full doctrinal agreement on what constitutes a medical error, what its constituent characteristics are and what constitutes the evaluation criteria of reference.

We often have the impression that forensic evaluations regarding the qualification of the error are marked by an excessive subjectivity of interpretation.

An important factor is the use of the best scientific literature references based on the principle of meta-analysis (in accordance with the legal principle of subsumption under laws of science).

But forensic reports do not always make use of this tool.

Recently, legal medical doctrine, also at the urging of the scientific reference, indicated the use of guidelines and protocols as a logical path, indispensable for reducing the vagueness of the classic categories of fault (precisely defined as generic): imprudence, incompetence, negligence.

However, the most recent criminal jurisprudence does not seem to accept this criterion.

The Judgement n. 1873/2010 of the IV Criminal Court of Cassation annulled the acquittal decision in favor of a cardiologist who had dismissed a patient in accordance with guidelines, which resulted in the death of the patient a few hours later at his home, criticizing the use of uncritical and scientifically justified guidelines without a proper assessment of the health status of the patient who was dismissed.

If we also add those lengthy trials involving both criminal and civil matters, the perspective given is that of a system of often contradictory sanctions, with serious consequences for both the medical profession and health expenses.

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Chapter 12
Medical Responsibility and Liability in Lithuania, Latvia and Estonia

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Abstract This chapter includes three subchapters, specifically devoted to Lithuania, Latvia and Estonia. *Lithuania*: this subchapter begins with an overview of the judicial and normative situation regarding medical liability in Lithuania,

Editors' Note: Lithuania, Latvia and Estonia are countries traditionally lacking a solid background in management of medicolegal cases involving alleged malpractice. The information resulting from the practice in use within these settings is the consequence of a context not comparable with the European level in the field.

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discussing judicial/extra-judicial institutions and operative roles within that context. The second section of the subchapter describes the ascertainment methodology for living persons and cadavers in Lithuania, while the third section examines the evaluation criteria. The subchapter ends with a discussion on the future perspectives for medical liability in Lithuania. *Latvia*: the first section of the subchapter contains an overview of the legislation governing the medical practitioner's liability and is followed by a description of the extra-legal activity in Latvia. The main section of the subchapter outlines the ascertainment methodology for living persons and cadavers in Latvia, while the fourth section examines the evaluation criteriology currently in effect. The subchapter ends with a discussion on the future perspectives for medical liability in Latvia. *Estonia*: this subchapter begins with a judicial and normative overview of medical liability in Estonia, while the second section outlines the judicial/extra-judicial institutions and operative roles. The third section details the ascertainment methodology, in Estonia, for living persons and cadavers, while the penultimate section focuses on the evaluation criteria. This subchapter ends with a discussion on the future perspectives for medical liability in Estonia.

Contents

12.1 Medical Responsibility and Liability in Lithuania

12.1.1 Judicial and Normative Overview

Recently, the issue of medical malpractice and professional responsibility has become of critical importance. Cases of medical malpractice occur nearly every day in considerable numbers. The effectiveness of evaluation and reduction of this situation could be achieved by increasing discussion between doctors, lawyers and third-party insurers about the nature and numbers of undesirable occurrences and their legal consequences (Caplinskiene and Pauliukevičius 2008; Mulheron 2010). The quality assurance and improvement of patient safety have become a focus of attention (Eisenmenger 2007).

Specific norms and legislation related to medical responsibility exist in Lithuania, The Law on Patients Rights and Compensation for Medical Injuries of the Republic of Lithuania (Law 102-2317; Law 115-4284) and the Penal Code. Medical Responsibility is handled through the Judicial System in Lithuania in Penal and Civil areas. The rights of patients are regulated by the Constitution of the Republic of Lithuania, the Civil Code of the Republic of Lithuania, the Law on the Rights of Patients and Compensation of the Damage to their Health and other laws and legal acts.

Lithuania has ratified many international conventions relating to this field, such as the Convention on Human Rights and Biomedicine, the Ljubljana Charter, the European Convention for the Protection of Human Rights and Fundamental Freedoms, etc.

A patient has the right to qualified and accessible health care; to correct and understandable information about the healthcare system, healthcare services and opportunities to make use of them; to select a physician, medical services, nursing staff member, diagnostic and treatment methods and a healthcare institution; to information on his or her health, medical examination results, treatment methods, and treatment prognosis; to refuse to participate in the instruction process, scientific and medical experiments; to refuse treatment; to be informed of the name, surname, position and qualifications of the physician treating him or her and the nursing staff member nursing him or her; to make a complaint against the healthcare institution or the physician treating him or her; to inviolability of personal privacy; to compensation of the damage to health due to the fault of a healthcare institution.

12.1.2 Judicial and Extra-Judicial Institutions and Operative Roles

In Lithuania judicial cases are handled after the pre-trial investigation is completed and the case is submitted to the court. In Civil Law judicial cases are handled when settling the civil claim in court. The extra-judicial cases are handled during the

process of pre-trial investigation (when the case is settled prior to trial and the case does not reach the court) as well as during the Commission on Evaluation of Damage to Patients Health meetings (determination of the amount of compensation for damage to health) (Law 22-678). The Medico-legal Professional becomes involved in death and judicial cases as well, including other medical specialists of respective spheres.

The State Medical Audit Inspection examines violations of patients' rights and evaluates the quality of the healthcare specialists' work. The Commission on Evaluation of Damage Inflicted upon the Health of Patients under the Ministry of Health examines disputes regarding compensation for the damage made to patients. The Commission decides whether the damage was made to a patient in a healthcare institution and, if yes, the amount of compensation he or she must receive (Law 22-678; Law 16-565).

12.1.3 Ascertainment Methodology

12.1.3.1 Living

In Lithuania there are no operative Guide Lines and Protocols regarding ascertainment methods in the case of malpractice involving a living party. There are no recommendations in these situations as to which method to use. The injured party undergoes a medical visit and/or evaluation. The evaluation is done by the clinician's related area. This is considered a medico-legal evaluation. An evaluation is done by a medical specialist in the area of the presumed medical error together with clinicians. The examinations are carried out by clinical-documental, clinical-anamnestic, clinical-objective and non-invasive and radiological instrumental assessments (with ionised and/or without ionised radiation). Only medical specialists' actions are evaluated, whether the doctor's behaviour is adequate to the guidelines of the treatment.

12.1.3.2 Cadaver

In the case of malpractice resulting in death operative Guide Lines and Protocols regarding ascertainment methods exist. The algorithms on the treatment of different diseases and pathological states are issued and approved by the Ministry of Health of the Republic of Lithuania and in particular hospitals (not in all hospitals). The recommendations exist regarding the methods to use in these situations. These recommendations are in forms like the algorithms on the treatment of different diseases and pathological states and are approved by the Ministry of Health of the Republic of Lithuania and in particular hospitals (not in all). The deceased sometimes undergo an autopsy and this decision is followed by the order established by the Ministry of Health of the Republic of Lithuania. There are no pre-autoptic exams like

the body CT, NMR or Ecography carried out. The autopsy is done by the medico-legal expert, forensic pathologist and anatomo-pathologist. During the post-autoptic exams the histological and toxicological investigations are carried out. Forensic medicine experts, together with clinicians, answer the questions provided by legal institutions (pre-trial investigation officers or the court). The issues with regard to guilt and responsibility are considered by legal institutions.

12.1.4 Evaluation Criteria

12.1.4.1 Living

In the case of malpractice involving a living party there are no operative Guide Lines or Protocols regarding evaluation criteriology. Recommendations exist as to the evaluation criteria to be used in these situations in Lithuania. The algorithms on the treatment of different diseases and pathological states are issued and approved by the Ministry of Health of the Republic of Lithuania and in particular hospitals (not in all). The physiopathology of the injury or disease is reconstructed by the medico-legal expert or other medical specialist of a related area. The presence of error and/or misconduct in the medical and non-medical professionals is identified by the legal doctor or other medical specialist.

In order to define "good clinical practice" or "standard of care" different references are used, such as the Guide Lines/Recommendations of International Scientific Societies, Guide Lines/Recommendations of National Scientific Societies, Scientific evidence derived from International Literature, Scientific evidence derived from National Literature, Algorithms on the treatment of different diseases and pathological states issued and approved by the Ministry of Health of the Republic of Lithuania in particular hospitals (not in all hospitals).

The definition of inobservance of medical conduct is determined by non-compliance with Guide Lines of International Scientific Societies, Protocols of International Scientific Societies, Recommendations of International Scientific Societies, Guide Lines of National Scientific Societies, Protocols of National Scientific Societies and Recommendations of National Scientific Societies.

Only medical specialists' errors are evaluated. Medical error is defined as a medical doctor's actions causing worsening of the patient's health or death, which (i.e. worsening of the patient's health or death) are not considered as a natural complication of a particular disease or trauma, and which are commonly avoided.

Medical error is classified into categories which are commonly employed, such as diagnostic error, prognostic error, therapeutic error, delayed diagnosis and delayed therapy. The existence of an error does not always imply the guilt of the medical professional. The causal link between error and patient injury is evaluated, but not always. This causal link determines or evaluates the medico-legal expert, other medical specialist, non-medico-legal institutions or others, such as the State

Medicine Audit Inspection under the Ministry of Health of the Republic of Lithuania.

Only the biological damage to the patient is evaluated. The biological damage/injury is evaluated by a medico-legal expert, another medical specialist, lawyer, insurance professional or the State Medicine Audit Inspection under the Ministry of Health of the Republic of Lithuania. Non-biological damage/injury is evaluated by the medico-legal expert or lawyer.

12.1.4.2 Cadaver

In the case of malpractice involving death no operative Guide Lines and Protocols regarding evaluation criteria exist in Lithuania. Nor there are any recommendations regarding the evaluation criteria to be used in these situations.

The physiopathology of the Injury/Diseases of the deceased is reconstructed by the medico-legal expert, anatomo-pathologist or other medical specialist. The presence of error and/or misconduct in the medical and non-medical professionals is identified by the medico-legal expert or other medical specialist.

There are different references, such as Guide Lines/Recommendations of International Scientific Societies, Guide Lines/Recommendations of National Scientific Societies, Scientific evidence derived from International Literature, Scientific evidence derived from National Literature, which is used to define "good clinical practice" or "standard of care".

The definition of inobservance of medical conduct is determined by non-compliance with Guide Lines of International Scientific Societies, Protocols of International Scientific Societies, Recommendations of International Scientific Societies, Guide Lines of National Scientific Societies, Protocols of National Scientific Societies or Recommendations of National Scientific Societies.

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12.1.5 Future Perspectives

In the present situation aspects of quality assurance and improvement of patient safety have become the focus of attention. Priority must be given to investigations

based on the use of new technology (Recommendation R99; Pauliukevičius and Caplinskiene 2004, 2007).

A better management of the information transfer process in order to facilitate exploitation of academic research with the potential application in medical malpractice evaluation should be envisaged. An uninterrupted access to the full range of forensic and legal medicine services of the required quality standards should be facilitated (Caplinskiene and Pauliukevičius 2008).

The medical malpractice reporting systems must be promoted by uniform medico-legal guidelines, approved and adopted by the European Medico-Legal Community.

12.2 Medical Responsibility and Liability in Latvia

12.2.1 Legislation Governing the Medical Practitioner's Liability

Quality of health care and the liability of medical practitioners in Latvia are regulated by:

- latvian Constitution, where article 111 defines that the state shall protect human health and guarantee a basic level of medical assistance for everyone;
- medical Treatment Law states that everyone has the right to receive emergency medical aid in the order stated by Cabinet of Ministers and that the medical practitioner has a duty to grant first and emergency aid;
- regulations No. 1046 issued by Cabinet of Ministers as of December 19th, 2006 "Order of health care organisation and financing", which defines the nature and scope of medical services which are paid by state budget and by means of a recipient and regulates the services mentioned, as well as regulating on how centralised shall be organised the rows for reception of the planned healthcare services;
- personal data protection law, where information regarding the health of a person and his/her sexual life are admitted as sensitive data and permission for the processing of this data is received only in special cases; rules of law are also applied to medical practitioners and establish a duty to observe confidentiality, if such data has become available;
- the quality of professional and working expertise of health care in Latvia is controlled by the Health Inspectorate, acting under the Ministry of Health.

The Health Inspectorate reviews and inspects applications submitted by physical and legal persons on the quality of health care, applications on substantiation of the issued sick list, assesses the conformity of medical establishments to the requirements of legislation, etc. Certified medical experts work in the Health Inspectorate who give expert opinions on the revision results of each application

and adopt decisions according to the Administrative Procedural Law—declared or undeclared performance violations by medical practitioners—decision on termination of administrative cases or decisions, on application of administrative penalty according to the Latvian Administrative Violation Code. According to the rules of Administrative Procedural Law the adopted decision can be disputed by Head of the Health Inspectorate and in Administrative Court.

During expertise doctors from the Health Inspectorate request and analyse all the necessary medical documentation, clarifications are obtained from the medical personnel and the expert's opinion is prepared. For the preparation of the expert's substantiated and objective opinion in complicated cases the necessary specialists are invited.

Latvian Administrative Violation Code, Chap. 5, define "Administrative Violations in the Protection of Labour and Citizens Health":

- section 45 of the Code, anticipates a fine up to the amount of LVL 250 (in the case of a person who is not educated in medicine, but who performs private medical treatment which is not registered in the order stated by legislation);
- section 45.1 of the Code anticipates a fine up to the amount of LVL 500 in the cases of violations related to medicinal care, medical opinions and expertise;
- section 45.2; 45.3 of the Code anticipates a fine up to the amount of LVL 250 in the cases of illegal release of confidential information obtained in a process of medical treatment;
- criminal liability of medical practitioners in Latvia is defined in chapter XIII of the Latvian Criminal Law—Criminal offences against the Health of a Person—CL section 138, Improper Performance of Professional Duties by a Medical Practitioner: if the medical practitioner fails to fulfil professional duties or negligently fulfils such duties, if it has resulted in the infection of the victim with human immunodeficiency virus or hepatitis B or C virus, or has been the cause of the death of the victim, the applicable punishment is deprivation of liberty for a term not exceeding five years, with or without deprivation of the right to engage in the practice of medical treatment for a period not exceeding five years;
- section CL 141 defines criminal liability for *Abandonment without Assistance*, for a person who knowingly commits abandonment without assistance of a person who is in a state in which their life or health is endangered and who is unable to save him/herself due to his/her juvenility, old-age, illness, or feebleness, if the offender was able to provide assistance to the victim and had an obligation to take care of him or her, or if the offender him/herself has put the person in the life-endangering state;
- Section CL 139 defines criminal liability for — *Illegal Removal of Tissue and Organs from a Human Being;*
- Section CL 197 defines criminal liability *on neglect*.

Private persons in Latvia with claims and applications can address themselves to the Administrative and Regional Court on the basis of rules of Administrative Procedural Law and Civil Procedural Law. Section 92 of Administrative

Procedural Law provides that everyone is entitled to claim due compensation for financial loss or personal harm, including moral detriment, which has been caused to him or her by an administrative act or an action of an institution.

Remuneration of losses in administrative procedure is regulated by the Law on Loss Remuneration caused by State authorities, as of July 1st, 2005. The legal act mentioned does not expect a sum for property losses, this is stated by the applicant and the court defines it by using evidence and by taking into account the legal practice. The Maximum amount for personal and moral harm is 20,000 Lats.

In all of the above mentioned cases, before the court adopts the final ruling—in criminal processes against medical practitioners, in administrative and civil processes on property, moral and personal detriment recovery—forensic medical expertise is used where experts of forensic medicine give opinions on the execution of the professional duties of medical practitioners, on whether the medical practitioner or practitioners have violated the treatment, which result in specific consequences.

Pre-trial investigation in criminal procedures is made by the police; the decision on criminal liability is adopted by the prosecutor; but judgement in cases is made by the court.

After the restoration of independence of the Latvian Republic in 1991, with an order issued by the Ministry of Welfare as of December 4th, 1992 and beginning on the January 4th, 1993, the Office of Forensic Medical expertise was restructured as the Latvian Forensic Medicine Expertise Centre. On the February 1st, 2003 the Ministry of Health of LR was established and since then the expertise centre is under the Ministry of Health. The main task of the State Forensic Medicine Expertise Centre is to provide forensic medical expertise to victims and suspects, as well as medical expertise concerning the dead in criminal, administrative and civil procedures on the bases of decision of proceedings or court. Experts of the Centre provide expertise on possible negligence of professional duties by medical practitioners. All of this expertise provides for an expertise commission, which invites the necessary specialists from other branches of medicine.

12.2.2 Extra-Legal Activity in Latvia

On the December 17th, 2009 the Law on the Rights of the Patient was adopted, which came into force on the March 1st, 2010. The purpose of this Law is to promote favourable relationships between a patient and the provider of healthcare services, facilitating active participation of the patient in his or her health care, as well as providing him or her with an opportunity to implement and protect his or her rights and interests.

The law defines that a patient has the right to information regarding the opportunities for the receipt of healthcare services and the procedures for the

payment for healthcare services. This information shall be available to the public. In accordance with the procedures specified in the Medical Treatment Law, each person has the right to receive medical treatment corresponding to the state of health. Medical treatment is permissible if a patient has given informed consent and the patient has rights to refuse treatment by testifying to it with his signature. A patient has the right to choose a physician and medical treatment institution, and has the right to become acquainted with his or her medical documents.

Information regarding a patient may only be disclosed with his or her written consent or in the cases prescribed by this Law.

Section 16 defines that a patient has the right to compensation for any harm caused to his or her life or health, as well as for any non-material damage which has been caused by the medical practitioner working in the medical treatment institution during medical treatment through his or her acts or failure to act. A patient has the right to receive compensation from the Medical Treatment Risk Fund for the following:

1. harm caused to his or her life or health—in the amount of the harm caused, but not more than 100,000 Lats or
2. non-material damage caused to him or her—in the amount of the damage caused, but not more than 5,000 Lats.

The holder of funds and operator of the Medical Treatment Risk Fund is the Health Payment Centre. The decision of the Health Payment Centre and the action regarding remuneration to be paid can be disputed in the Ministry of Health. The decision of the Ministry of Health can be appealed in the order stated in Administrative Procedure Law.

Duties of the patient are also defined by this law.

Independent organisation such as the Patients' Ombud is active in Latvia, which consults, helps to find the solution, makes recommendations to healthcare organisations on quality, issues of patient rights for both patients and medical practitioners, as well as for the specialists of the relevant branch.

The mission of the Ombud is to improve the quality of the healthcare system by promoting positive communication and exchange of information between all those involved in the healthcare system, as well as by processing the feedback received from the clients and personnel, transforming it into recommendations for providers and formers.

The Goal of the Patients' Ombud is to be independent and self-dependent in decisions that are instrumental to the healthcare system. In situations of claims and problems the Ombud wishes to promote the attitude of society, which foresees the possibility of learning from mistakes and making improvements, instead of punishment.

12.2.3 Ascertainment Methodology

12.2.3.1 Living

Patients with claims about healthcare quality, unfavourable process and result of disease (untypical complications, prolonged treatment, invalidity and other) can address themselves to the managers of medical establishments, in regional/city municipal departments, in the Health inspectorate of the Ministry of Health, in law enforcement institutions and to ombudsman.

In certain situations the patient or his relatives have a substantiated desire and the moral right to receive quality assessment of the healthcare received, which also means possible violations of care and the statement of mistakes, which can be the legal basis for claims on remuneration for the health and moral damages incurred.

According to the legislation on Criminal and Civil procedures, by starting the relevant procedure—so called "medical affairs"—the law enforcement institutions determine the forensic expertise commission by involving the relevant specialists (interns, surgeons, gynaecologists/obstetrician, and others). The action of the experts' commission is regulated by the specially accredited "Regulations for execution of commission expertises" of the Council of Forensic Experts, which contain detailed indications on the order of review of documents, preparation of opinion and other indications according to the procedural requirements.

12.2.3.2 Cadaver

Forensic medical investigation according to the decision of the procedures is made on the basis of the accredited "Order of forensic medical inquests performance". If in the autopsy there are objective findings that could be connected to improper health care (defects of medical aid), these facts are specially stipulated in the opinion, but assessment of the quality of the medical care will be given by the experts' commission according to the Criminal procedure Law (section 198) and Law on Forensic Experts (section 12).

12.2.4 Evaluation Criteria

The experts' commission decides on the proper or improper fulfilment of professional duties of the medical practitioners, by comparing the conformity of the exact action/inaction of treatment (assessment of anamnesis, examination of patients for the proper diagnostics, implementation of treatment, rehabilitation and prophylactic measures) with the modern medical scientific knowledge in the relevant subject, with local or international guidelines, governmental laws and

regulations in the field of health care and with job descriptions of medical practitioners.

Medical practitioners, like any public body, are responsible for their own actions in the disciplinary, administrative, civil and criminal order. For the assessment of professional duties performed by the medical practitioners the commission of forensic expertise is mainly assigned to criminal procedures where, with the help of specific knowledge in medicine, liability will be clarified according to section 138 of the Criminal Law, which provides for two levels of liability with relevant sanctions.

Section 138. Improper Performance of Professional Duties by a Medical Practitioner

1. For a person who, being a medical practitioner, fails to fulfil his/her professional duties or negligently fulfils such duties, if such an offence has, due to the negligence of the offender, caused serious or moderate bodily injury to the victim, the applicable sentence is *Deprivation of liberty for a term not exceeding two years, community service, or a fine not exceeding forty times the minimum monthly wage, with or without deprivation of the right to engage in the practice of medical treatment for a period not exceeding three years.*

2. For a person who commits the same offence, if it has resulted in the infection of the victim with human immunodeficiency virus or hepatitis B or C virus, or has been the cause of death of the victim, the applicable sentence is *deprivation of liberty for a term not exceeding five years, with or without deprivation of the right to engage in the practice of medical treatment for a period not exceeding three years.*

12.2.5 Future Perspectives

Assessment of professional duties performed by medical practitioners in relation to criminal aspects is quite a sensitive problem. The practical experience of experts has created doubts as to whether the current criminal regulation in this field is optimal. It is admissible that in relevant cases profound analyses of forensic practice can promote constructive ideas for the improvement of legislation in the future. It is also possible that so-called “medical affairs” in the future can be reviewed by international expert commissions, because in such a small country, in several narrow specialities, the number of specialists who can be invited as experts is limited. Besides, doctors of certain specialities have joined in associations and know each other well, which creates circumstances where there could be a conflict of interests.

12.3 Medical Responsibility and Liability in Estonia

12.3.1 Judicial and Normative Overview

The quality of medical care and the field of medical errors in Estonia are regulated by the following acts (Nomper 2002, 2007):

Section 28 of the Constitution of the Republic of Estonia, according to which everyone has the right to the protection of health.

According to the Healthcare Services Organisation Act, the patient has the right to receive emergency care.

According to subsection 6 (1) of the same act, every person in the territory of the Republic of Estonia has the right to receive emergency care.

And according to subsection 16 (2), every person in the territory of the Republic of Estonia has the right to receive emergency medical care services.

The requirements for access of healthcare services (2004) provide the necessary timely assistance.

The Health Insurance Act emphasises the need for disease prevention.

Section 768 of the Law of Obligations Act establishes the duty to maintain confidentiality.

Providers of healthcare services shall maintain the confidentiality of information regarding the identity of patients and their state of health, which has become known to them in the course of the provision of healthcare services, and they shall ensure that the information contained in the documents does not become known to other persons.

The provider of healthcare services shall inform the patient of the results of examination of the patient, the state of his or her health, any possible illnesses and the development thereof, the nature and purpose of the healthcare services provided, the risks and consequences associated with the provision of such healthcare services and of other available and necessary healthcare services. A patient may be examined and healthcare services may be provided to him or her only with his or her consent.

The criminal liability of physicians in Estonia is regulated by the Penal Code (2002).

Section 125. Leaving another person in a situation which is life-threatening and section 126. Refusal to provide medical assistance to sick persons.

The refusal to provide medical assistance to a sick person without a valid reason by a healthcare provider who had the obligation and opportunity to provide such assistance, if the failure to act resulted in serious consequences.

Civil liability has been summarised in the Contracts and Non-Contractual Obligations Act.

Chapter 38 of the act regulates the Contract for Provision of Healthcare Services. The regulation of the Contract for Provision of Healthcare Services serves as a basis for the contractual liability of physicians.

Quality requirements for the provision of healthcare services have been laid down by the Law of Obligations Act, and the Minister of Social Affairs has established the requirements for the quality and accessibility of healthcare services under the Healthcare Services Organisation Act.

The third chapter of the Penal Code (2001) regulates offences endangering life and health, including medical errors such as putting patients' lives at risk, refusal to provide assistance, termination of pregnancy, etc.

12.3.2 Judicial and Extra-Judicial Institutions and Operative Roles

12.3.2.1 Judicial Institutions

Legal organisations are the police, the prosecutor's office, and the court. Medical errors are always handled with the help of forensic medical examination. Forensic medical experts are experts who work at the state forensic institution, the Estonian Forensic Science Institute. The Estonian Forensic Science Institute is a national expert body that was established on the 1st of January 2008 and is administered by the Ministry of Justice.

12.3.2.2 Extra-Judicial Institutions

The Estonian Patient Advocacy Association is a non-profit organisation working on a project basis which aims to represent the interests of patients at the individual, systematic and international levels, and to provide customers with counselling, case management and legal assistance. An important part of the activities of the Estonian Patient Advocacy Association is systematic work to improve occupational health, to increase patient friendliness in the social welfare system and to help to resolve various difficulties. Systematic cases arise in the course of customer work where the cases of different customers are similar and refer to a specific problem in the healthcare system. Also, the organisation makes proposals to solve problems at the national level and represents the interests of patients in legislative processes.

The Estonian Patient Advocacy Association considers it to be very important to inform patients of their rights. For this reason, awareness lectures are organised for patient organisations and healthcare institutions. Informing patients and medical institutions will contribute to improving healthcare organisation and increasing patient satisfaction. You can order lectures from us on patients' rights and social and healthcare legislation.

State supervision over the compliance of the requirements of healthcare providers is carried out by the Health Board. It is regulated by the requirements for

assuring quality of healthcare services (2004, No. 128) and the rules of procedure of the expert committee of the quality of healthcare services (2008, No. 27).

Since its foundation until 2002 the Medical Assessment Committee acted under the Ministry of Social Affairs. From there on until December 31st, 2007 it operated at the Healthcare Board, and since the January 1st, 2008 it has acted under The Minister of Social Affairs. High-quality healthcare services must meet the requirement in force at the time of providing the services, including vocational and professional requirements, the overall level of modern medical science, available resources and the needs and satisfaction of the patient.

When assessing the quality of healthcare services, the committee draws, among other things, on the following:

1. documents certifying the provision of healthcare services;
2. explanations of the person seeking evaluation from the committee;
3. requirements of the provision of healthcare services set by legislation.

The committee consists of representatives of various specialties; an expert in internal medicine, an expert in surgery; an expert in obstetrical care and gynaecology, an expert in pathology, an expert in patients' rights, etc.; a representative of the Department of Healthcare of the Ministry of Social Affairs; a representative of the Estonian Health Insurance Fund and the head of the Supervision Department of the Healthcare Board.

12.3.3 Ascertainment Methodology

12.3.3.1 Living

A patient may file a complaint with the physician, the medical director of the healthcare institution, the city or rural municipality medical officer, the county doctor or the treatment quality committee of the Ministry of Social Affairs. A patient, his/her relatives or representative have the right to request a medical audit to assess the quality of treatment and to determine the errors in treatment. After the death of the patient, the relative or representative of the patient has the right to request a medical audit. The patient, his/her relative or representative has the right to claim that the person at fault would compensate for the damage caused upon the provision of treatment.

If the patient has filed such an application to the body conducting proceedings (the police, the prosecutor's office, the court), the forensic medical examination is designated pursuant to law. The forensic medical expert committee, which usually involves a medical specialist of that particular field, examines all medical documents and tries to find an answer to the question: could this have been a medical error? And, if yes, did it cause injuries or health disorders to the patient? Very often the forensic medical expert has to go to court in such cases, in order to answer additional questions. The final judgment is made by the court.

12.3.3.2 Cadaver

In Estonia, the civil or criminal proceedings are commenced on the basis of a person's written complaint, i.e. if the complaint is not filed, such cases are not handled.

According to the Establishment of Cause of Death Act, all cases involving the suspicion of medical errors should be within the competence of forensic medical experts, i.e. the forensic medical examination should be conducted. If the forensic medical expert determines upon autopsy the cause of death that might have been caused by the wrongful activity of the physician, the forensic medical expert shall set it down in his or her autopsy or expert's report. At the same time, the forensic medical expert shall answer all other questions that the police ask in connection with this case. The forensic medical expert's report is delivered to the body conducting proceedings and further activity depends on his/her work.

12.3.4 Evaluation Criteria

Assessment of the quality and accuracy of the medical care must meet the requirement in force at the time of providing the services, including vocational and professional requirements, the overall level of modern medical science, available resources and the needs and satisfaction of the patient.

Upon assessment, the qualification, skills and possibilities of the physician to provide health care in that particular situation are taken into account, i.e. the main criterion is the principle that the physician was able to provide health care and if he/she did everything that he/she could do in order to avoid that situation. If the provision or non-provision of health care resulted in damage to health, then in addition to the medical criteria, also the preceding condition of the patient is taken into account, i.e. how much it has influenced the current situation.

12.3.5 Future Perspectives

When Estonia regained its independence, it commenced the building up a modern legal system. One of the features of this system is the principle that everybody is responsible for the consequences of his/her actions, and this led to the first cases of physician's responsibility.

Since Estonia is the only Baltic country where there is no law to protect patients, it must be adopted in the near future.

In Estonia, the possibilities for patients to protect their rights should be precisely fixed by the law, including how they can file a complaint and if they have suspicions concerning the correctness of medical care provision.

Also, the Establishment of Cause of Death Act should be amended, in order to make the performance of an autopsy 100 % obligatory in case of suspicion of medical errors. Current regulation gives doctors an opportunity not to perform an autopsy and some cases may therefore remain undiscovered.

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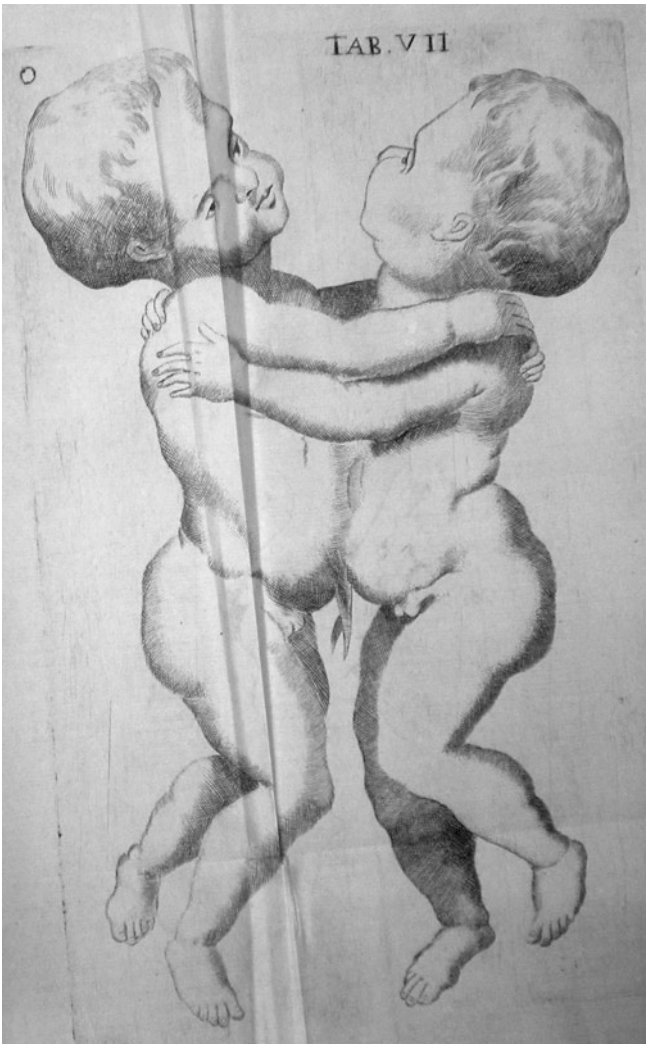
Part V
Consensus Document: European Guidelines



Antonio Vallisneri—Istoria della generazione dell'uomo e degli animali se sia da'vermicelli spermatici o dalle uova; con un trattato nel fine della sterilità, e de' suoi rimedj; con la critica de'superflui, e de'nocivi; con un discorso accademico intorno alla connessione di tutte le cose create; e con alcune lettere, Istorie rare, Osservazioni d'uomini illustri: di Antonio Vallisneri ... In Venezia: appresso Gio. Gabbriel Hertz, 1721. Courtesy of Historical "Vincenzo Pinali" Medical Library, University of Padova

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*.

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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.

Contents

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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.

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- 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

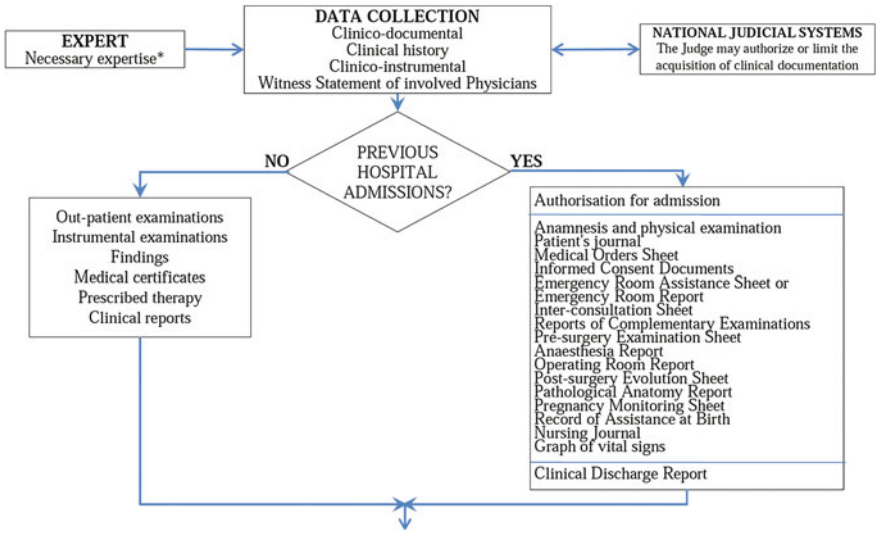


Fig. 13.1 Step 1

(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

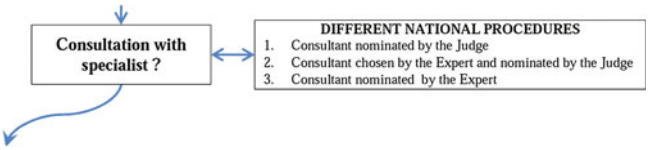


Fig. 13.2 Step 2

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

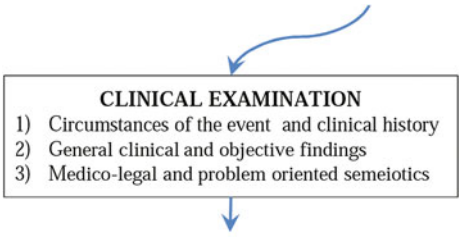
Preliminary evaluation of the clinical and healthcare documentation may reveal the need/suitability of requesting the advice of one or more medical specialists in the ascertainment phase, to ensure better definition of the case in question. This involvement should preferably take place before clinical 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.

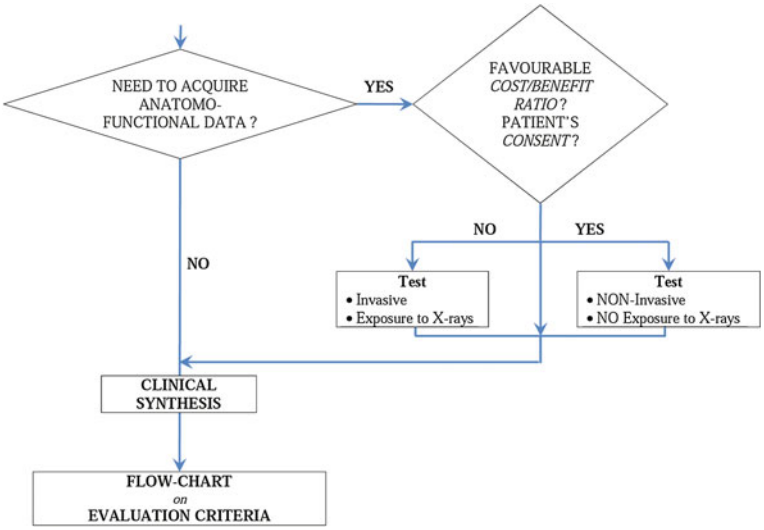


Fig. 13.4 Step 4 and 5

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).

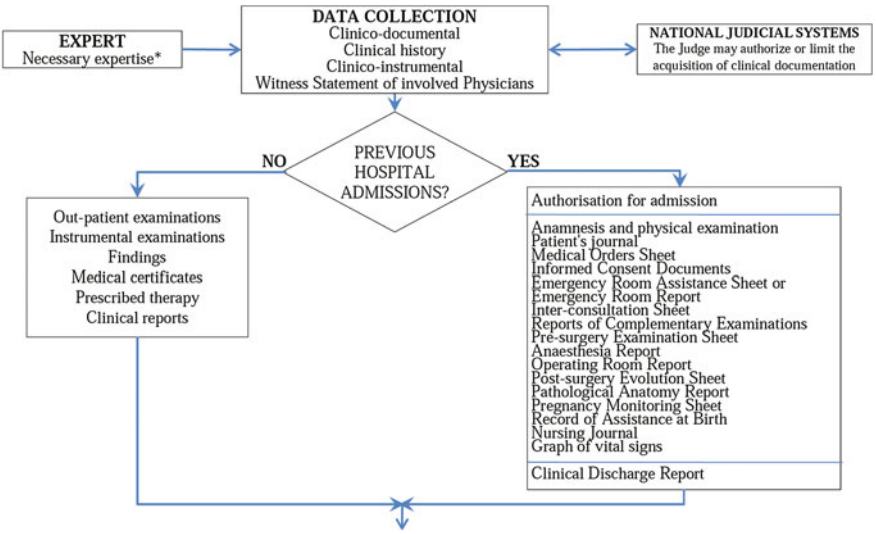


Fig. 13.5 Step 1

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",

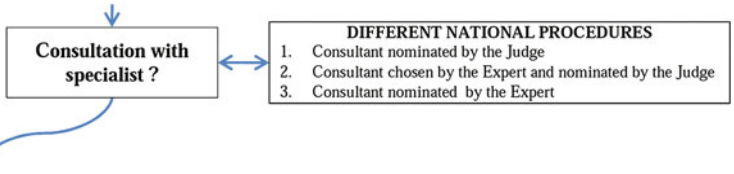


Fig. 13.6 Step 2

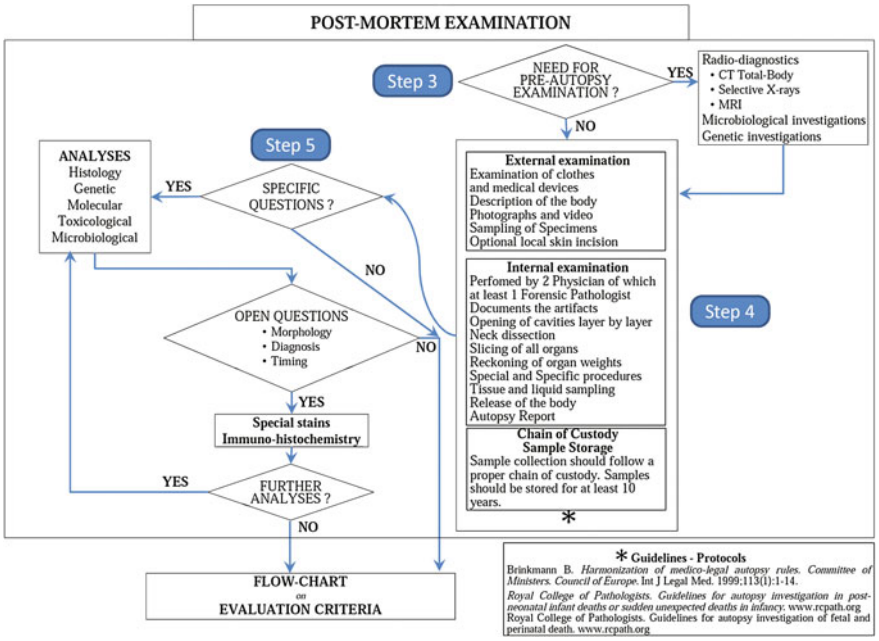


Fig. 13.7 Step 3 to 5

(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).

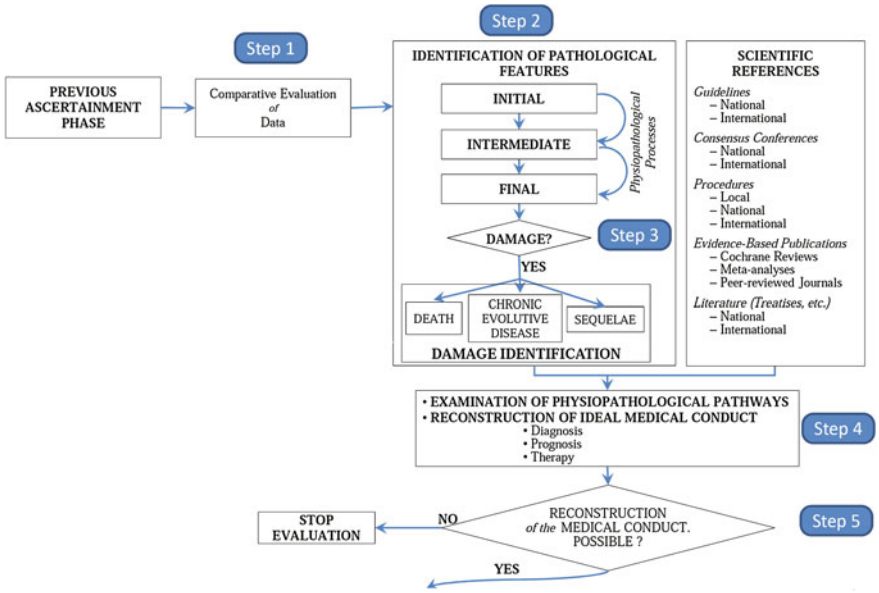


Fig. 13.8 Steps 1–5

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).

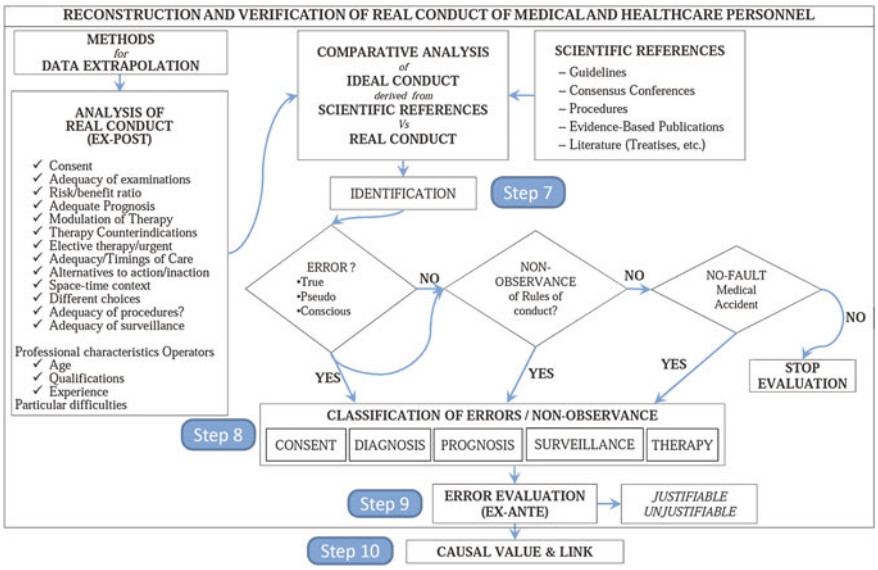


Fig. 13.9 Steps 6–9

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.

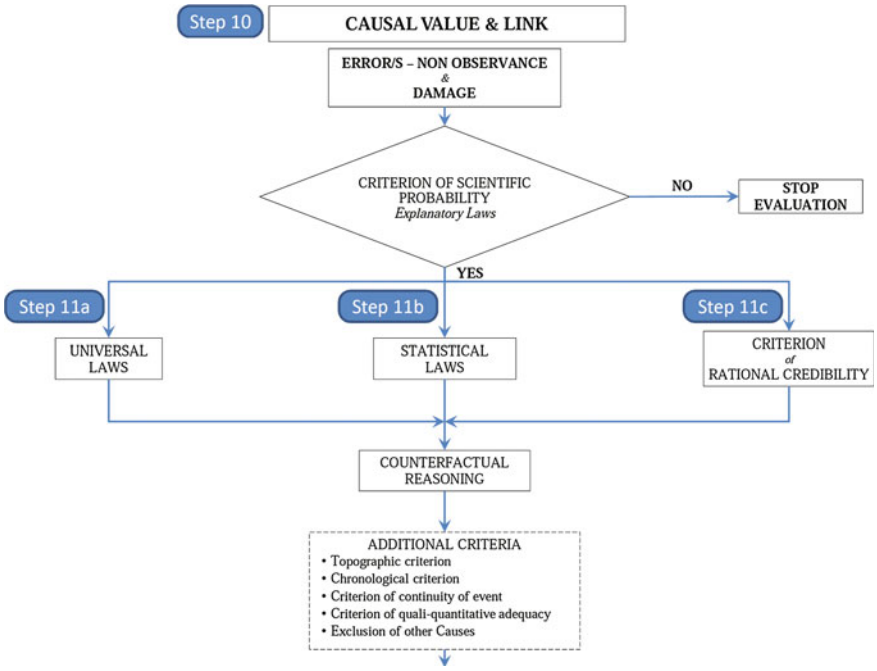


Fig. 13.10 Steps 10–11 (from a to c)

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:

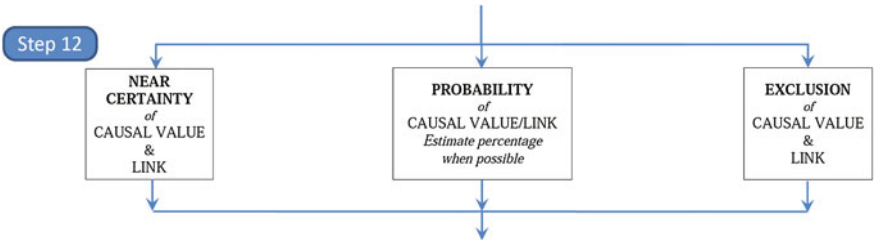
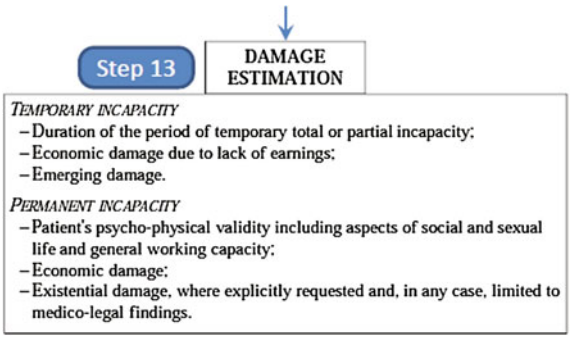


Fig. 13.11 Step 12

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.

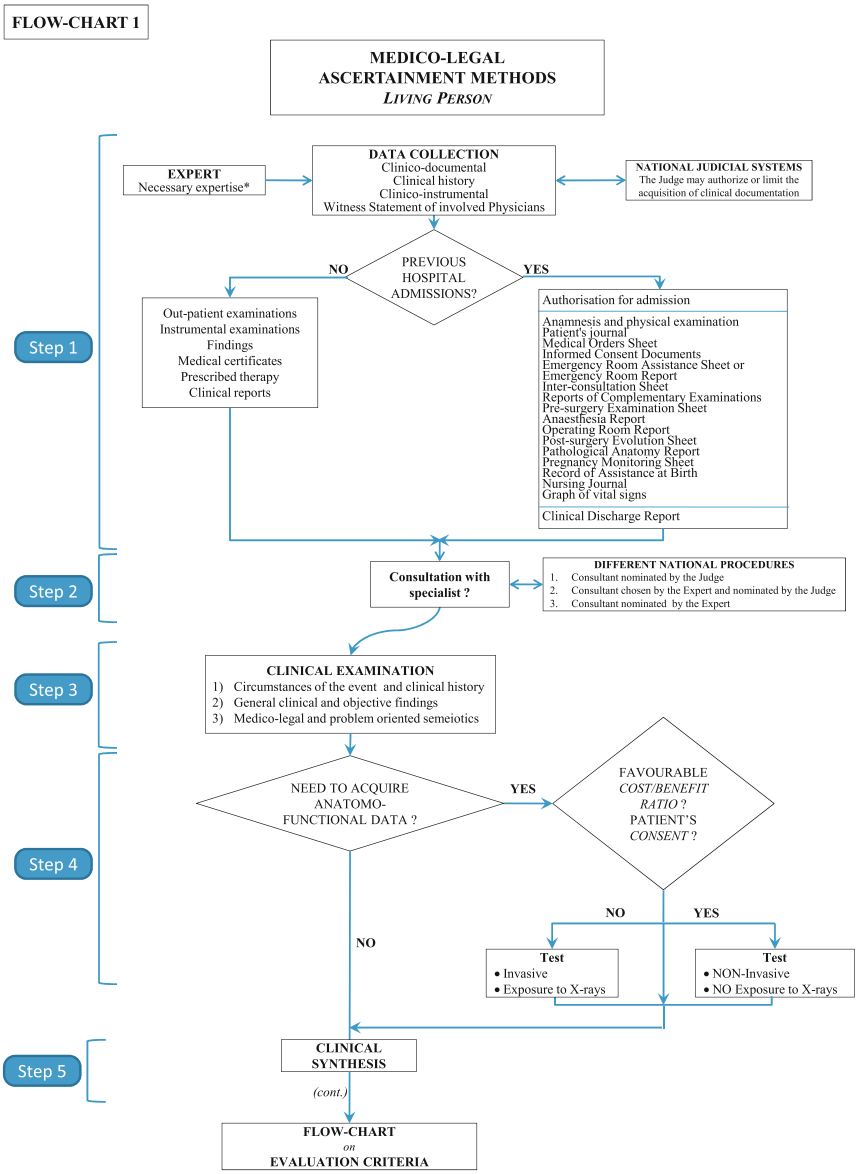
13.6 Conclusions

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.

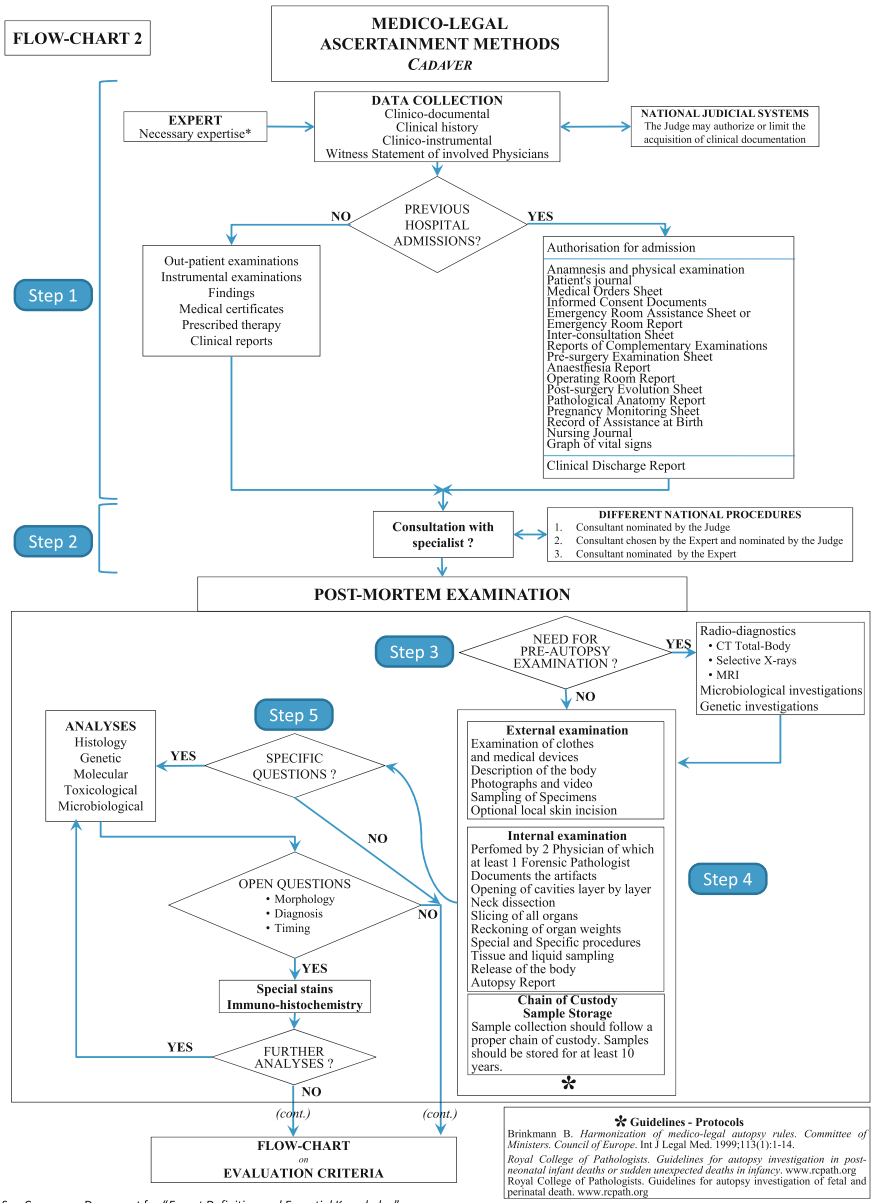
Appendixes: Flow Charts

Methods of Ascertainment on Living Persons



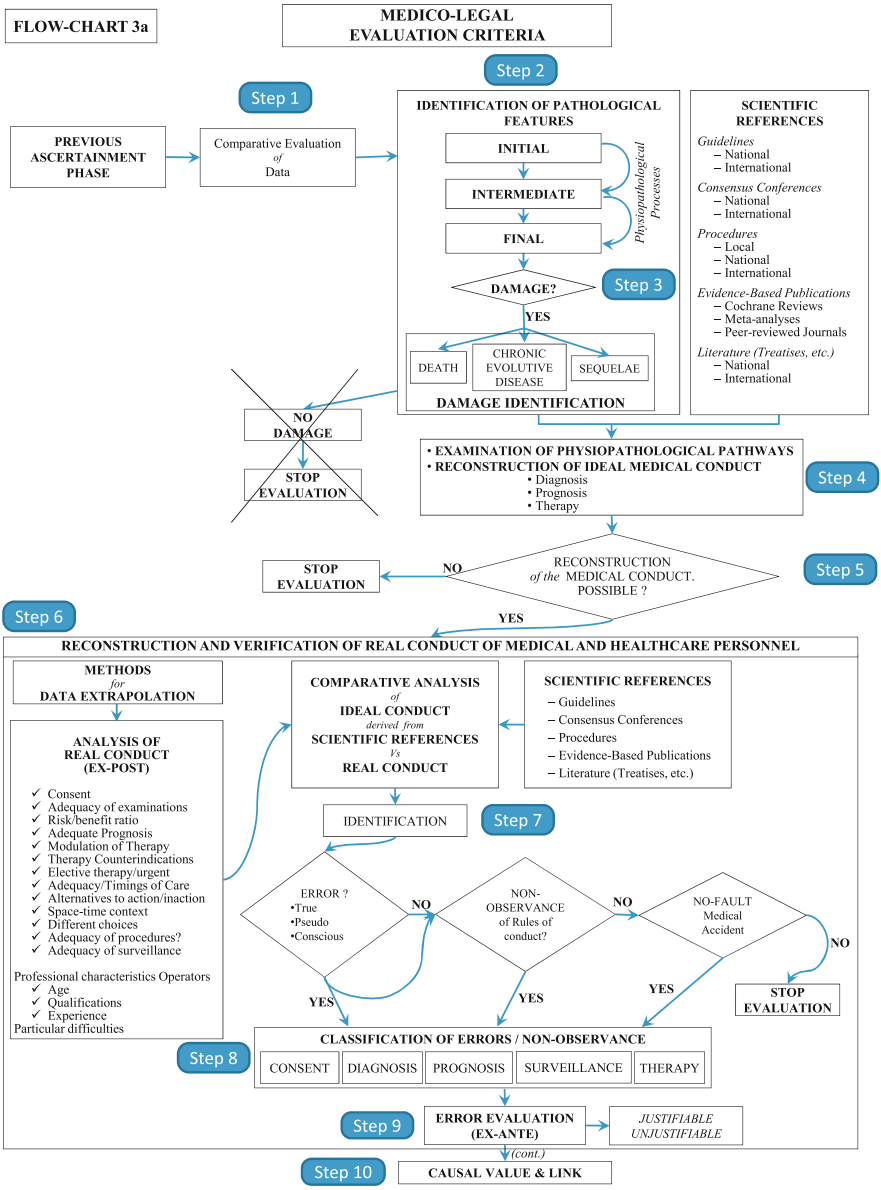
* See Consensus Document for "*Expert Definition and Essential Knowledge*"

Methods of Ascertainment on Cadavers

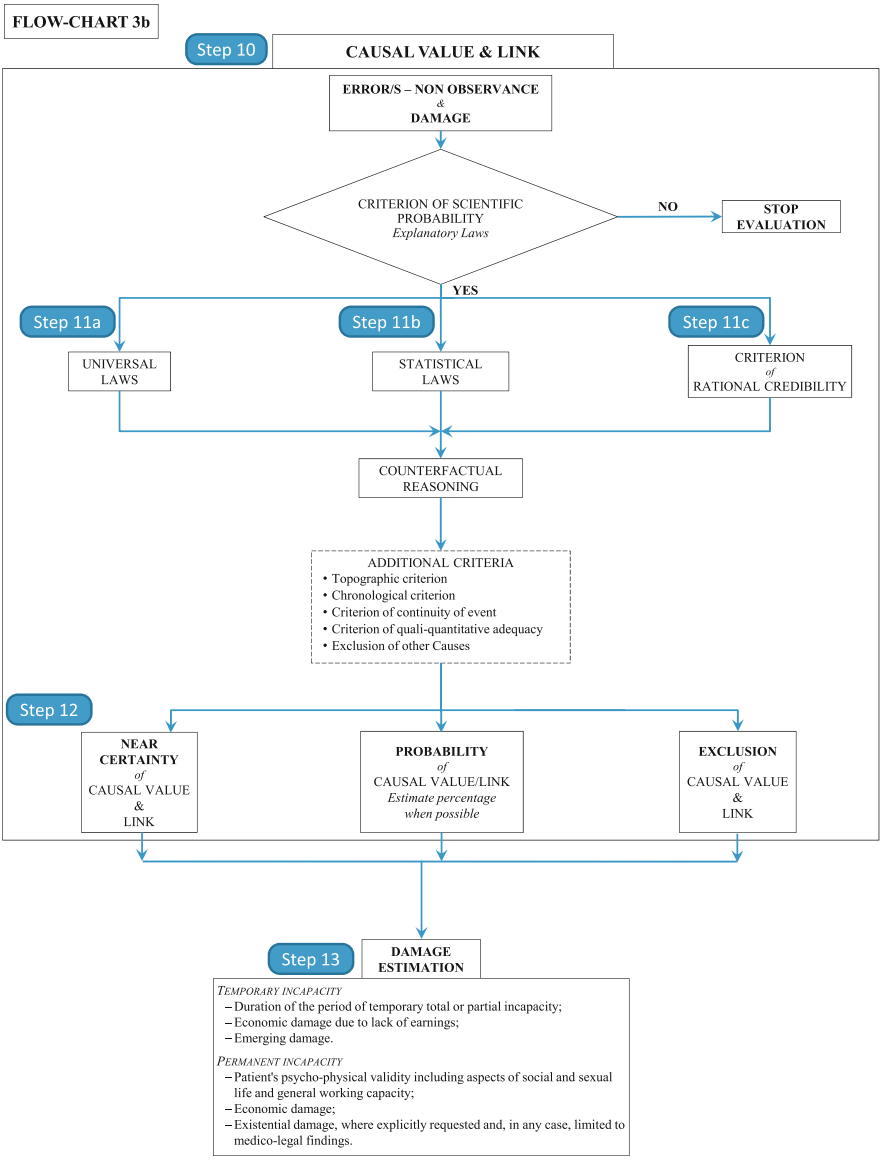


* See Consensus Document for "*Expert Definition and Essential Knowledge*"

Evaluation Criteria: Part a



Evaluation Criteria: Part b



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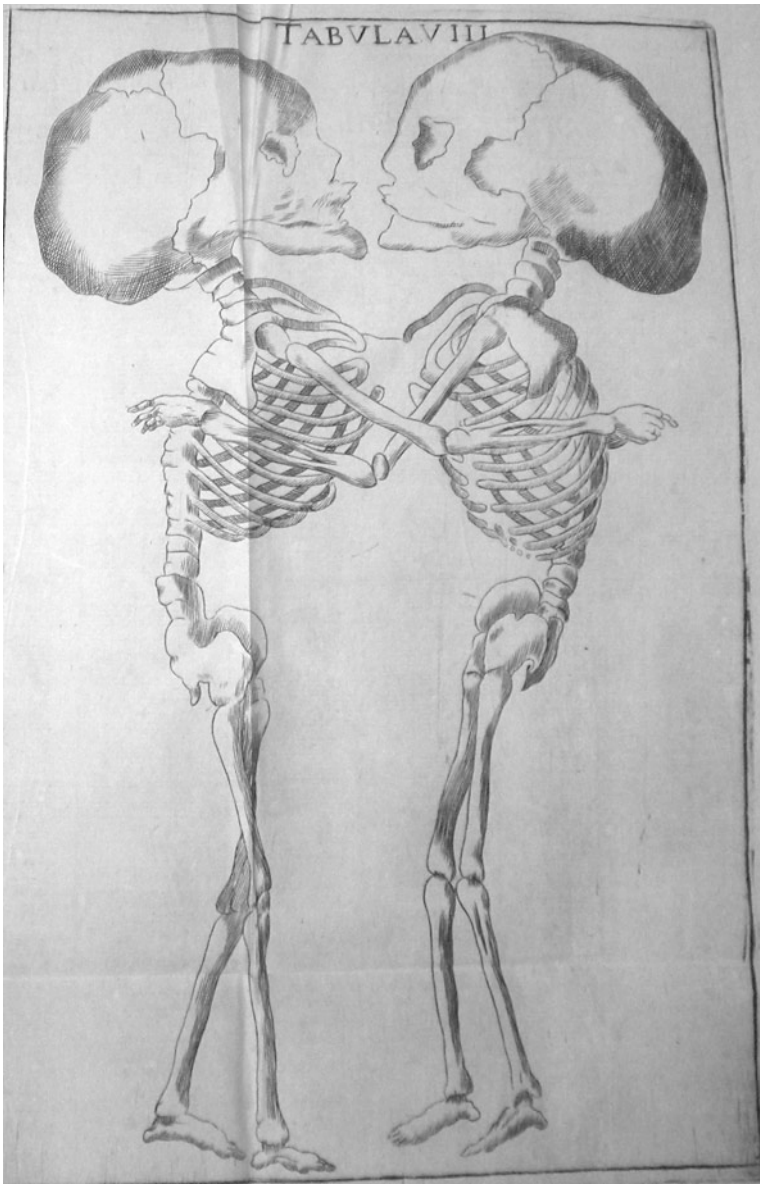
Part VI
Final Statements



Antonio Vallisneri—Istoria della generazione dell'uomo e degli animali se sia da'vermicelli spermatici o dalle uova; con un trattato nel fine della sterilità, e de' suoi rimedj; con la critica de'superflui, e de'nocivi; con un discorso accademico intorno alla connessione di tutte le cose create; e con alcune lettere, Istorie rare, Osservazioni d'uomini illustri: di Antonio Vallisneri ... In Venezia: appresso Gio. Gabbriel Hertz, 1721. Courtesy of Historical "Vincenzo Pinali" Medical Library, University of Padova

Chapter 14
Requirements and Final Recommendations

S. Davide Ferrara, Rafael Boscolo-Berto and Guido Viel

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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S. D. Ferrara et al. (eds.), *Malpractice and Medical Liability*,
DOI: 10.1007/978-3-642-35831-9_14,

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.

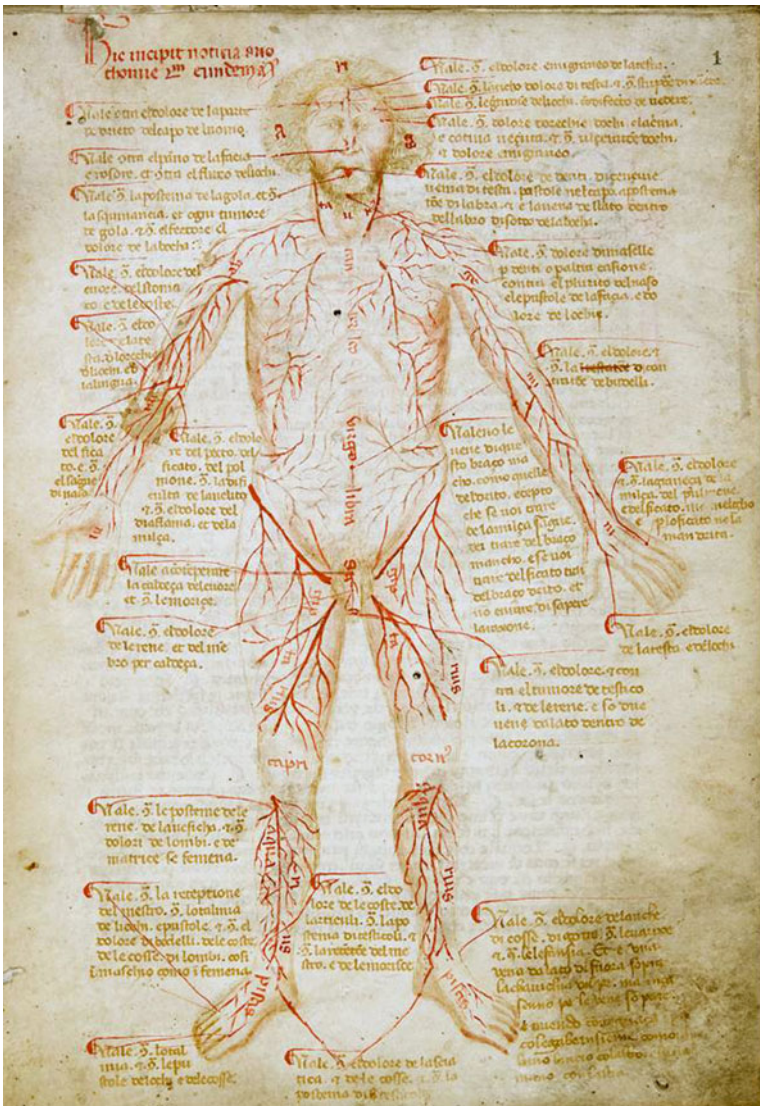
As regards *temporary incapacity,* the following should be quantified:

- 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.

Part VII
Iconography



Bartolomeo Squarcialupi—"Libro de cautery", XIV–XV century. Courtesy of Historical Section of the "Vincenzo Pinali" Medical Library of the University of Padova

Chapter 15
Historical Iconography from the "Vincenzo Pinali" Antique Medical Library

S. Davide Ferrara, Guido Viel and Rafael Boscolo-Berto

Abstract This chapter proposes a historical overview of antique iconography, taken from the historical section of the "Vincenzo Pinali" Medical Library of the University of Padova. The icons, dating from the fourteenth and eighteenth centuries, demonstrate the evolution of biomedical knowledge and of the constant presence of profiles of responsibility in the performance of medical and surgical practices.

A brief overview of historical iconography is proposed to the reader, concerning works in which profiles of personal responsibility can be identified in the performance of medical and surgical practices. In particular, these works are part of the heritage of the Historical Section of the "Vincenzo Pinali" Medical Library of the University of Padova.

The Historical "Vincenzo Pinali" Medical Library derives from the bequests of valuable collections transmitted by professors N. D'Ancona (1875–1931), A. De Giovanni (1838–1916), F. Fanzago (1764–1835), L. Lucatello (1863–1926), V. Pinali (1802–1875), A. Tebaldi (1833–1895), T. Vanzetti (1809–1888). The collection has been enriched by the donation of approximately 2,000 works of the physiologist V. Ducceschi (1871–1952), a passionate historian of medicine.

The "Sala Pinali" collects together around 7,500 works, mostly related to editions comprised between 1480 and 1830, including 7 incunables, over 600 from

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DOI: 10.1007/978-3-642-35831-9_15,

the sixteenth century and more than 20,000 contributions of biology and medicine of the past centuries.

The adjoining "Sala Ducceschi" contains the fund derived from the homonymous donor and a part of the bequests mentioned previously, a collection of 165 manuscripts autographed in part, dated to periods comprised between the fourteenth and eighteenth centuries, as well as a series of valuable anatomical waxes depicting aspects of anatomy and ocular pathology.

Worthy of special mention for their uniqueness and significant historical interest are the 17 icons taken from the "Libro de cautery" a parchment manuscript of the late fourteenth century, attributed to Bartolomeo Squarcialupi or Squarzalupi, operating at the University of Padua between 1397 and 1438, outlined in square Hebrew characters and appearing on page a1v after the opening words 'Qui comencael proemio del libro de le experieçe che fa il fuocho ne corpi humani co[m]pilato da…' (Figs. 15.1, 15.2, 15.3, 15.4, 15.5, 15.6, 15.7,15.8, 15.9, 15.10, 15.11, 15.12, 15.13, 15.14, 15.15, 15.16, 15.17, 15.18, 15.19,15.20, 15.21, 15.22, 15.23, 15.24, 15.25, 15.26, 15.27, 15.28, 15.29, 15.30, 15.31, 15.32, 15.33, 15.34, 15.35, 15.36, 15.37, 15.38, 15.39, 15.40, 15.41, 15.42, 15.43, 15.44, 15.45, 15.46, 15.47, 15.48, 15.49, 15.50, 15.51, 15.52, 15.53, 15.54, 15.55, 15.56, 15.57, 15.58, 15.59).

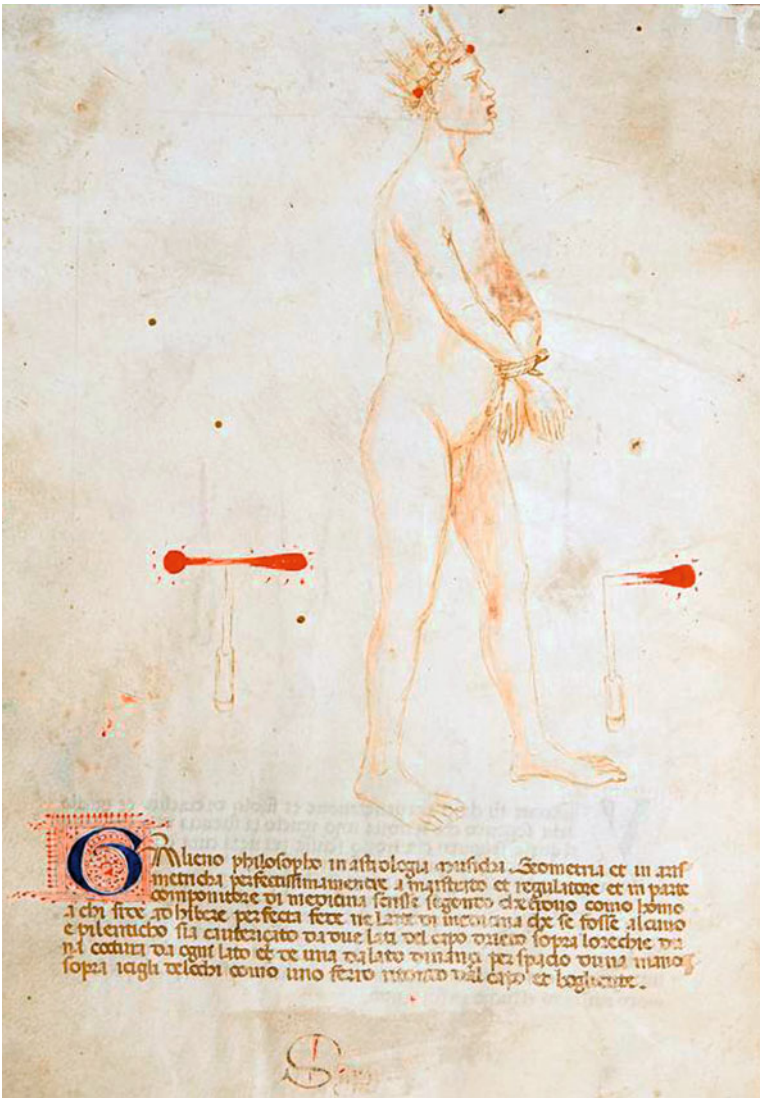


Fig. 15.1 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

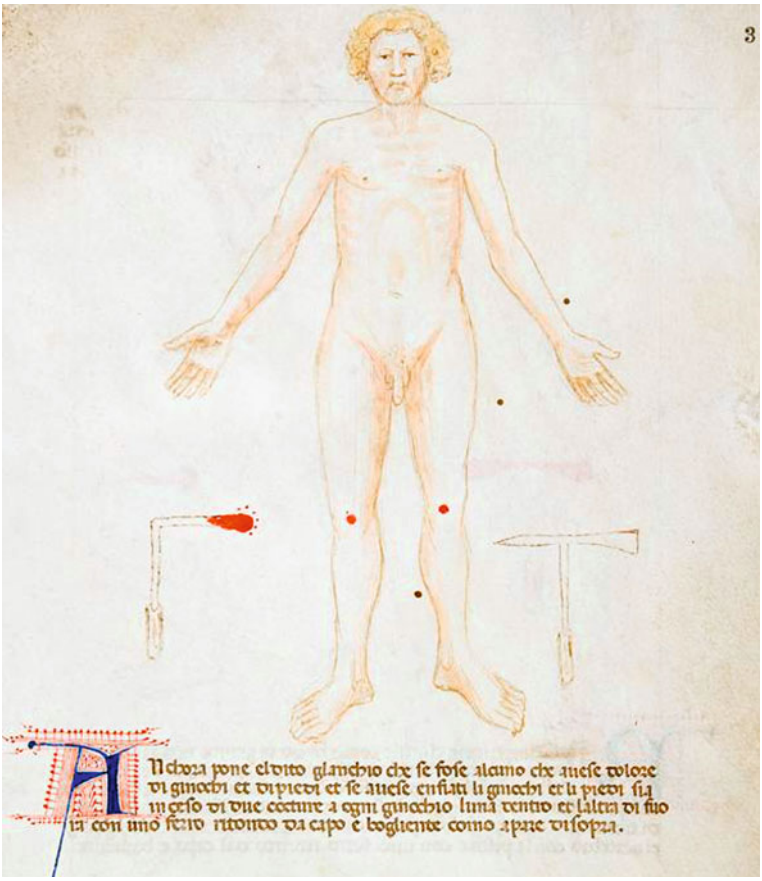


Fig. 15.2 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

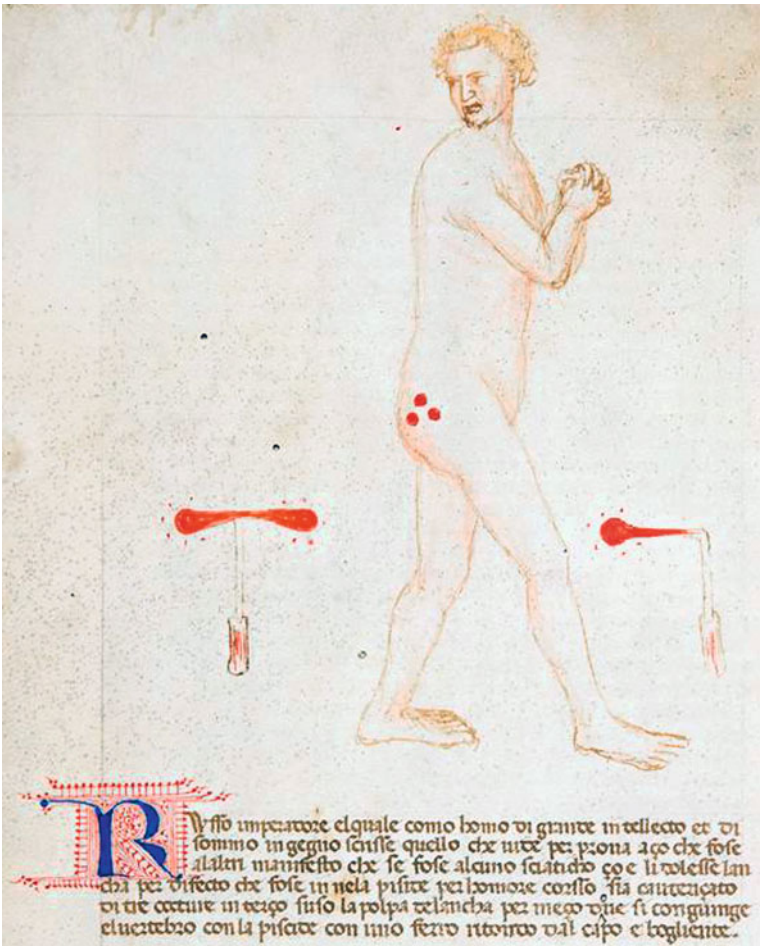


Fig. 15.3 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

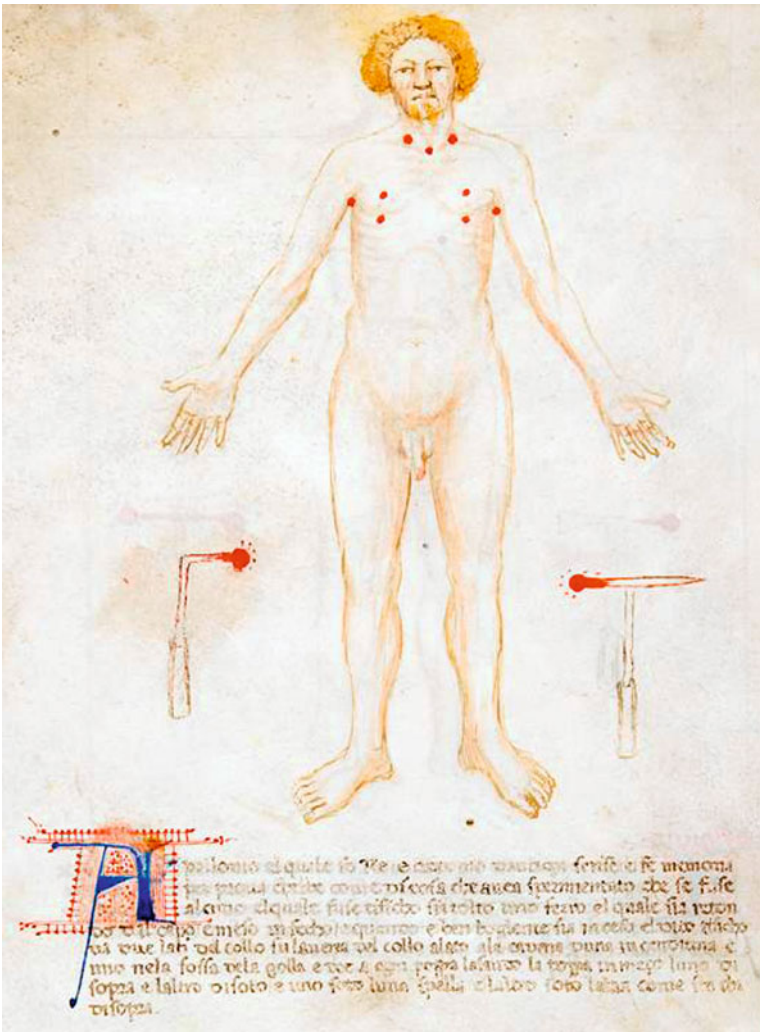


Fig. 15.4 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

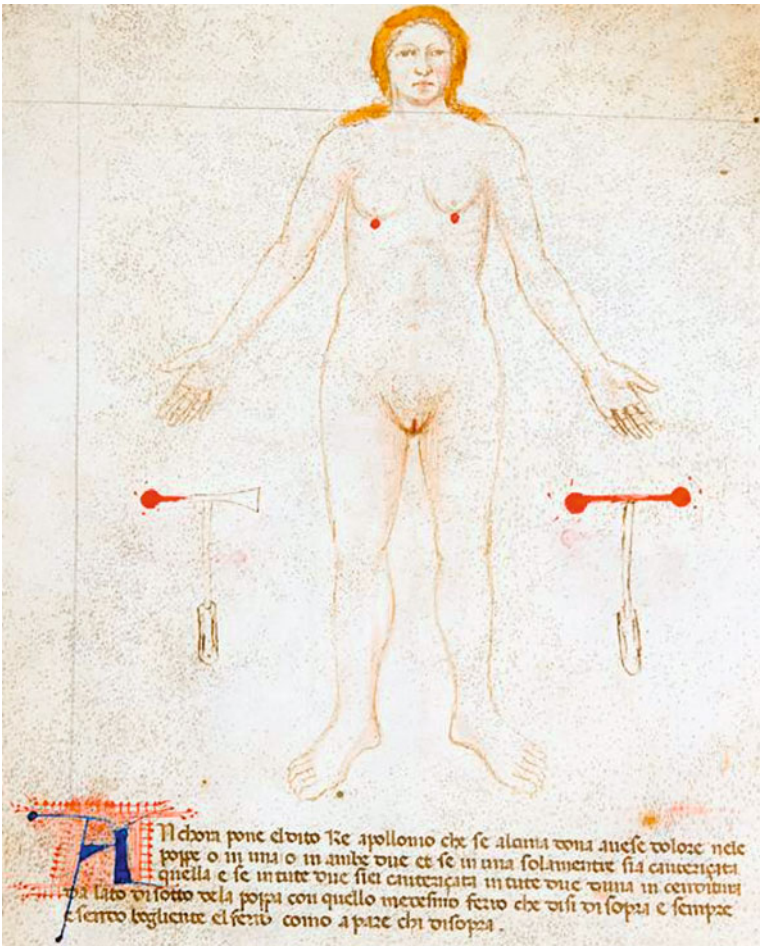


Fig. 15.5 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

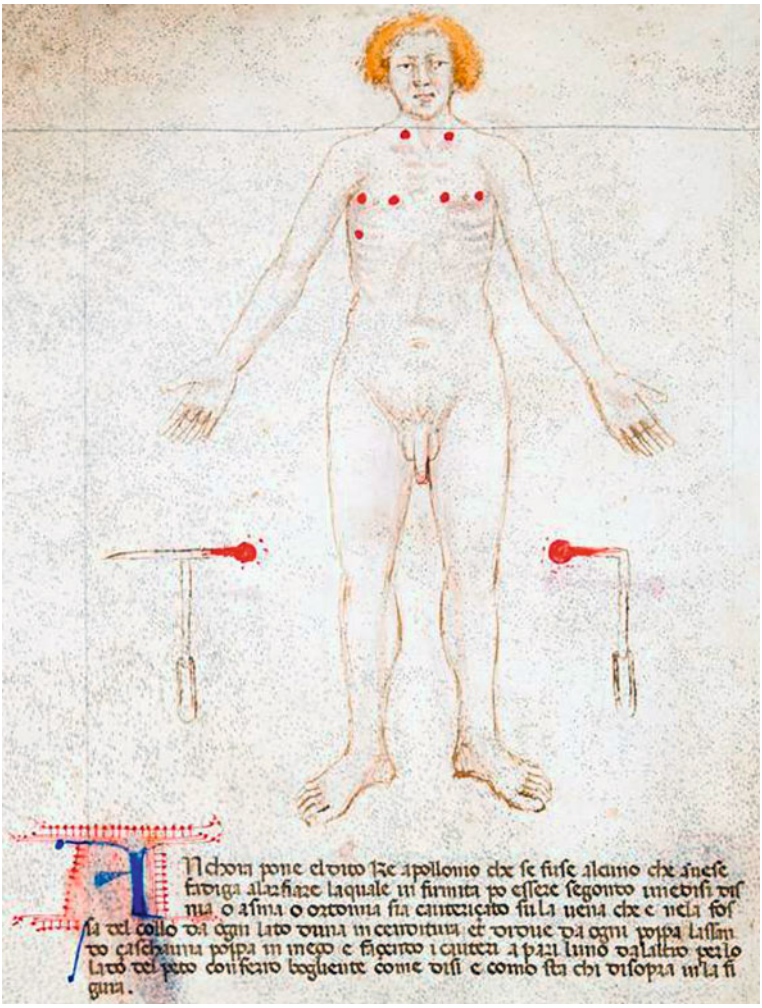


Fig. 15.6 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

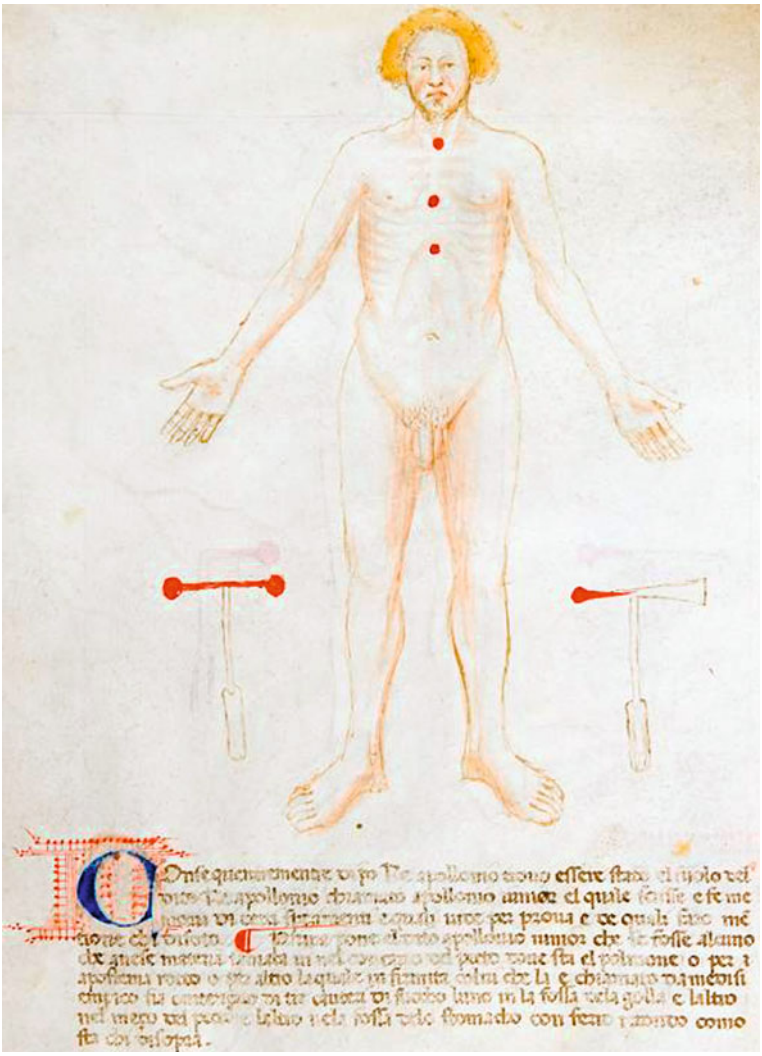


Fig. 15.7 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

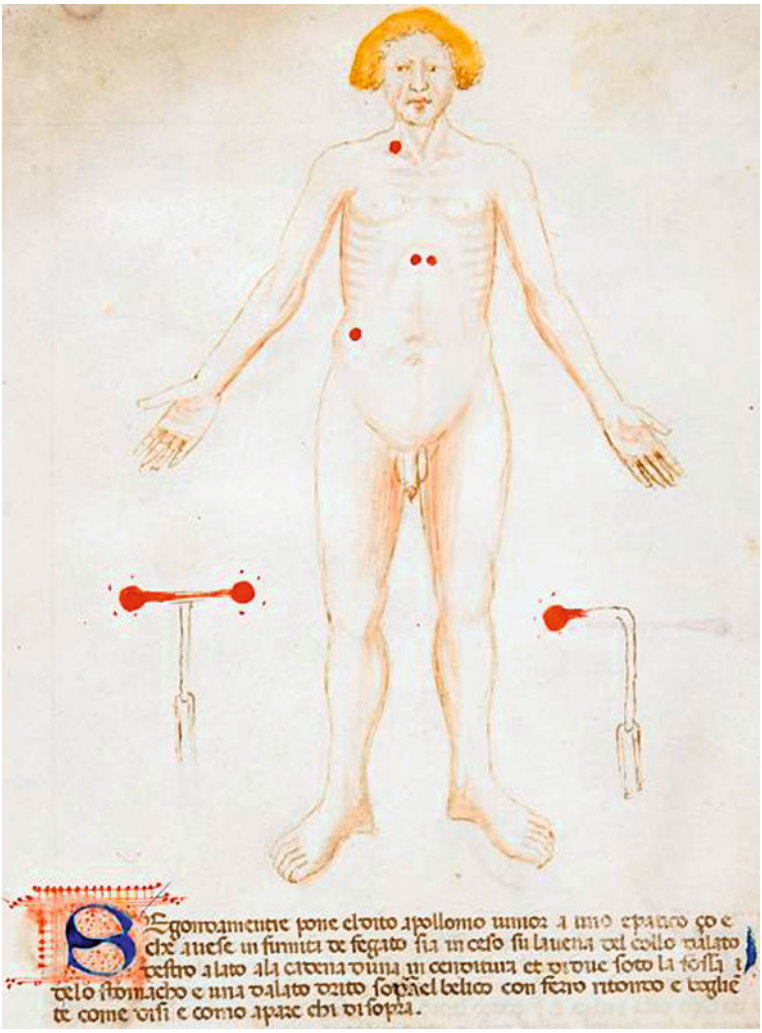


Fig. 15.8 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

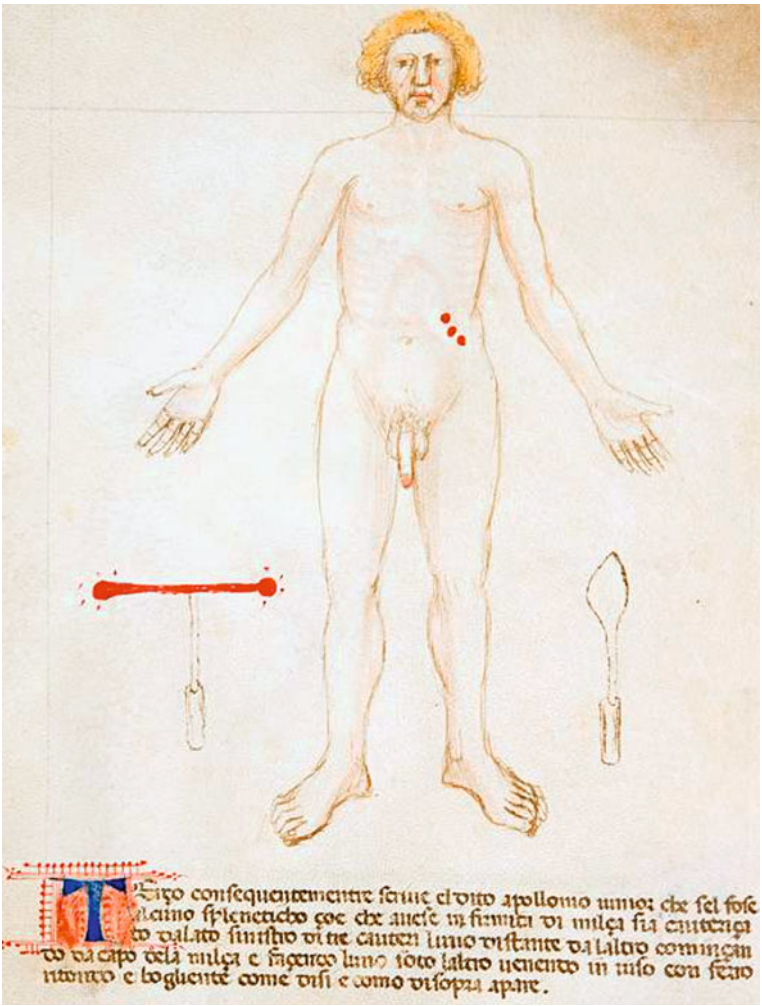


Fig. 15.9 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

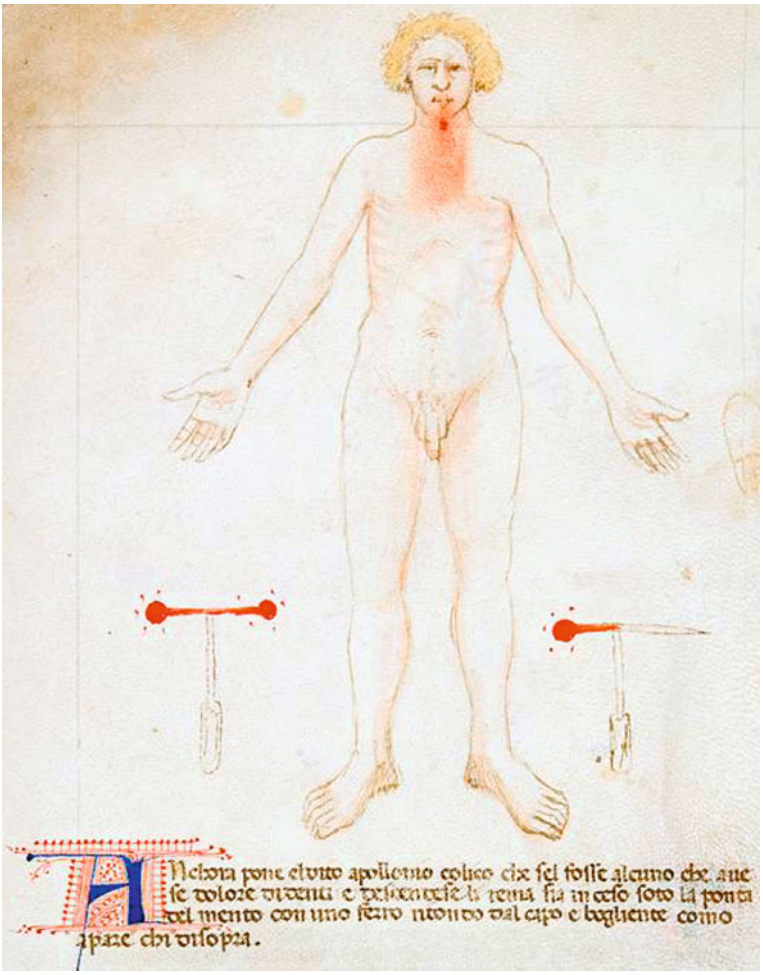


Fig. 15.10 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

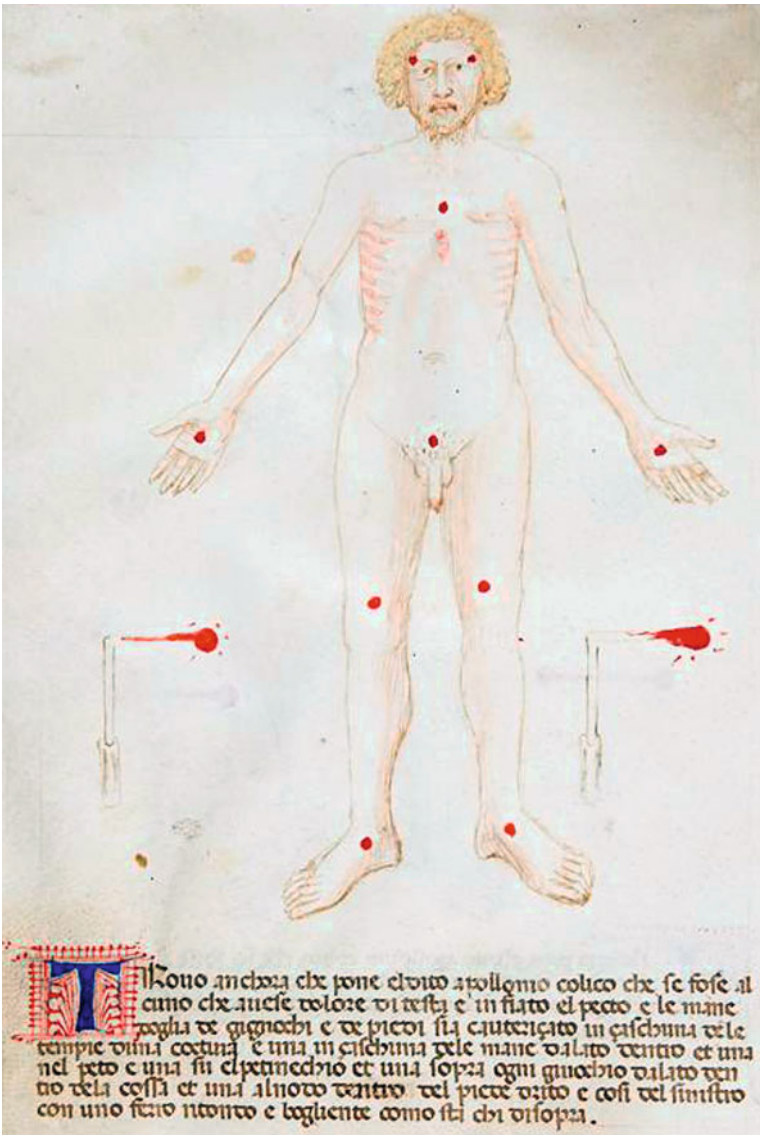


Fig. 15.11 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

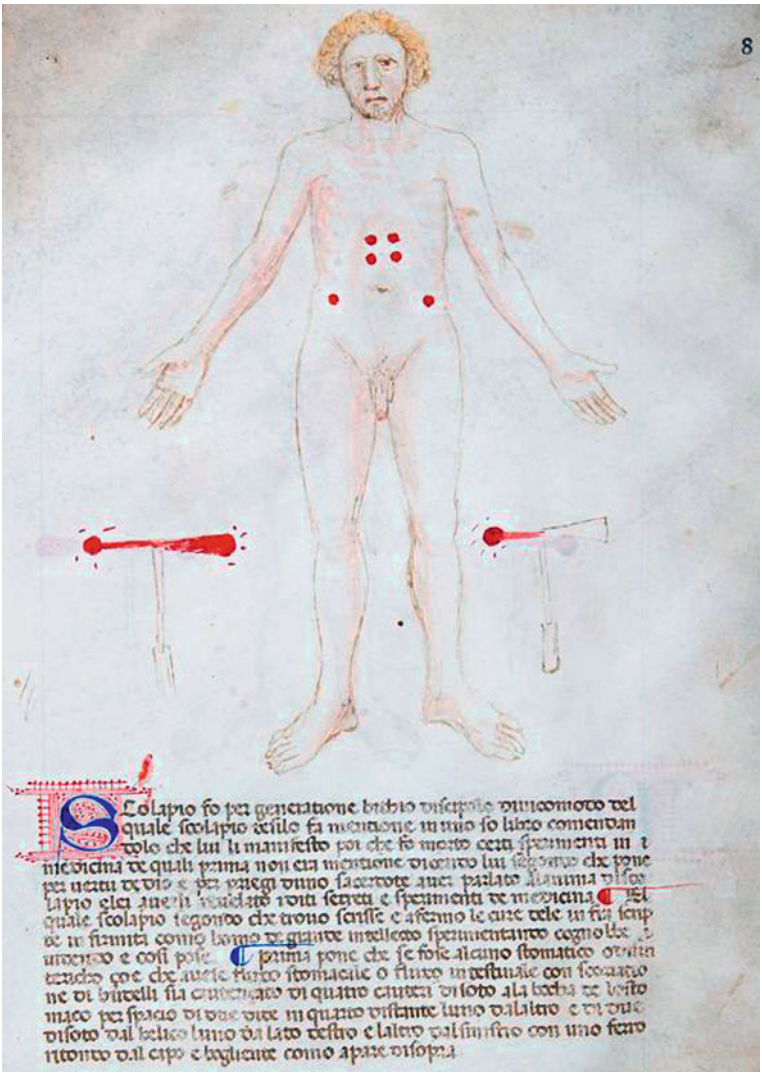


Fig. 15.12 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

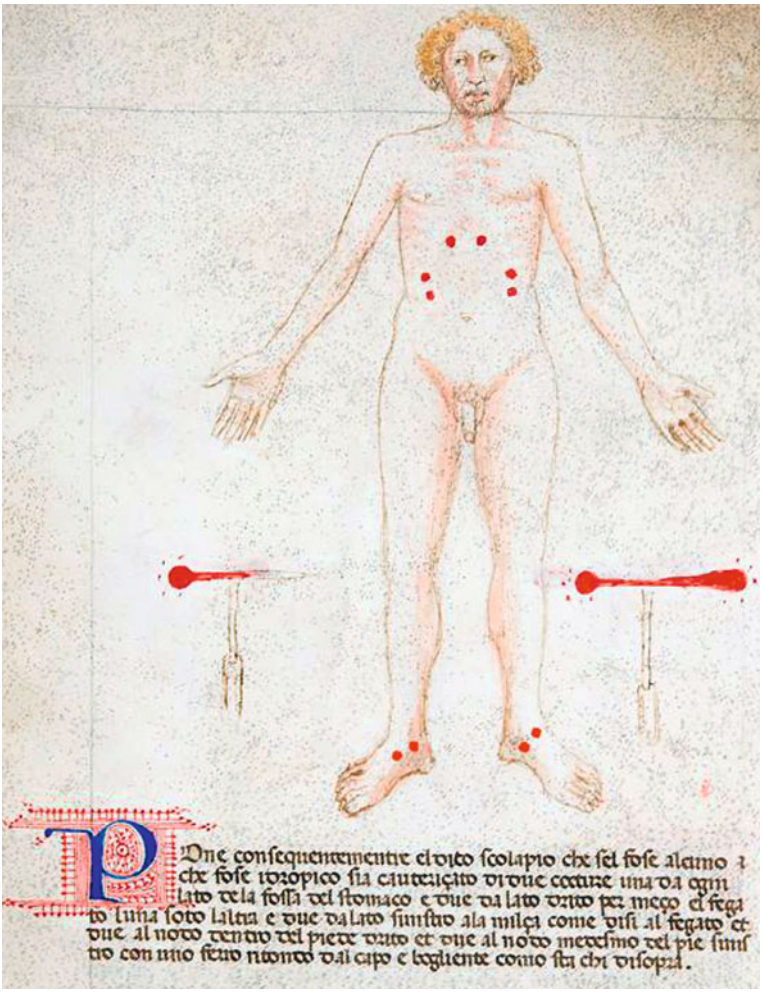


Fig. 15.13 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

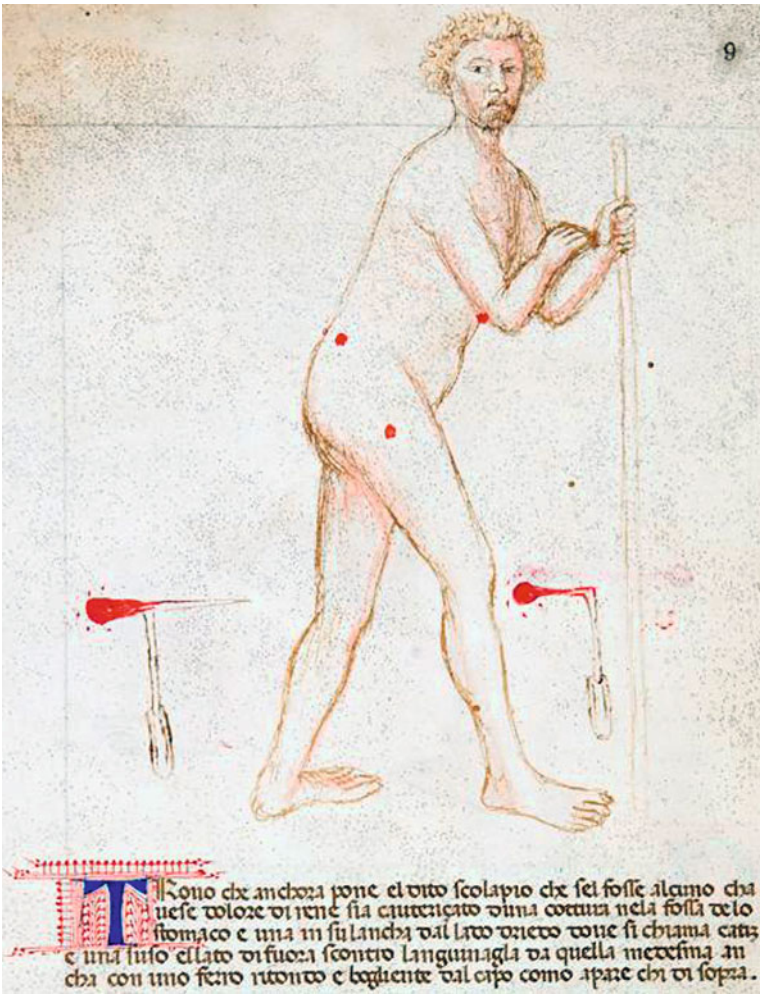


Fig. 15.14 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

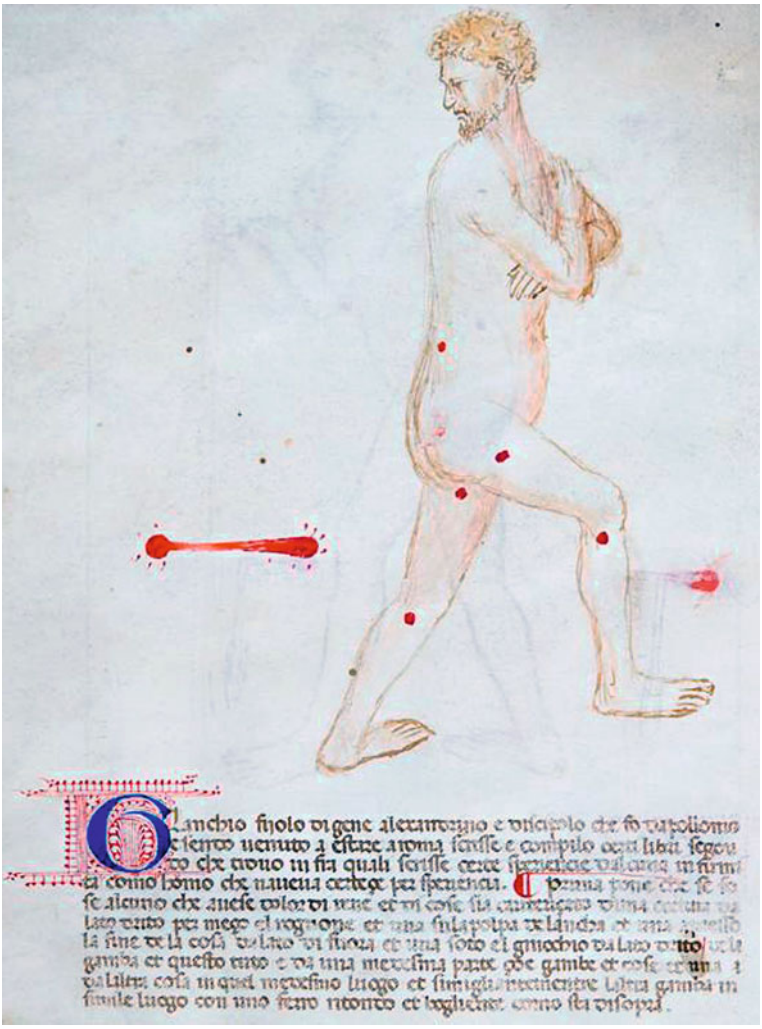


Fig. 15.15 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

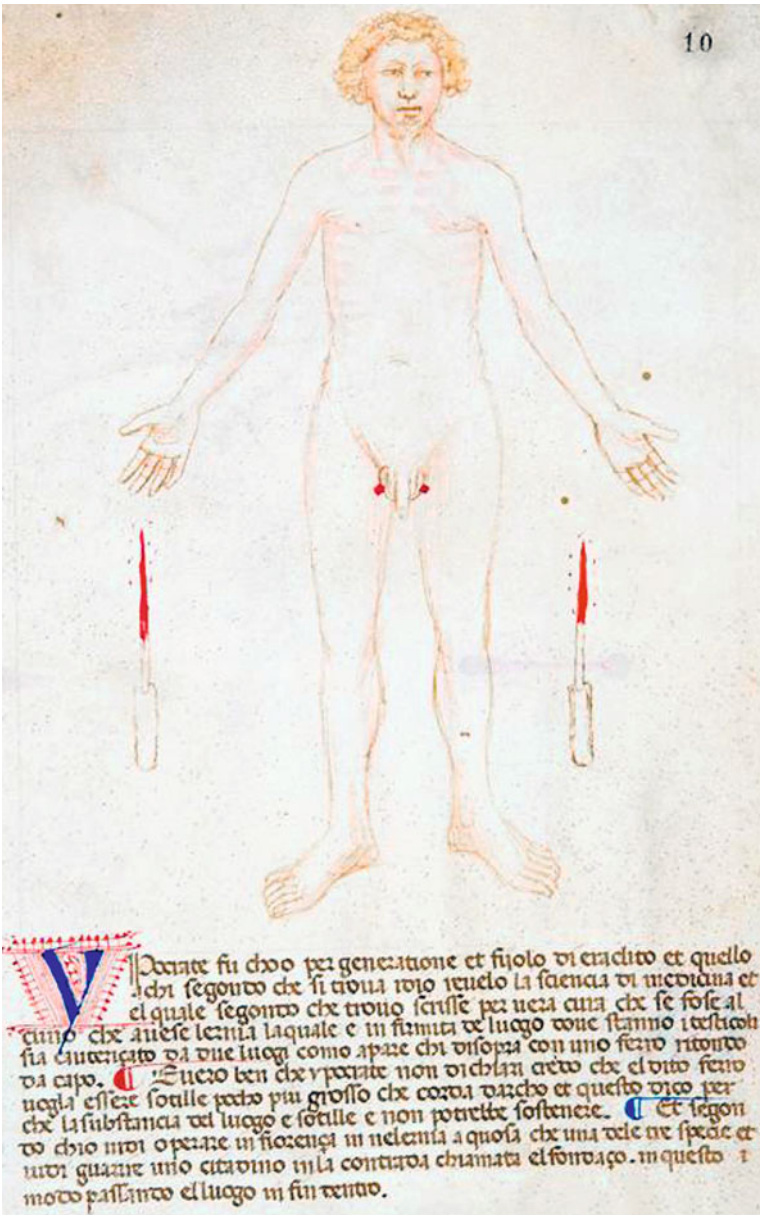
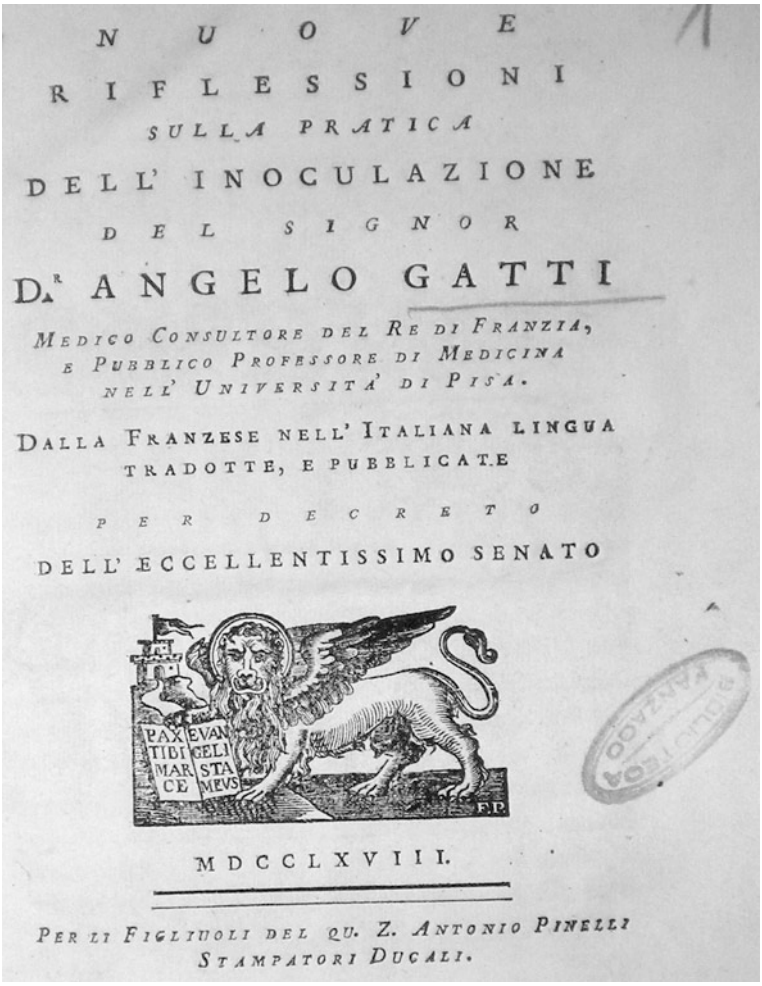


Fig. 15.16 Bartolomeo Squarcialupi—"libro de cautery", fourteenth–fifteenth century. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova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DEL SIGNOR
D.R ANGELO GATTI
MEDICO CONSULTORE DEL RE DI FRANZIA,
E PUBBLICO PROFESSORE DI MEDICINA
NELL' UNIVERSITA' DI PISA.
DALLA FRANZESE NELL' ITALIANA LINGUA
TRADOTTE, E PUBBLICATE
PER DECRETO
DELL' ECCELLENTISSIMO SENATO
PAX TIBI MAR CE EVAN GELI STA MEVS
F.P.
MDCCLXVIII.
PER LI FIGLIUOLI DEL QU. Z. ANTONIO PINELLI
STAMPATORI DUCALI.

Fig. 15.17 Angelo Gatti–Nuove riflessioni sulla pratica dell'inoculazione del signor d.r Angelo Gatti… dalla franzese nell'italiana lingua tradotte, e pubblicate per decreto dell'eccellentissimo Senato [Venezia]: per li figliuoli del qu. Z. Antonio Pinelli stampatori ducali, 1768. Courtesy of Historical "Vincenzo Pinali" Medical Library, University of Padova

Fig. 15.18 Pietro d'Abano—"Expositio preclarissimi atque eximii artium ac medicine doctoris Petri de Ebano. Patauini in librum problematum Aristotelis feliciter incipit [Venetiis]: impensa Ioannis Herbort Allemani", 1482. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

Fig. 15.19 Johannes de Ketham—"Fasiculo de medicina in volgare. Stampato in Venexia: per Zuane & Gregorio di Gregorii", 1493. Courtesy of Historical Archive, University of Padova

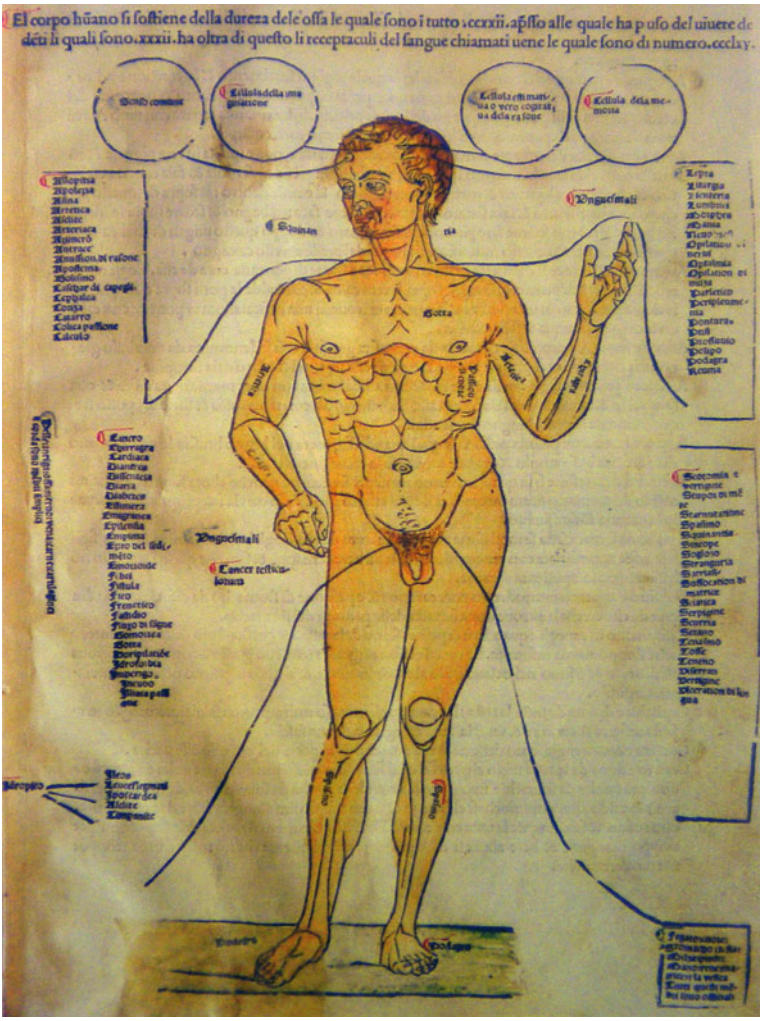


Fig. 15.20 Johannes de Ketham—"Fasiculo de medicina in volgare. Stampato in Venexia: per Zuane & Gregorio di Gregorii", 1493. Courtesy of historical archive, University of Padova

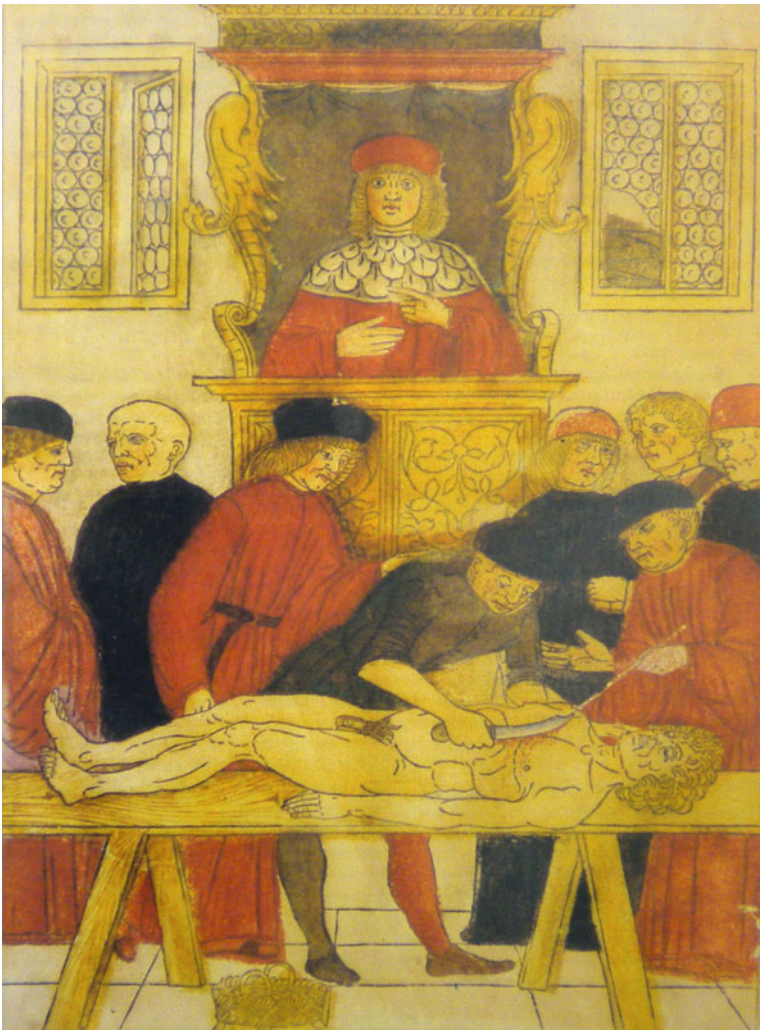


Fig. 15.21 Johannes de Ketham—"Fasiculo de medicina in volgare. Stampato in Venexia: per Zuane & Gregorio di Gregorii", 1493. Courtesy of historical archive, University of Padova

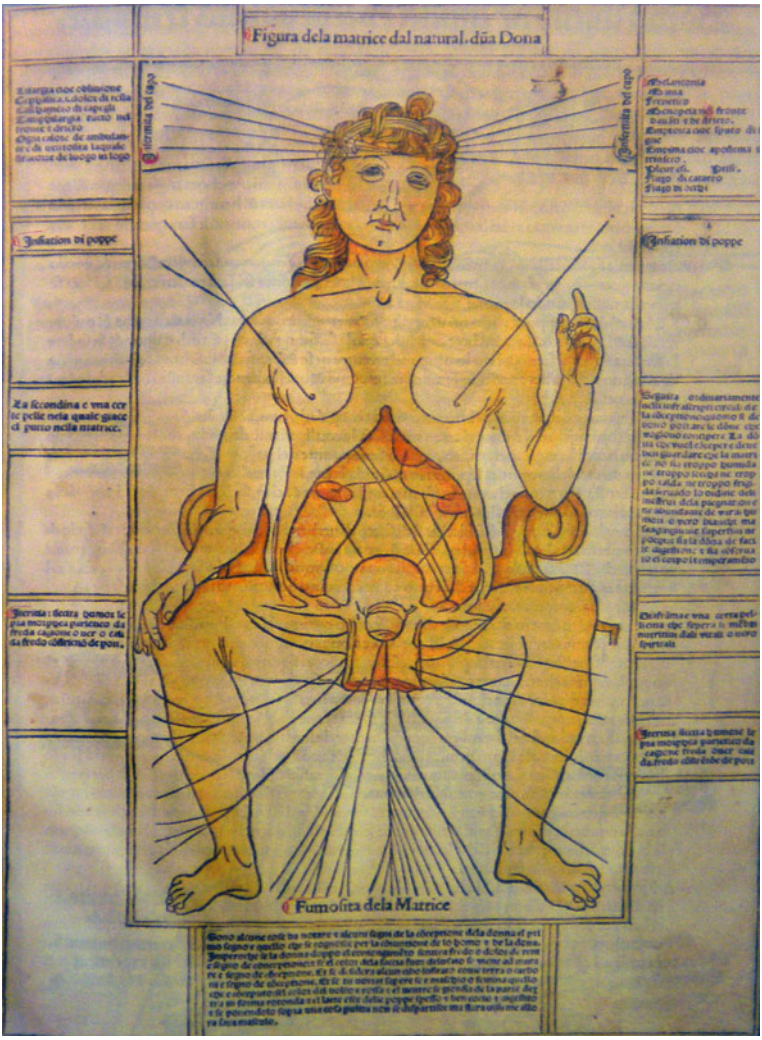
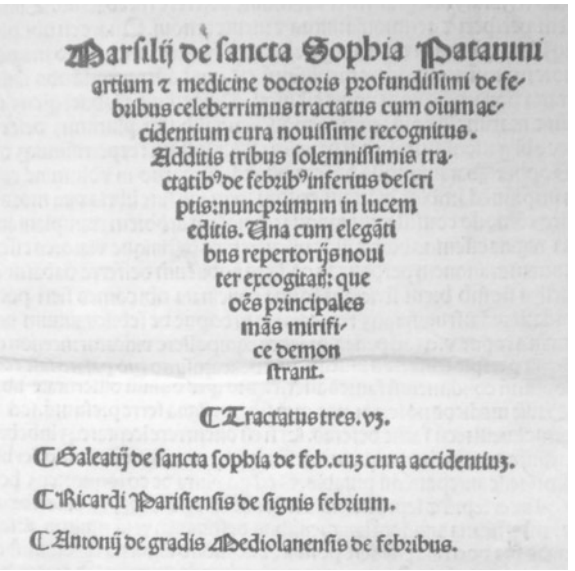


Fig. 15.22 Johannes de Ketham—"Fasiculo de medicina in volgare. Stampato in Venexia: per Zuane & Gregorio di Gregorii", 1493. Courtesy of historical archive, University of Padova


Marsilij de sancta Sophia Patauini
artium & medicine doctoris profundissimi de fe-
bribus celeberrimus tractatus cum oium ac-
cidentium cura nouissime recognitus.
Additis tribus solemnissimis tra-
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strant.
¶ Tractatus tres. vz.
¶ Galeatij de sancta sophia de feb. cuz cura accidentiuz.
¶ Ricardi Parisiensis de signis febrium.
¶ Antonij de gradis Mediolanensis de febribus.

Fig. 15.23 Marsilius de Sancta Sophia–Marsilij de Sancta Sophia… "De febribus celeberrimus tractatus cum omnium accidentium cura nouissime recognitus. Additis tribus solemnissimis tractatibus de febribus… nunc primum in lucem editis… Galeatij de Sancta Sophia de feb. cum cura accidentium. Ricardi Parisiensis de signis febrium. Antonij de Gradis Mediolanensis de febribus (Venetiis: mandato et impensis heredum… Octaviani Scoti… & sociorum… summa diligentia impressi… per Georgium Arriuabenum)", 1514. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

Fig. 15.24 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

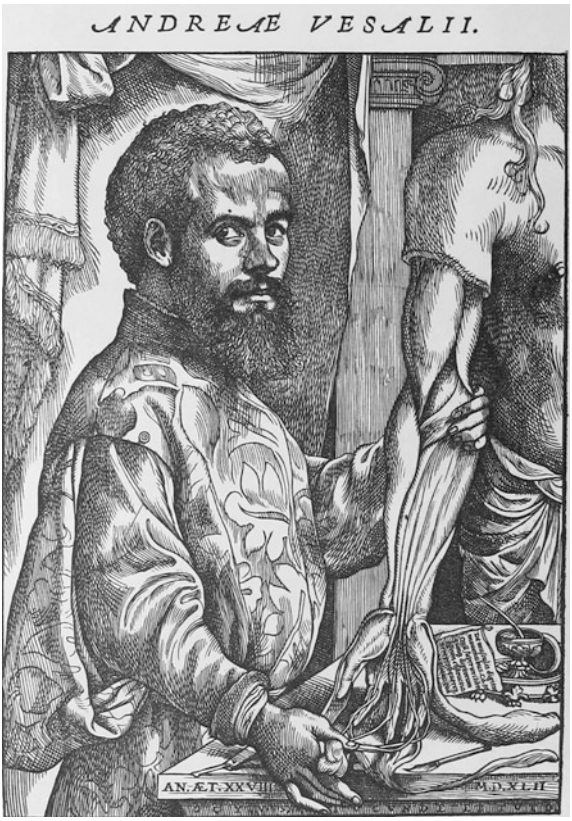


Fig. 15.25 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

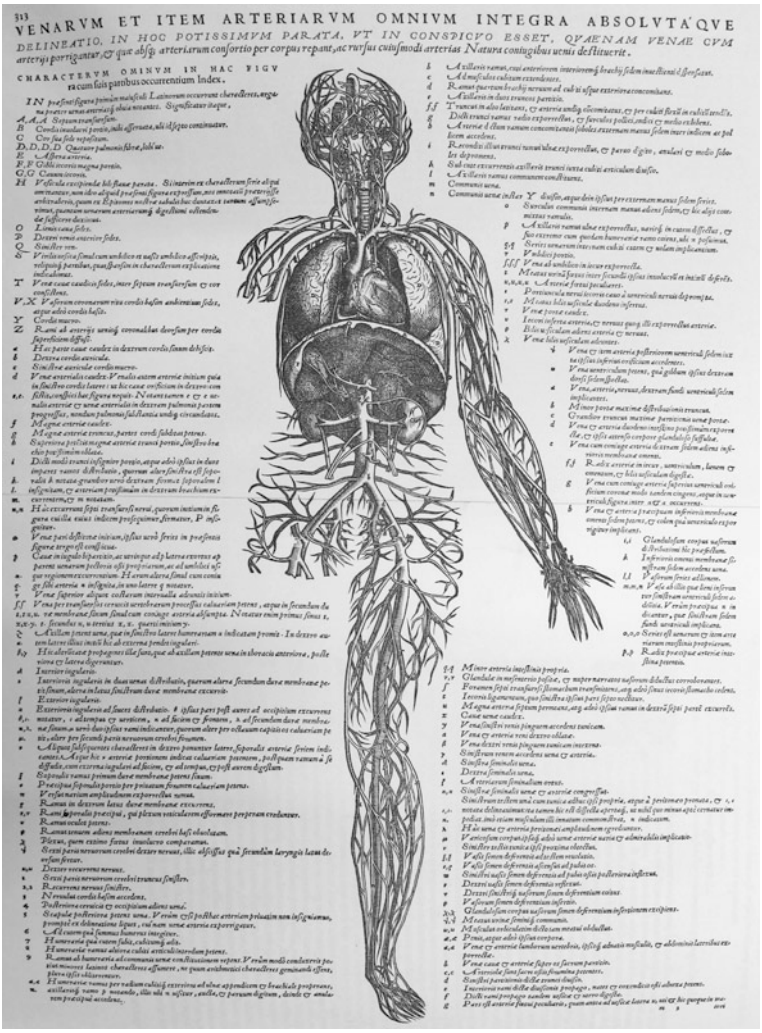


Fig. 15.26 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

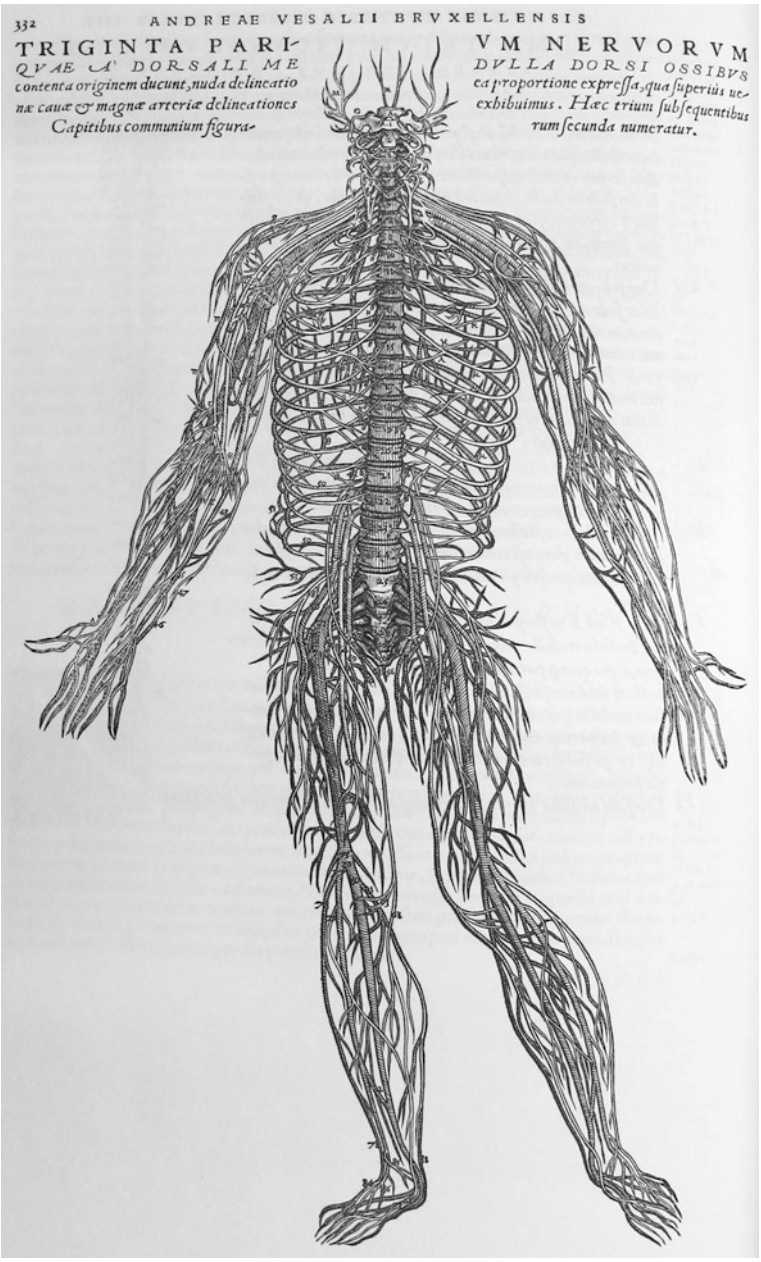


Fig. 15.27 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

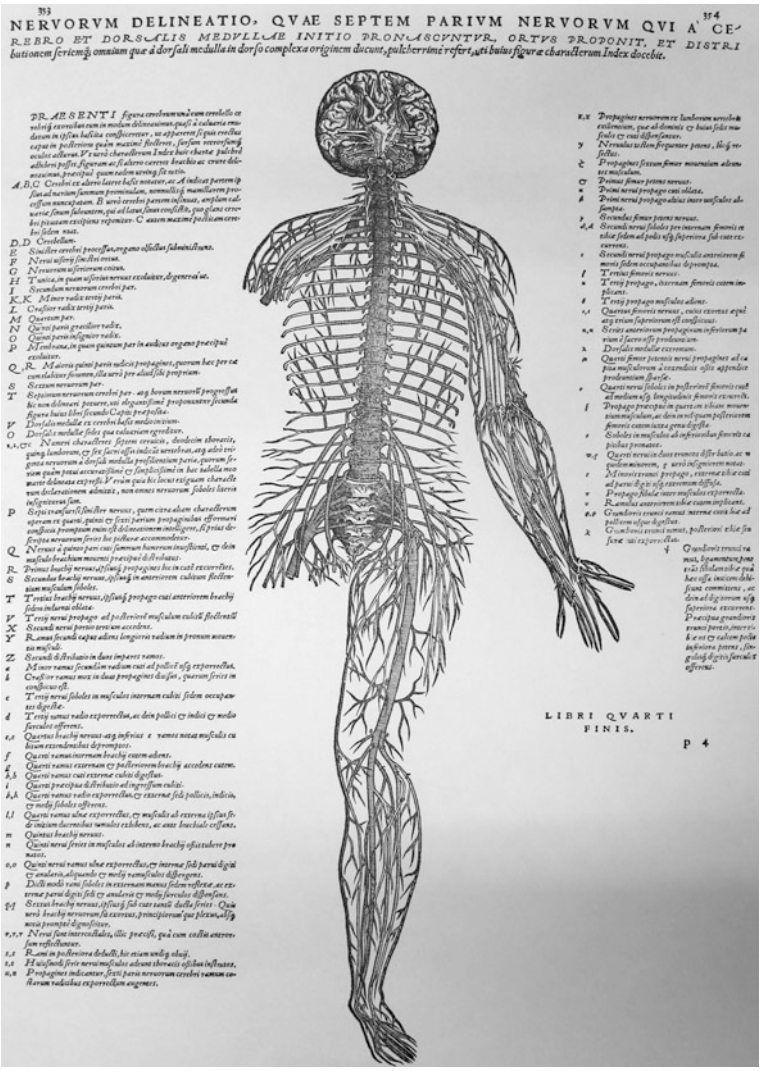


Fig. 15.28 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

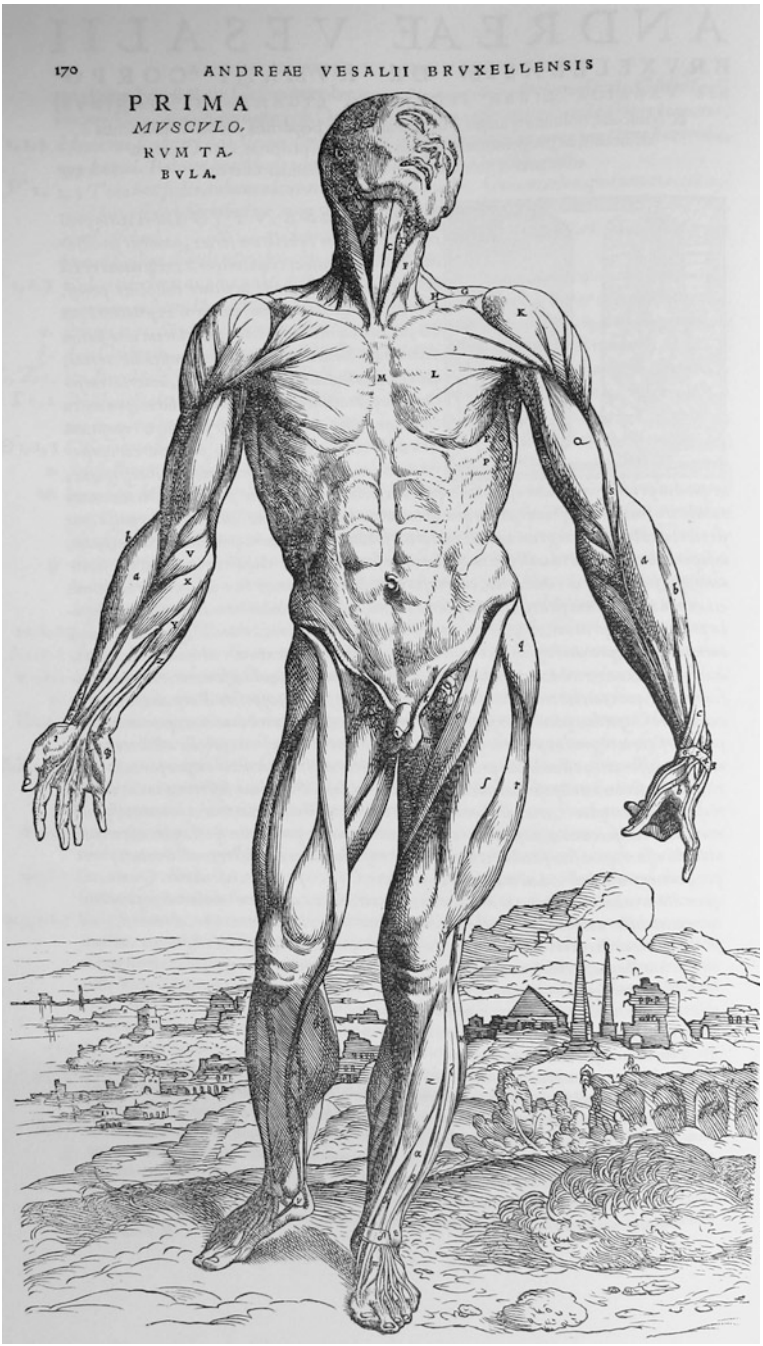


Fig. 15.29 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

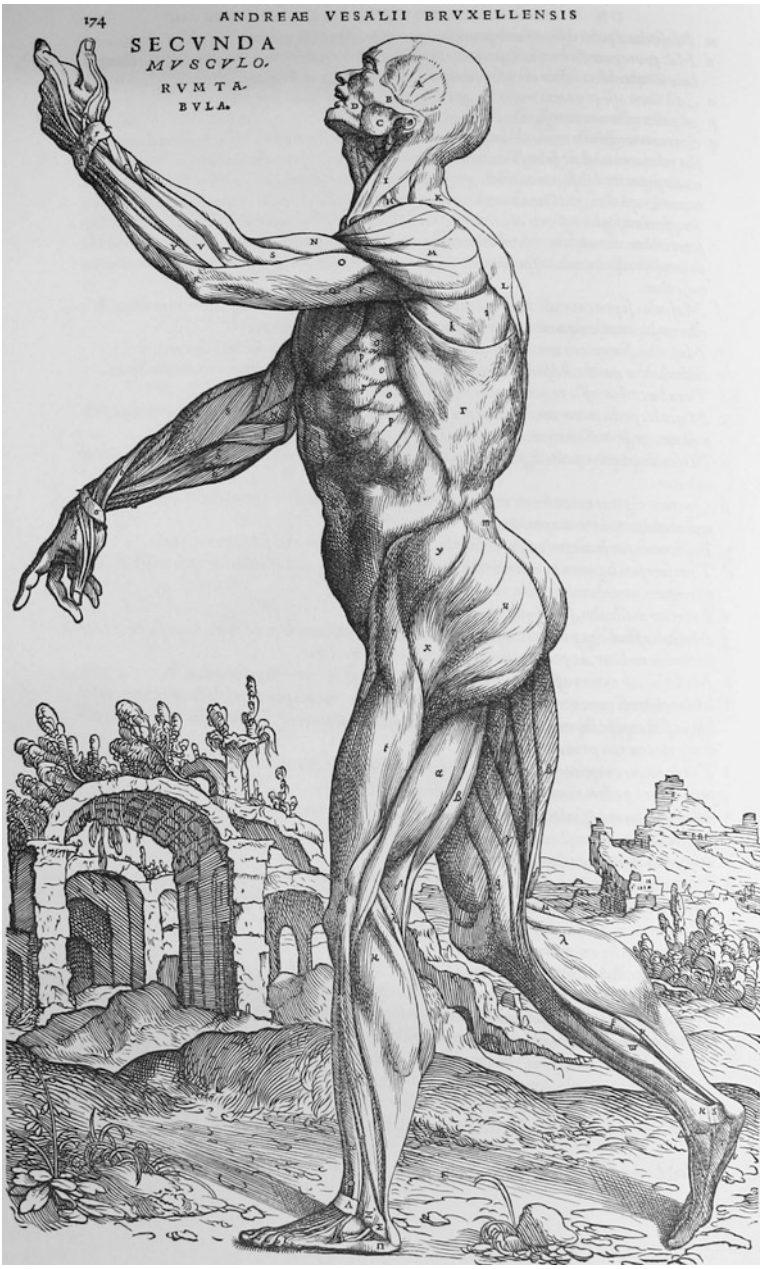


Fig. 15.30 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

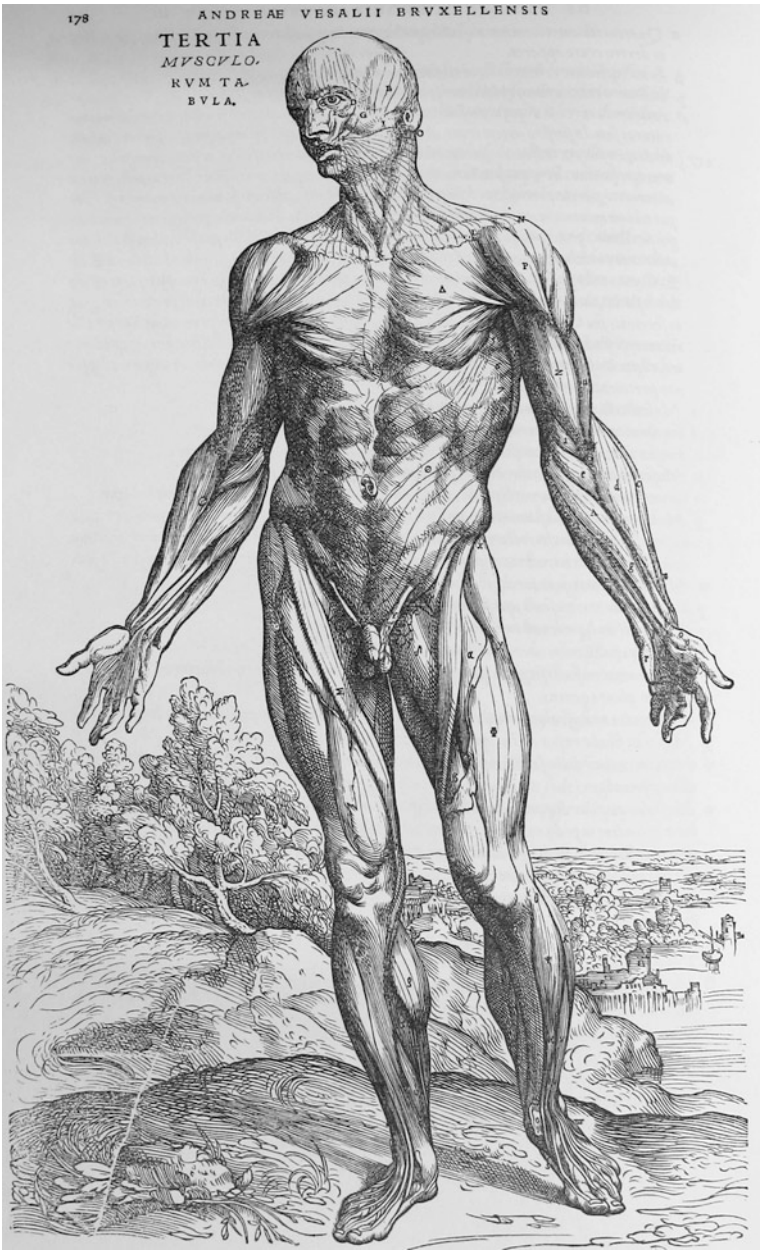


Fig. 15.31 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

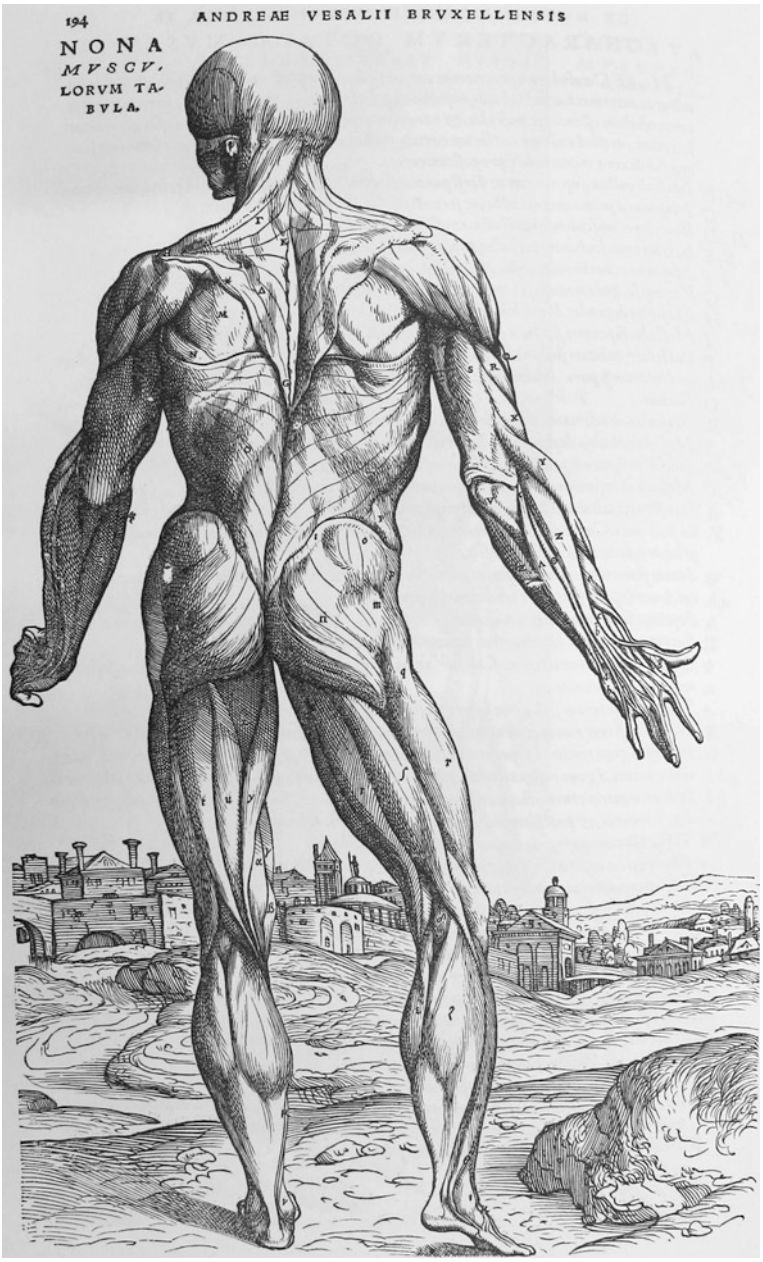


Fig. 15.32 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

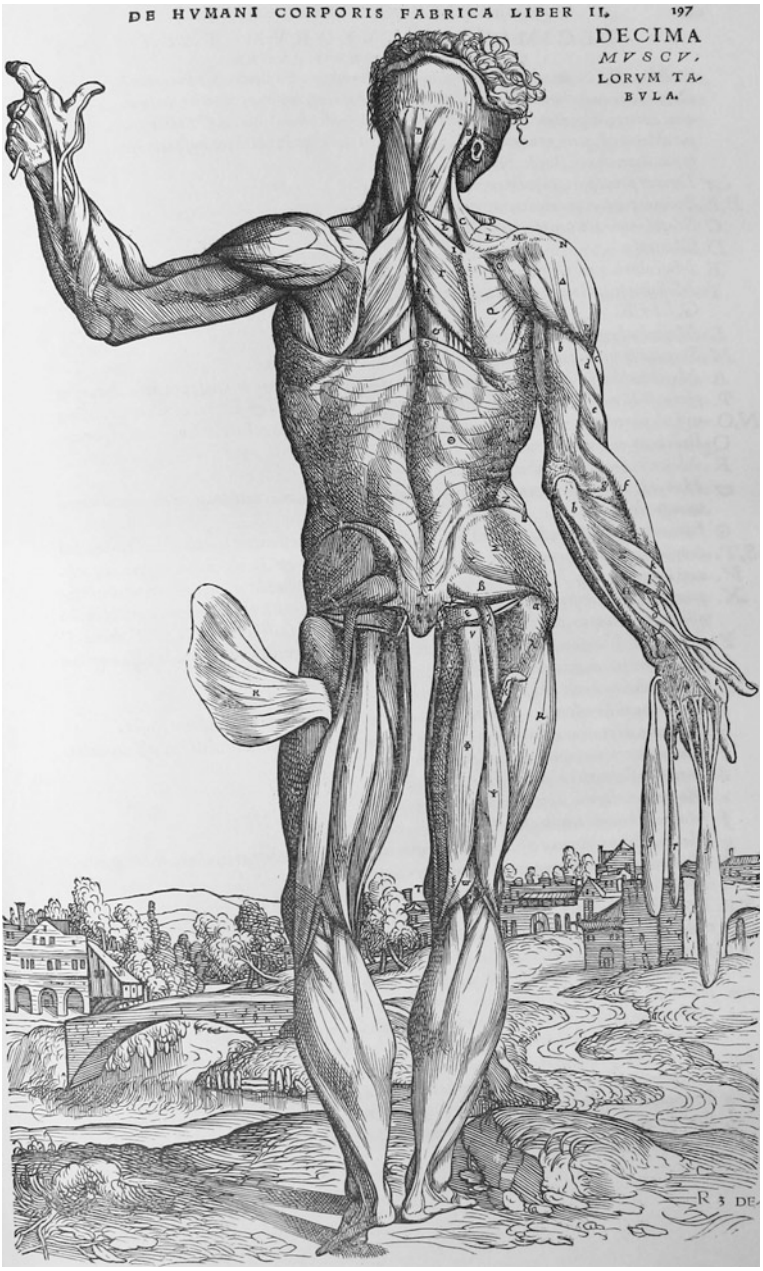


Fig. 15.33 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

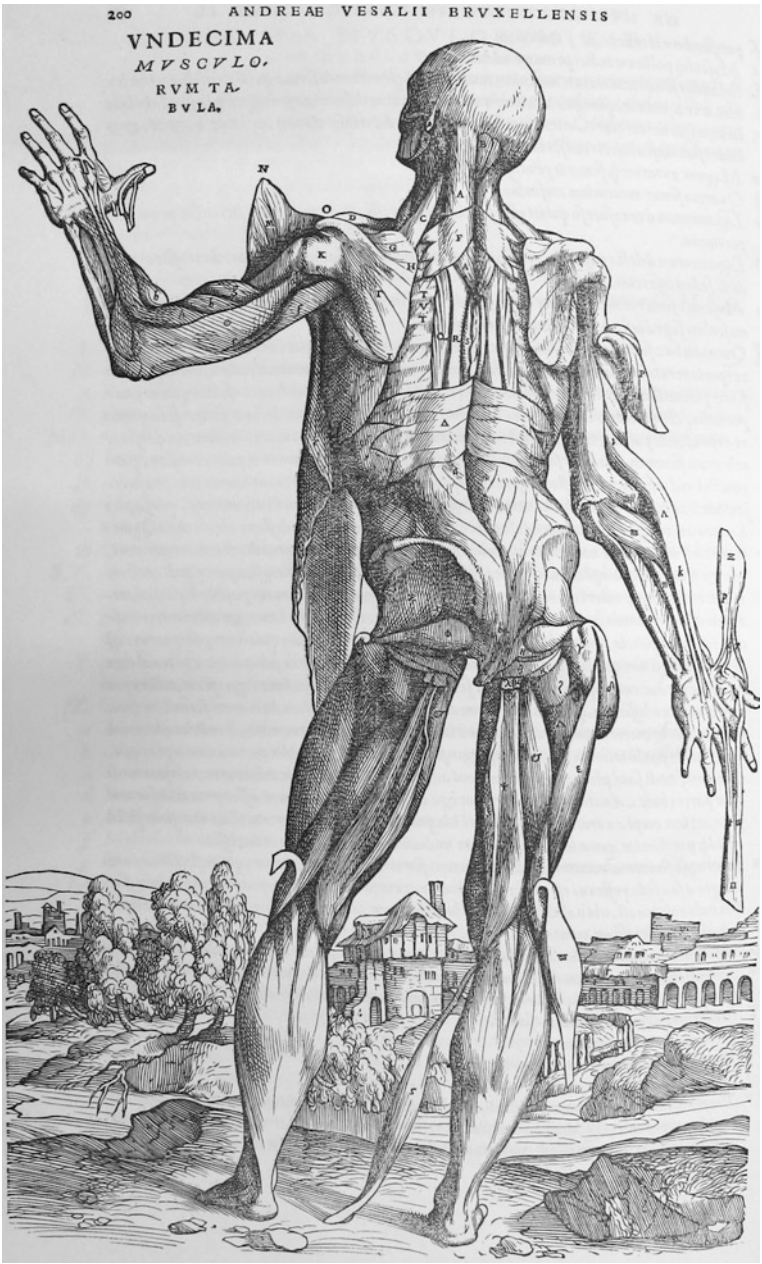


Fig. 15.34 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

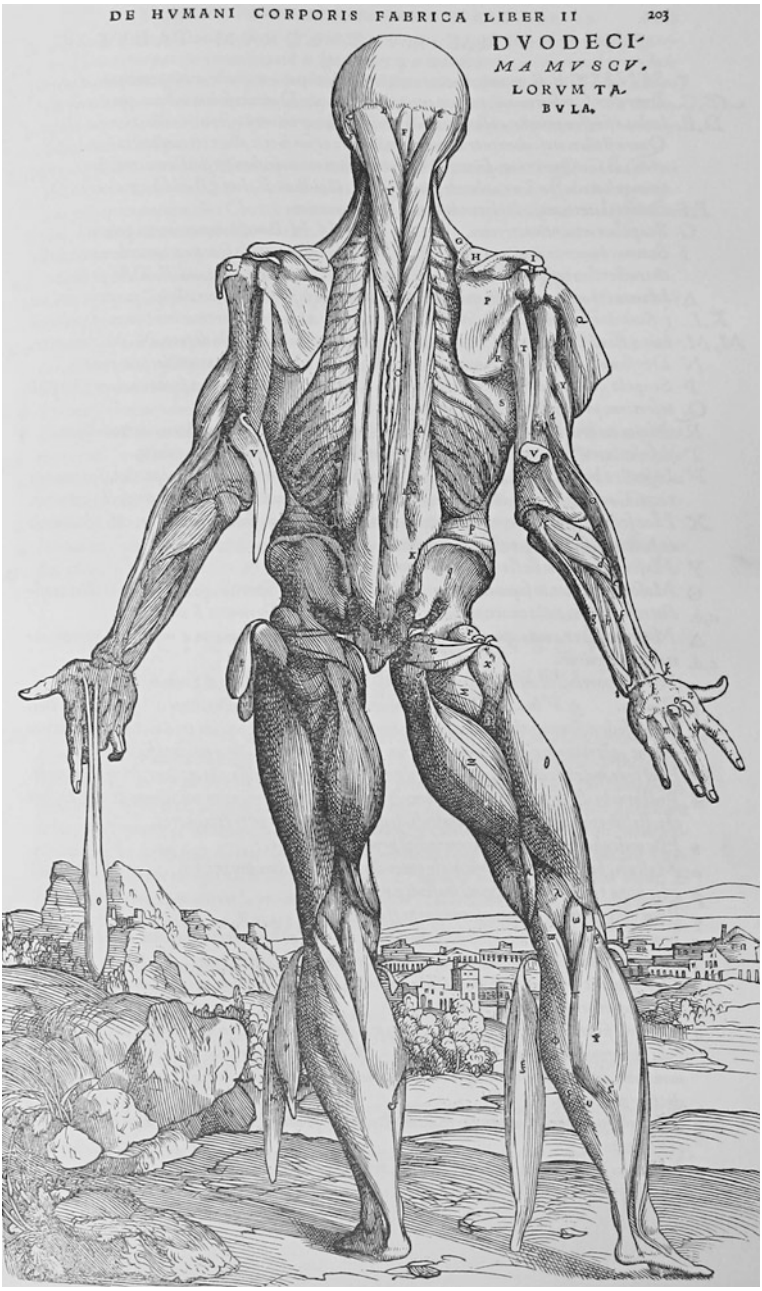


Fig. 15.35 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

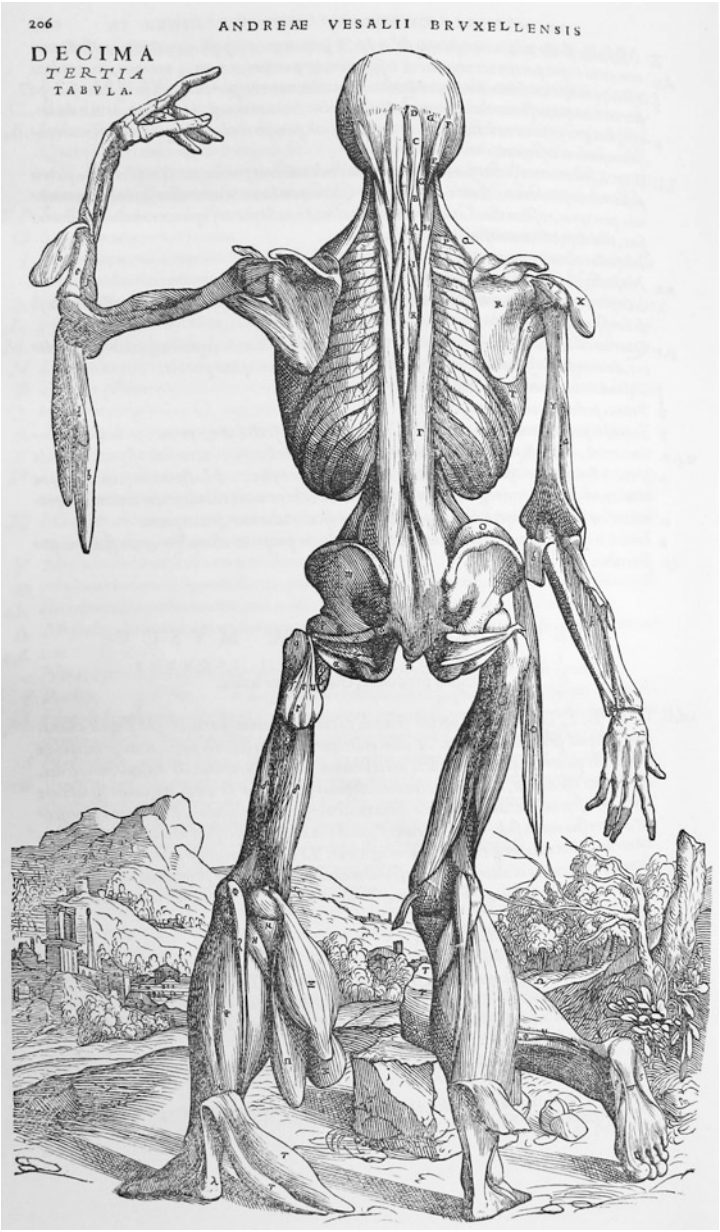


Fig. 15.36 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

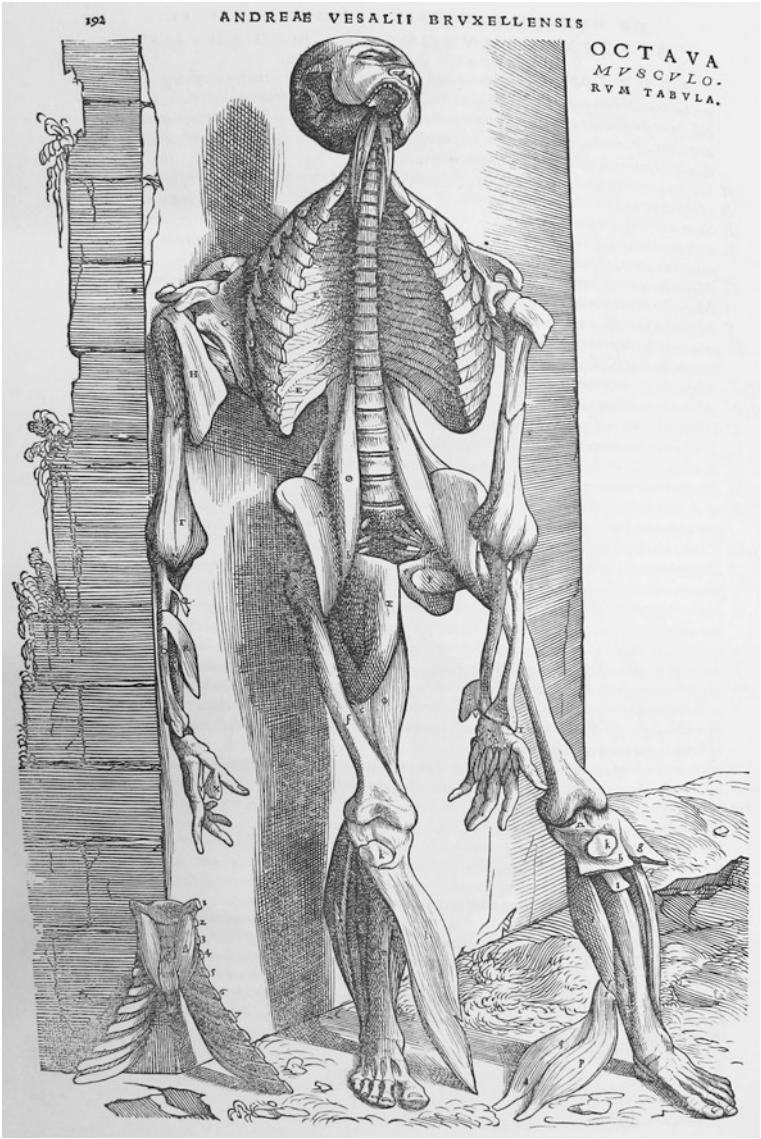


Fig. 15.37 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

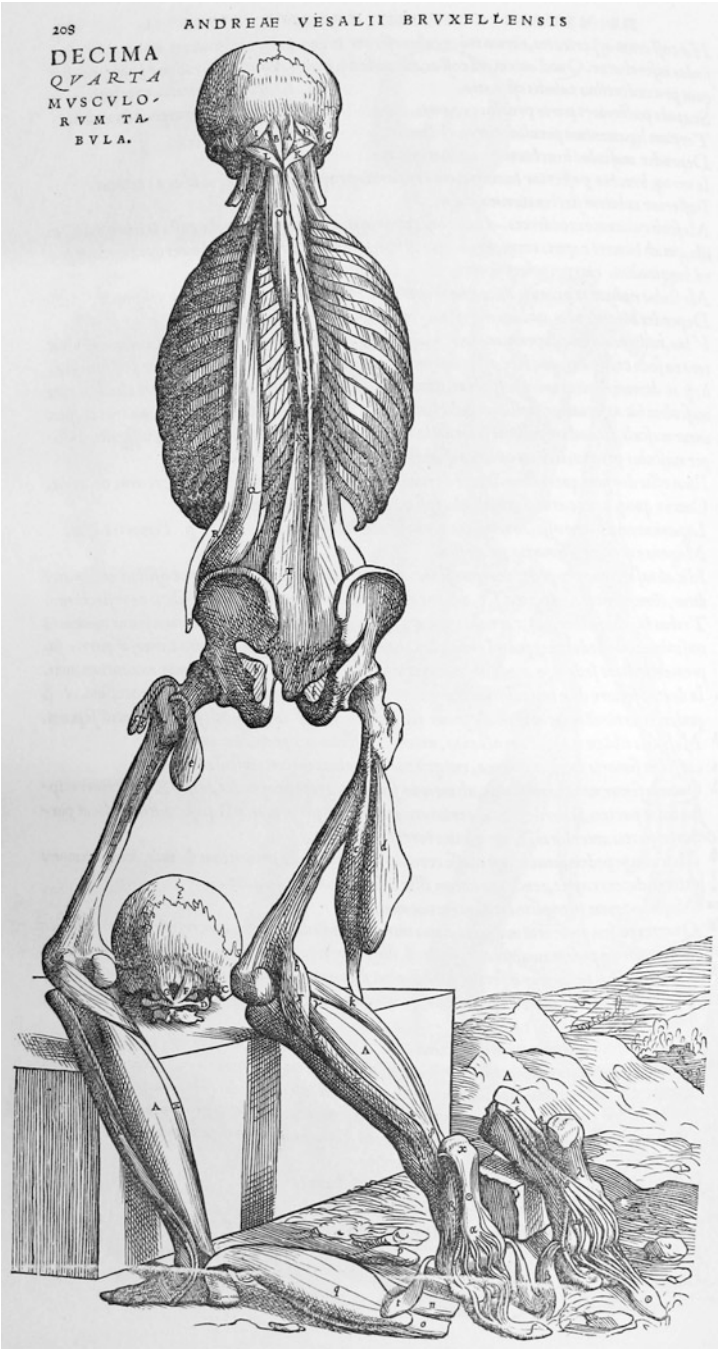


Fig. 15.38 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

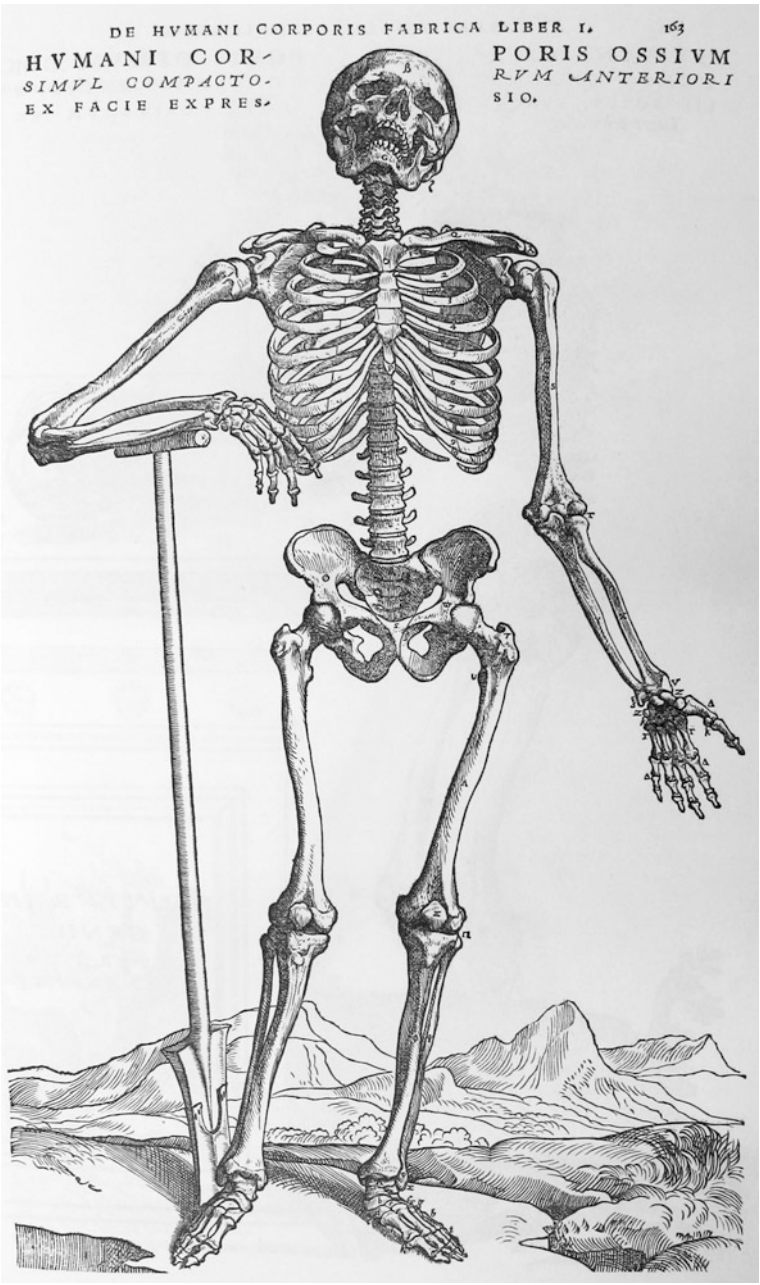


Fig. 15.39 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

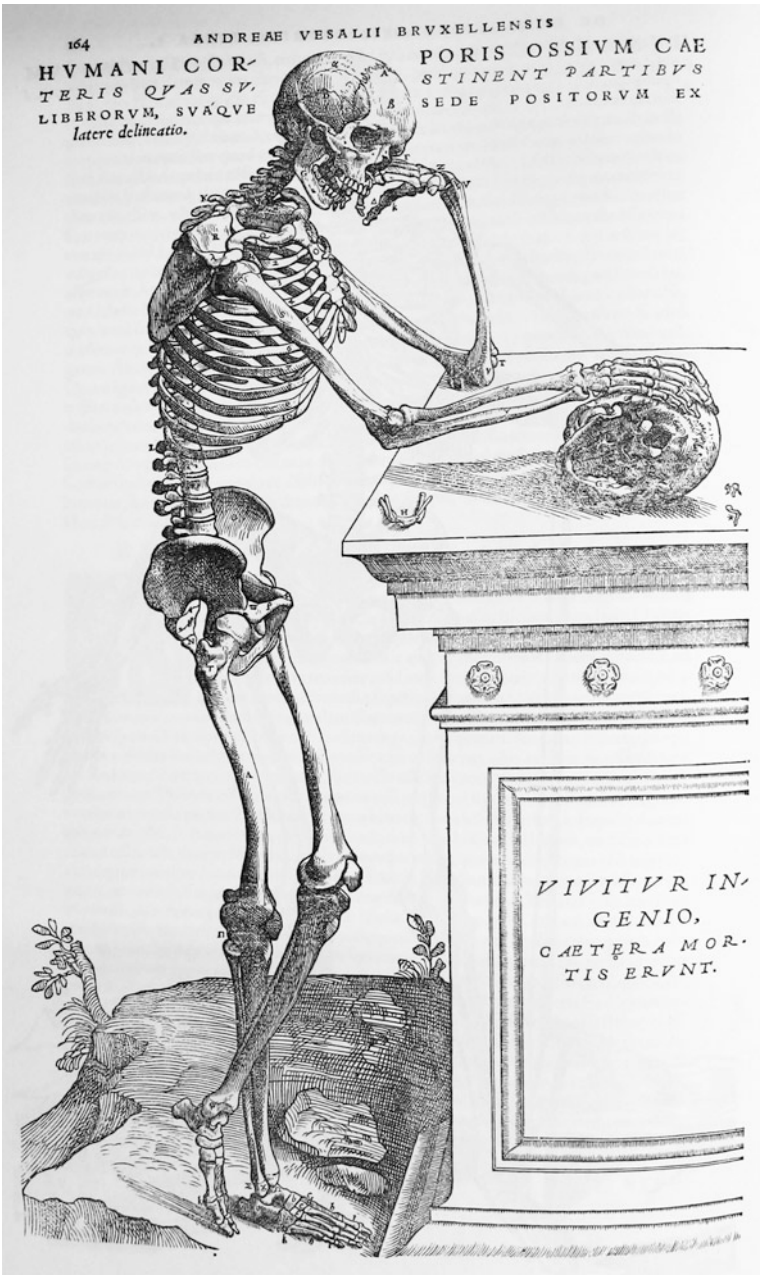


Fig. 15.40 Andreas Vesalius–Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

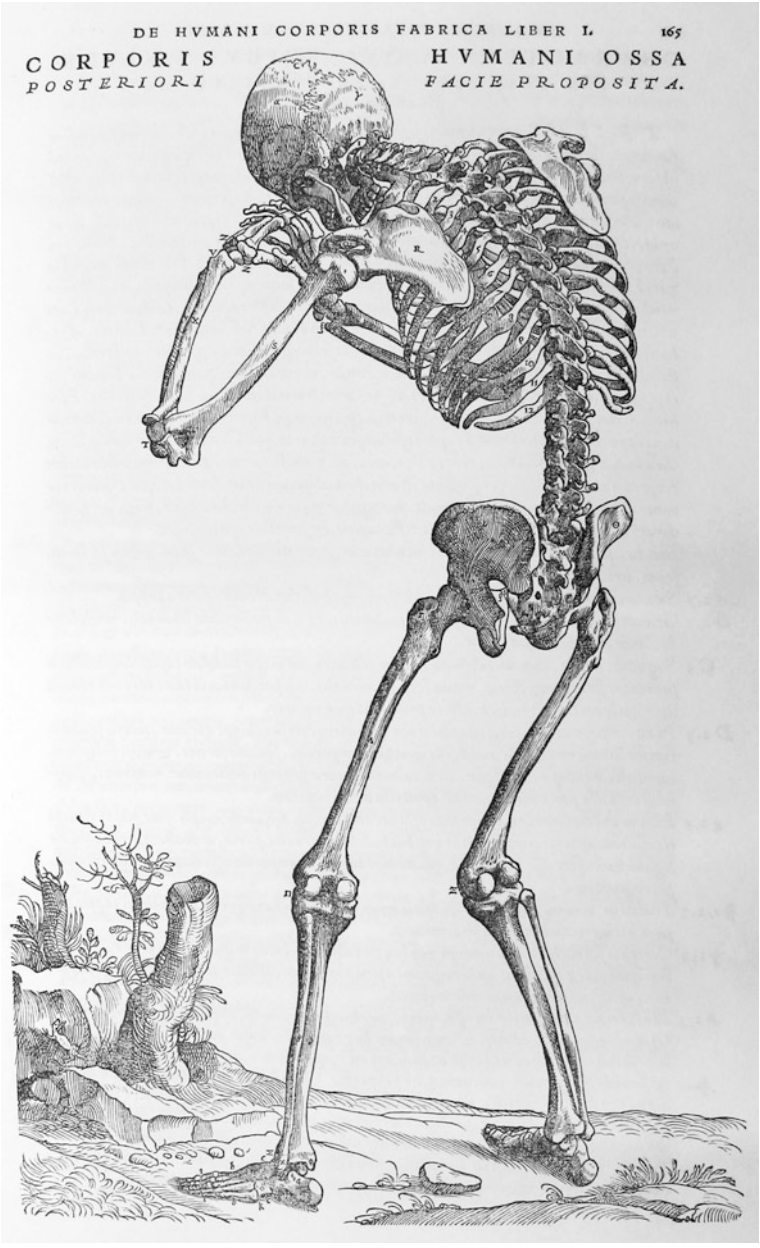


Fig. 15.41 Andreas Vesalius - Andreae Vesalii Bruxellensis, "Bruxellensis, scholae medicorum Patauine professoris, de humani corporis fabrica libri septem Basileae (Basileae: ex officina Ioannis Oporini)", 1543. Courtesy of Historical Section of the "Vincenzo Pinali" Medical Library of the University of Padova

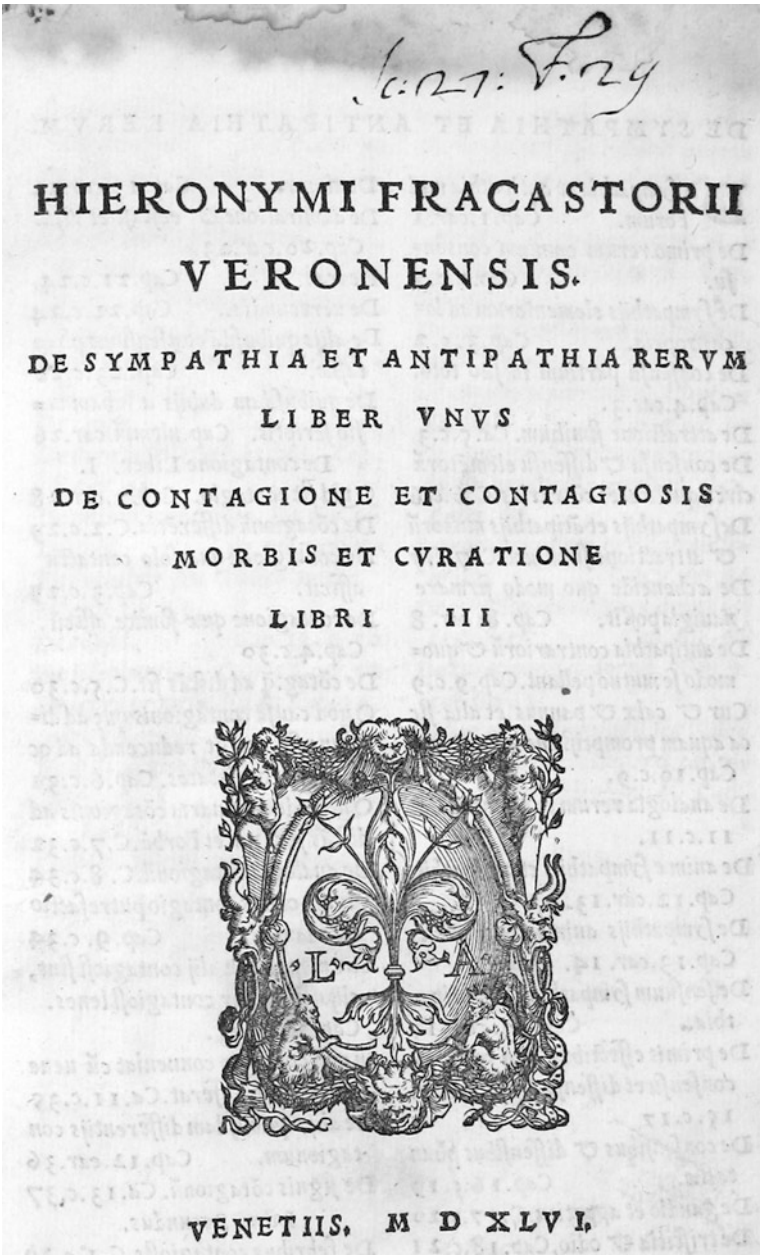
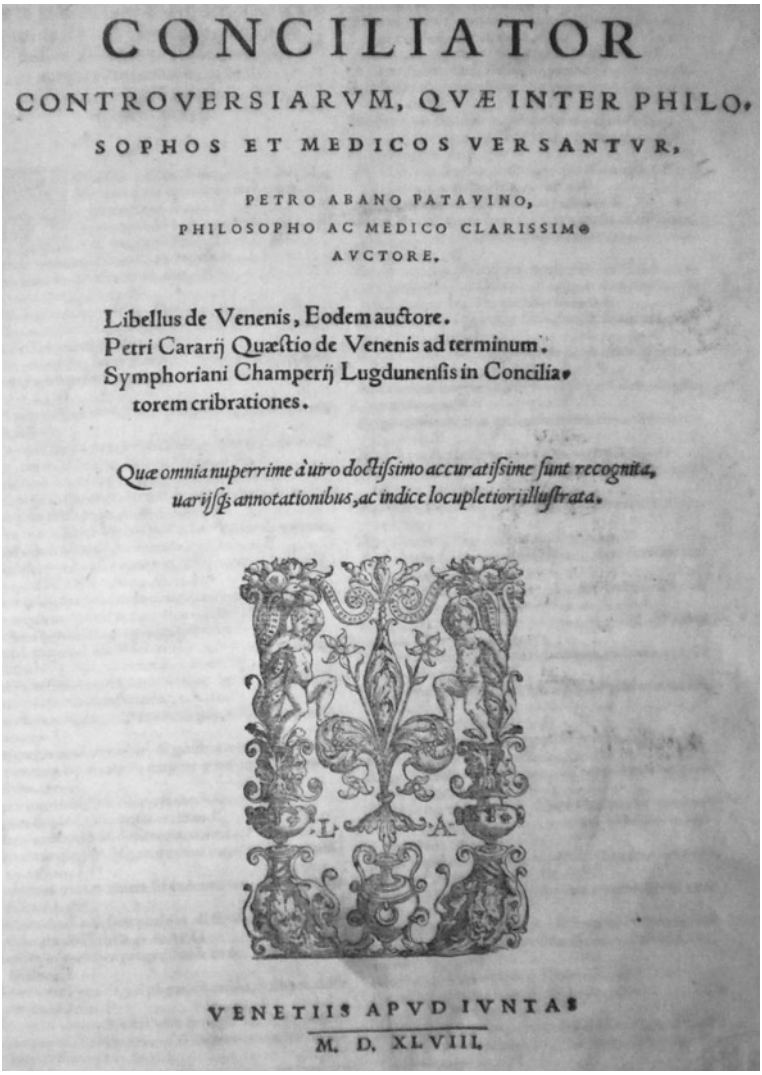


Fig. 15.42 Girolamo Fracastoro–Hieronymi Fracastorii Veronensis. "De sympathia et antipathia rerum liber vnus De contagione et contagiosis morbis et curatione libri 3 Venetijs: apud heredes Lucantonij Iuntae Florentini", 1546. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova


CONCILIATOR

CONTROVERSIARVM, QVÆ INTER PHILO-

SOPHOS ET MEDICOS VERSANTVR,

PETRO ABANO PATAVINO,

PHILOSOPHO AC MEDICO CLARISSIMO

AVCTORE.

Libellus de Venenis, Eodem auctore.
Petri Cararij Quæstio de Venenis ad terminum.
Symphoriani Champerij Lugdunensis in Conciliatorem cribrationes.

Quæ omnia nuperrime à uiro doctissimo accuratissime sunt recognita, uariisq; annotationibus, ac indice locupletiori illustrata.

VENETIIS APVD IVNTAS

M. D. XLVIII.

Fig. 15.43 Pietro d'Abano–"Conciliator controversiarum, quae inter philosophos et medicos versantur, Pietro Abano… auctore. Libellus de venenis, eodem auctore. Petri Carrarij Quaestio de venenis ad terminum. Symphoriani Champerij Lugdunensis in Conciliatorem cribrationes… Venetiis: apud Iuntas (Venetijs: impressus in officina haeredum Luceantonij Iuntae)" 1548. Courtesy of Historical Section of the "Vincenzo Pinali" Medical Library of the University of Padova

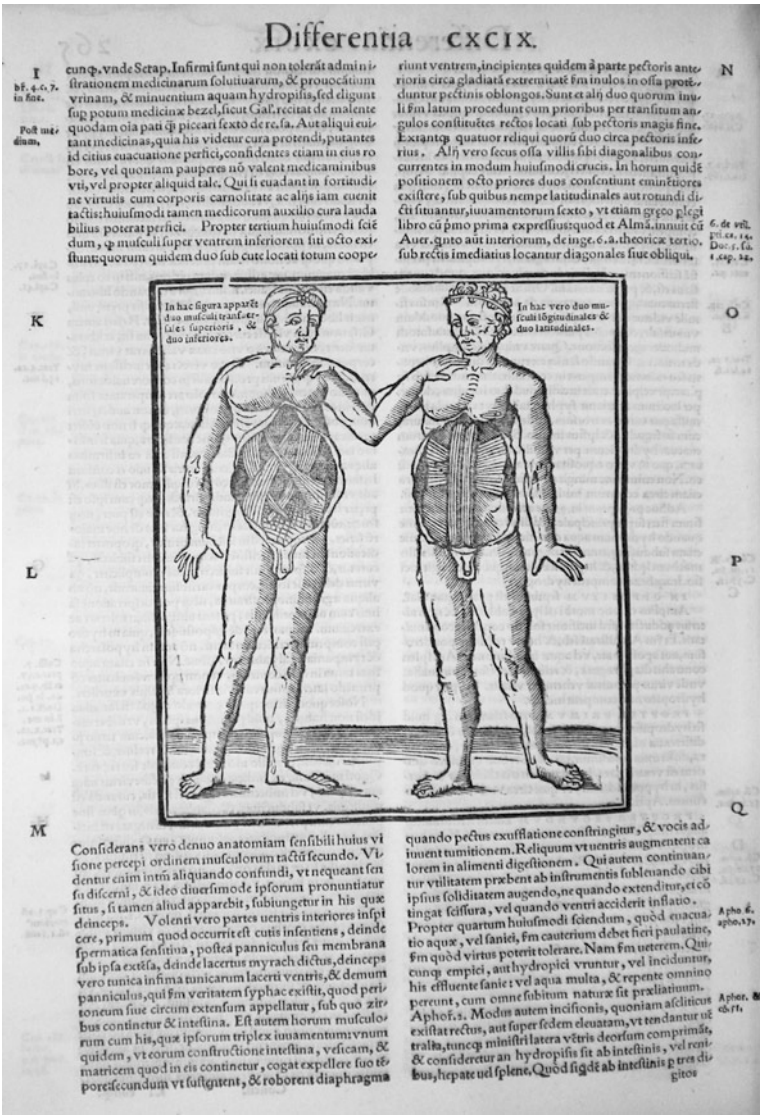


Fig. 15.44 Pietro d'Abano–"Conciliator controversiarum, quae inter philosophos et medicos versantur, Pietro Abano… auctore. Libellus de venenis, eodem auctore. Petri Carrarij Quaestio de venenis ad terminum. Symphoriani Champerij Lugdunensis in Conciliatorem cribrationes… Venetiis: apud Iuntas (Venetijs: impressus in officina haeredum Luceantonij Iuntae)" 1548. Courtesy of Historical Section of the "Vincenzo Pinali" Medical Library of the University of Padova

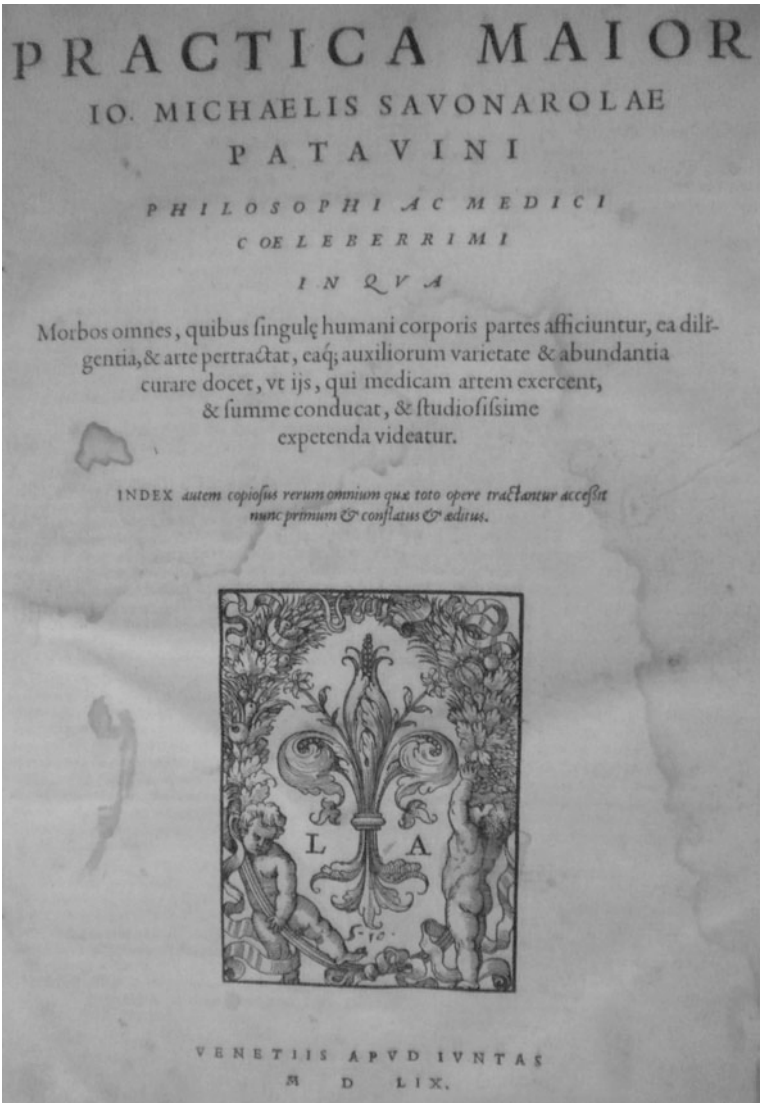


Fig. 15.45 Michele Savonarola—"Practica maior Io. Michaelis Sauonarolae Patauini philosophi ac medici coeleberrimi in qua morbos omnes, quibus singulae humani corporis partes afficiuntur, ea diligentia, & arte pertractat… Index autem copiosus rerum omnium quae toto opere tractantur accessit nunc primum & conflatus & aeditus Venetiis: apud Iuntas (Venetijs: impressum in officina haeredum Lucae Antonij Iuntae)", 1559. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

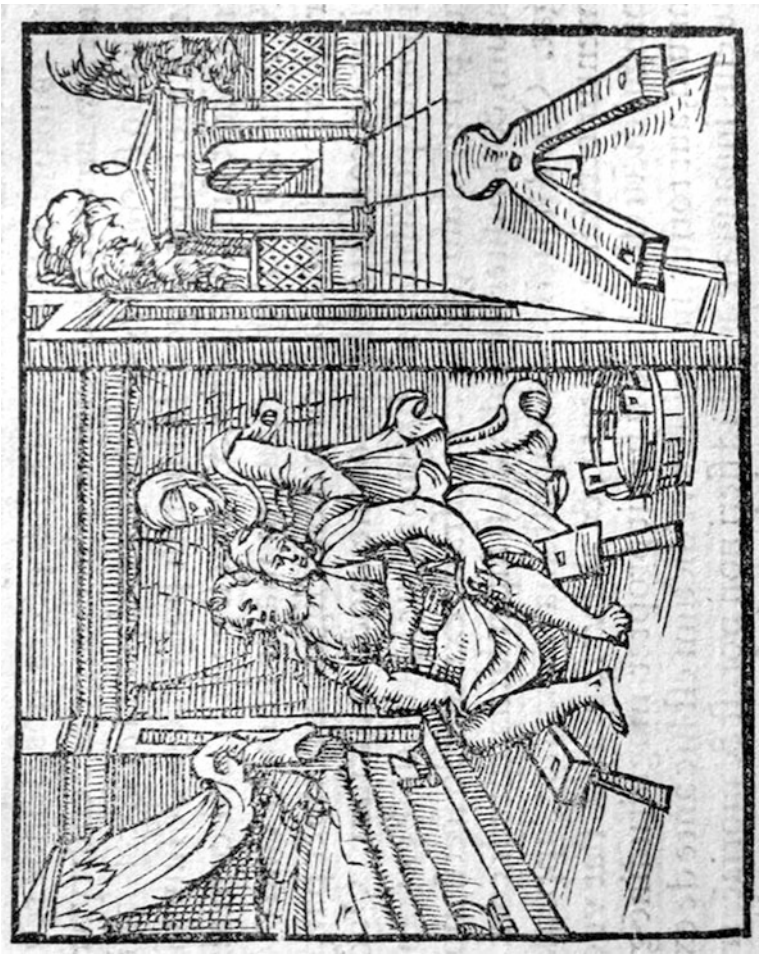


Fig. 15.46 Michele Savonarola—"Practica maior Io. Michaelis Sauonarolae Patauini philosophi ac medici coeleberrimi in qua morbos omnes, quibus singulae humani corporis partes afficiuntur, ea diligentia, & arte pertractat… Index autem copiosus rerum omnium quae toto opere tractantur accessit nunc primum & conflatus & aeditus Venetiis: apud Iuntas (Venetijs: impressum in officina haeredum Lucae Antonij Iuntae)", 1559. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

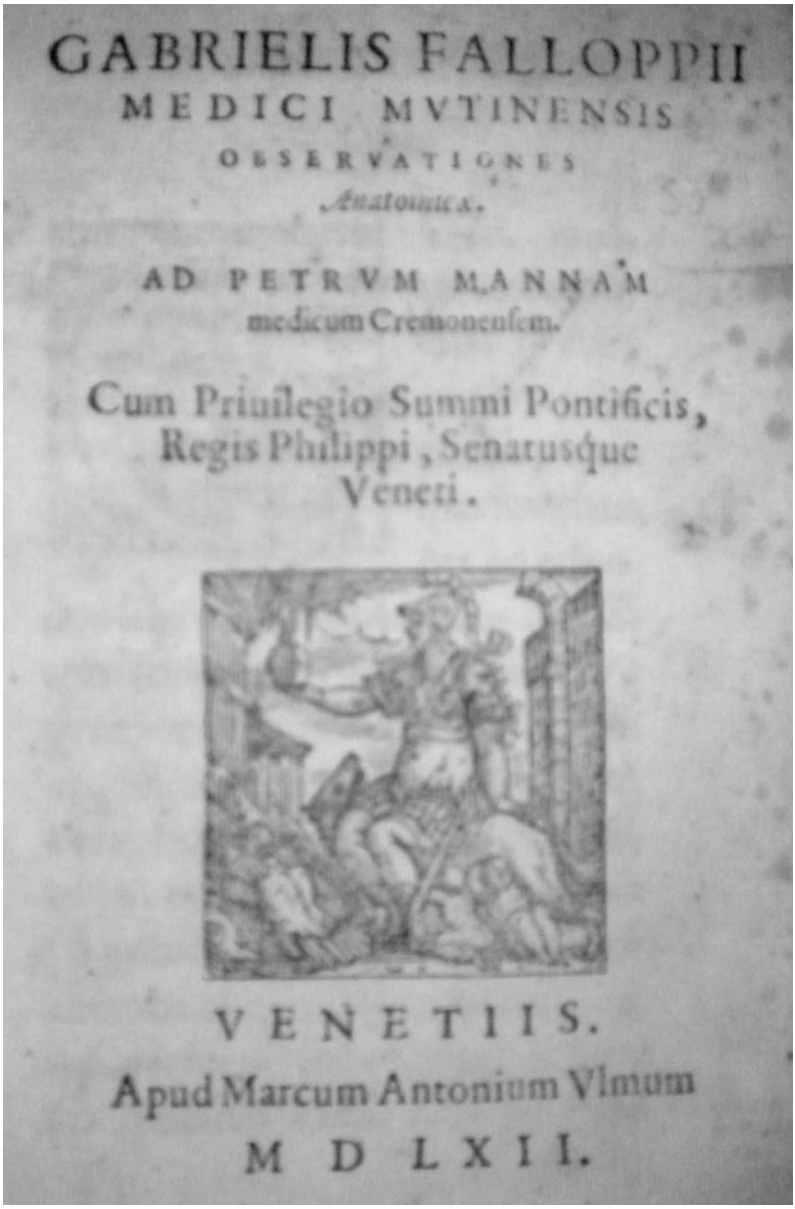


Fig. 15.47 Gabriele Falloppio–Gabrielis Falloppii… "Obseruationes anatomicae. Ad Petrum Mannam medicum Cremonensem Venetiis: apud Marcum Antonium Vlmum: [per Giovanni Grani]", 1562. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

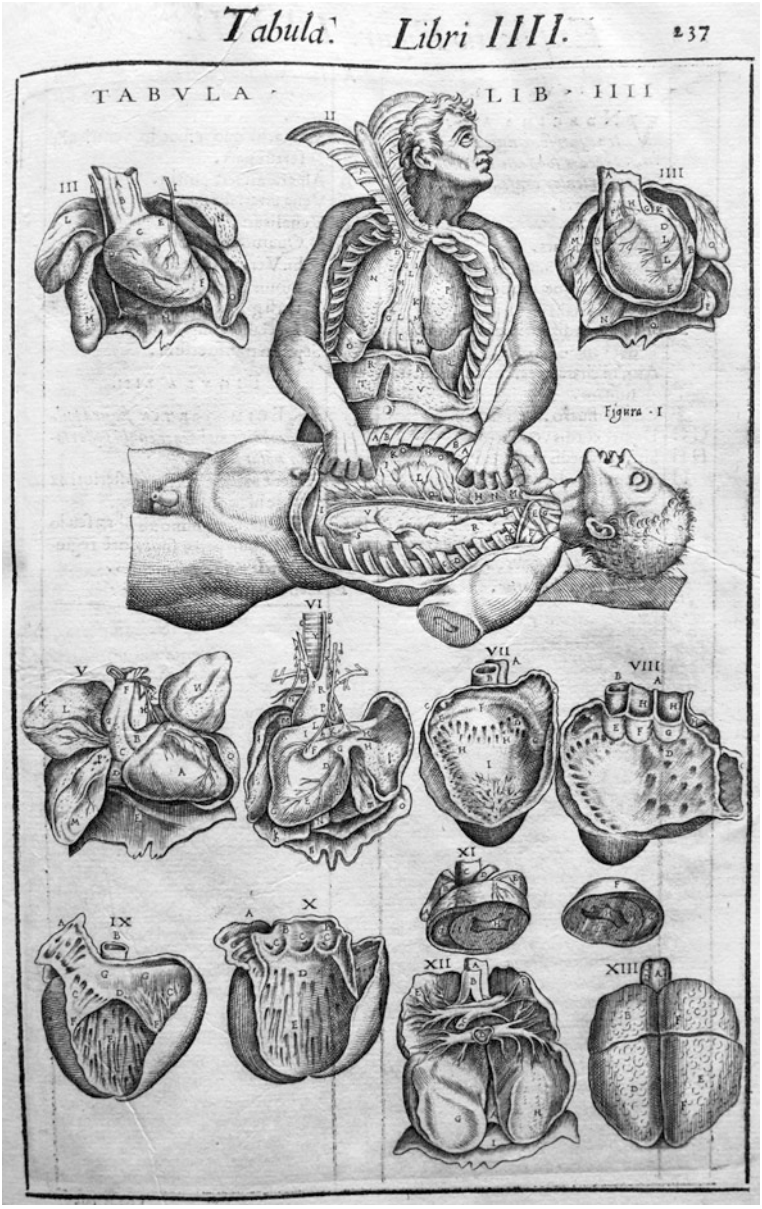


Fig. 15.48 Juan Valverde de Amusco—"Anatome corporis humani, auctore Ioanne Valuerdo. Nunc primum a Michaele Columbo latine reddita et additis nouis aliquot tabulis exornata Venetiis: studio et industria Iuntarum, 1589 (Venetiis: apud Iuntas, 1588)". Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

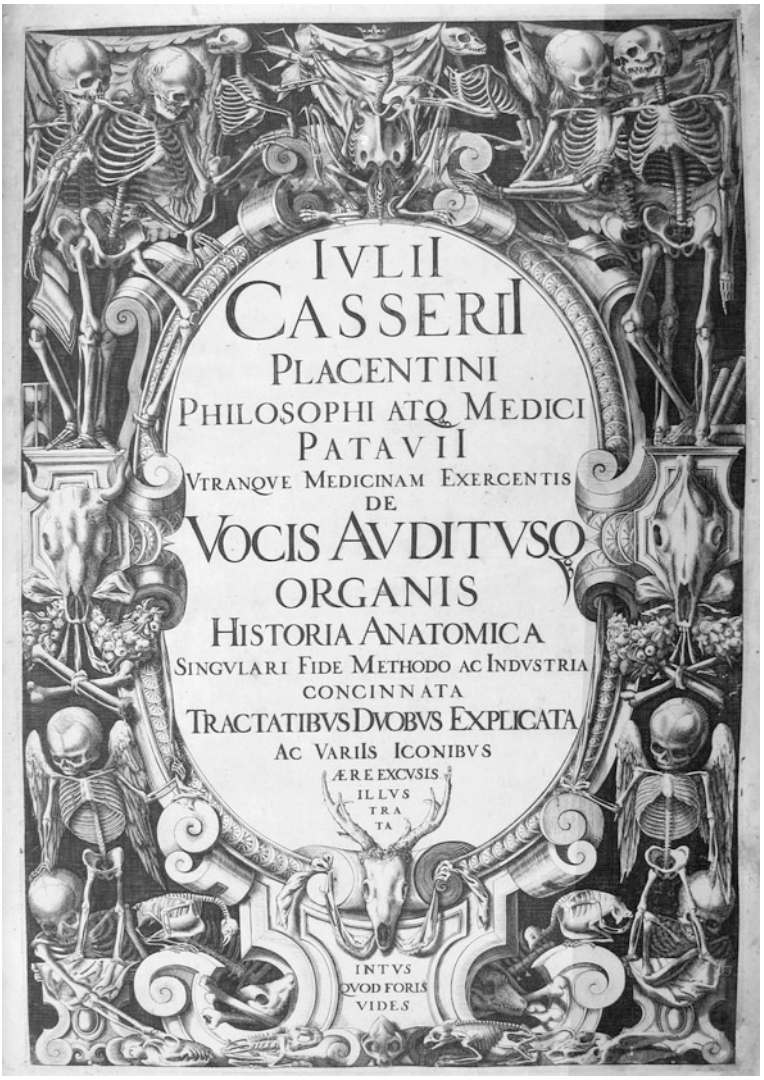


Fig. 15.49 Giulio Casseri–Iulii Casserii… "De vocis auditusque organis historia anatomica singulari fide methodo ac industria concinnata tractatibus duobus explicata ac variis iconibus aere excusis illustrata (Ferrariae: excudebat Victorius Baldinus typographus cameralis; Patauii: sumptibus Vnitorum)", 1600–1601. Courtesy of Historical Section of the "Vincenzo Pinali" Medical Library of the University of Padova


GABRIELIS
FALLOPPII
MVTINENSIS,
Phyſici, ac Chirurgi toto orbe clariſſimi,
IN TRIBVS GYMNASIIS ITALIAE FLORENTISSIMIS,
Ferrarienſi, Piſano, Patauino, rem Botanicam, Anatomicam, Chirurgicam mira cum
laude, ac honore, apertaque diuini ingenij, ac ſummæ rerum peritiæ
ſignificatione quondam profitentis, & exercentis.
OPERA GENVINA OMNIA,
TAM PRACTICA, QVAM THEORICA IAM PRIDEM A CVNCTIS
Medicinæ tum Studioſis, tum Profeſſoribus auidè expetita, & expectata.
Quorum pars vna, tota præſertim Chirurgia, & Tractatus de Morbo Gallico, Methodusque Conſultandi ab Auctore ad
editionem concinnata, & expolita, ac in præſens vſque ſuppreſſa, nunc primum lucem adſpicit;
pars verò altera è volumine incondito Francofurti nuper edito deſumpta, &
in ordinem redacta, plurimisq; mendis repurgata.
Nunc tandem ad auctoris gloriam, ad operis perfectionem, ad commune bonum ſedulò, & accuratè ſimul excuſa,
AC IN TRES TOMOS DISTRIBVTA;
nec ſolum in tractatus; ſed in capita quoque aptè ſecta, & diuiſa.
TOMVS PRIMVS.
Elenchi Tractatuum & Capitum ad ſingulorum tomorum initia ſunt appoſiti: ad margines verò totius Chirurgiæ Nouæ
annotatiunculæ vtiliſſimæ nouiter adſcriptæ; denique ad calcem tertij Tomi Index rerum,
& verborum, quæ obſeruanda ſunt, locupletiſſimus adiunctus eſt.
CVM PRIVILEGIIS.
VENETIIS, MDCVI.
Apud Io. Antonium, & Iacobum de Franciſcis.

Fig. 15.50 Gabriele Falloppio–Gabrielis Falloppii "Opera genuina omnia, tam practica, quam theorica iam pridem a cunctis medicinae tum studiosis, tum professoribus auide expetita, & expectata. Quorum pars una, tota praesertim chirurgia, & tractatus De morbo Gallico, metodusque consultandi ab auctore ad editionem concinnata, & expolita, ac in praesens usque suppressa, nunc primum lucem adspicit; pars vero altera e volumine incondito Francofurti nuper editio desumpta… et… repurgata. Nunc tandem ad auctoris gloriam, ad operis perfectionem, ad communem bonum sedulo, & accurate simul excusa, ac in tres tomos distributa; nec solum in tractatus; sed in capita quoque apte secta, & diuisa Venetiis: apud Io. Antonium, & Iacobum de Franciscis", 1606. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

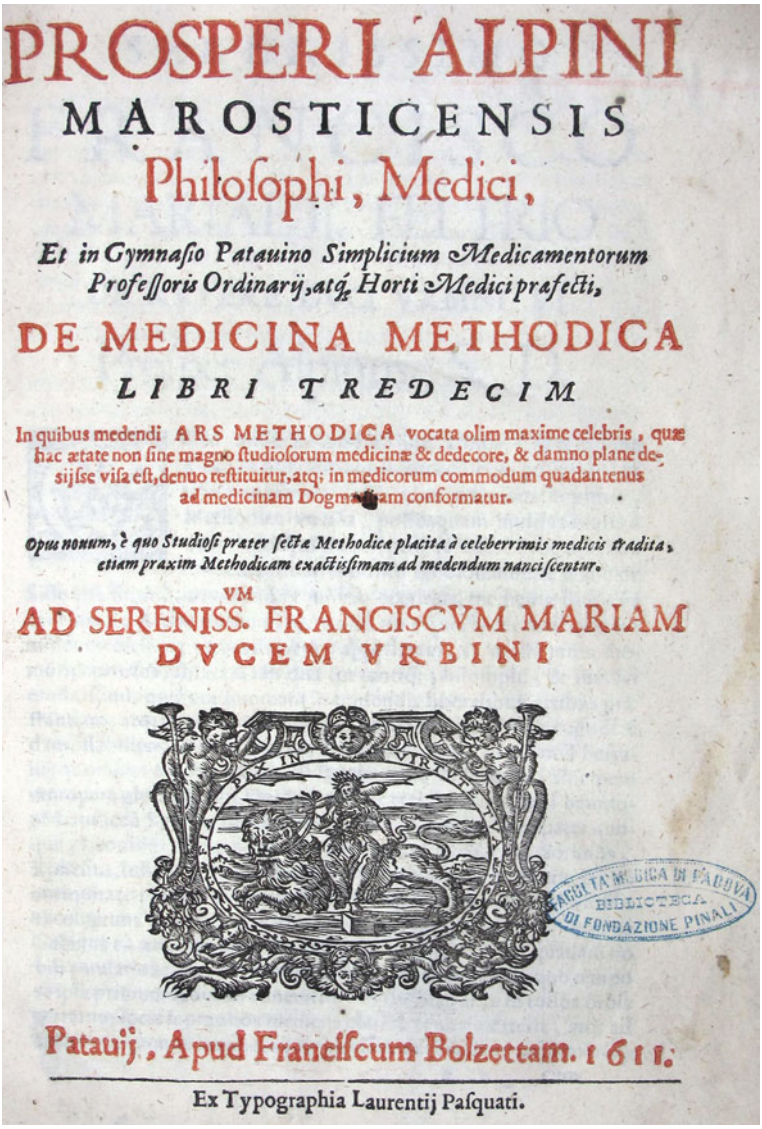

PROSPERI ALPINI
MAROSTICENSIS
Philoſophi, Medici,
Et in Gymnaſio Patauino Simplicium Medicamentorum
Profeſſoris Ordinarij, atq; Horti Medici prafecti,
DE MEDICINA METHODICA
LIBRI TREDECIM
In quibus medendi ARS METHODICA vocata olim maxime celebris, quæ
hac ætate non ſine magno ſtudioſorum medicinæ & dedecore, & damno plane de-
sijſse viſa eſt, denuo reſtituitur, atq; in medicorum commodum quadantenus
ad medicinam Dogmaticam conformatur.
Opus nouum, è quo Studioſi præter ſectæ Methodicæ placita à celeberrimis medicis tradita,
etiam praxim Methodicam exactiſsimam ad medendum nanciſcentur.
VM
AD SERENISS. FRANCISCVM MARIAM
DVCEM VRBINI
PAX IN VIRTVTE
FACOLTÀ MEDICA DI PADOVA
BIBLIOTECA
DI FONDAZIONE PINALI
Patauij, Apud Franciſcum Bolzettam. 1611.
Ex Typographia Laurentij Paſquati.

Fig. 15.51 Prospero Alpino–Prosperi Alpini Marosticensis… "De medicina methodica libri tredecim in quibus medendi ars methodica vocata olim maxime celebris, quae hac aetate non sine magno studiosorum medicinae & dedecore, & damno plane desijsse visa est, denuo restituitur, atque in medicorum commodum quadantenus ad medicinam dogmaticam conformatur… Patauij: apud Franciscum Bolzettam, ex typographia Laurentij Pasquati", 1611. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

Fig. 15.52 Johann Vesling–Ioannis Veslingii Mindani equitis,… "Syntagma anatomicum, locis plurimis auctum, emendatum, nouisque iconibus diligenter exornatum Patauii: typis Pauli Frambotti bibliopolae", 1647. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

Fig. 15.53 Antonio Molinetti–Antonii Molinetti… "Dissertationes anatomicae, et pathologicae de sensibus, & eorum organis Patauii: ex typographia Matthaei Bolzetta de Cadorinis", 1669. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

FORTUNATI FIDELIS,
MEDICI,
DE
RELATIONIBUS
MEDICORUM
LIBRI QVATUOR,
In qvibus ea omnia, qvæ in forensibus, ac publicis causis, Medici referre solent, plenissimè traduntur
Adjecto duplici Indice: Capitum scil. & Rerum Memorabilium, revisi,
ac
Mendis librariis plerisq; deletis,
Publico usui destinati,
Studiô
D. PAULI AMMANNI.
CUM PRIVILEGIO.

LIPSIÆ.
Impensis JOH. CHRIST. TARNOVII.
LITERIS CHRISTIANI MICHAELIS,
Anno M. DC. LXXIV.

Fig. 15.54 Fedele Fortunato–Fortunati Fidelis medici, "De relationibus medicorum libri quatuor, in quibus ea omnia, quae in forensibus, ac publicis causis, medici referre solent, plenissime traduntur. Adiecto duplici indice studio d. Pauli Ammanni Lipsiae : impensis Joh. Christ. Tarnovii, literis Christiani Michaelis", 1674. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

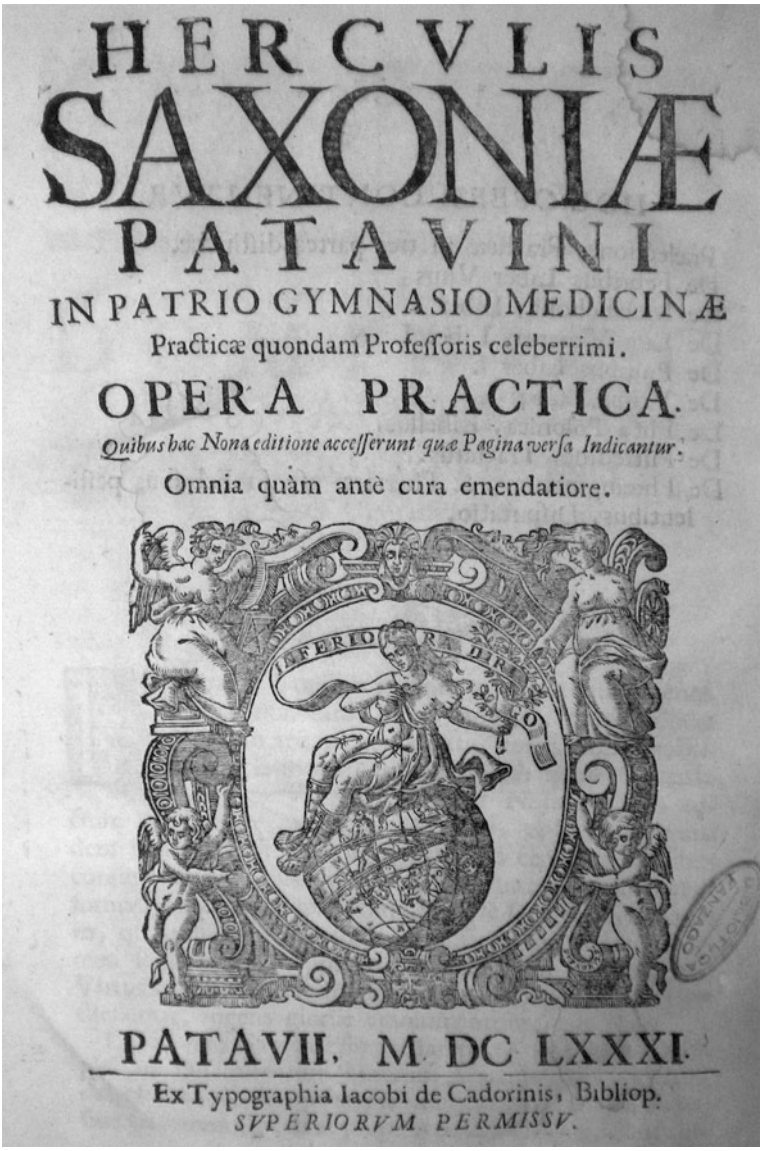


Fig. 15.55 Ercole Sassonia–Herculis Saxoniae Patauini… "Opera practica quibus hac nona editione accesserunt quae pagina versa indicantur. Omnia quam ante cura emendatiore Patauii: ex typographia Iacobi de Cadorinis bibliop…", 1681. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

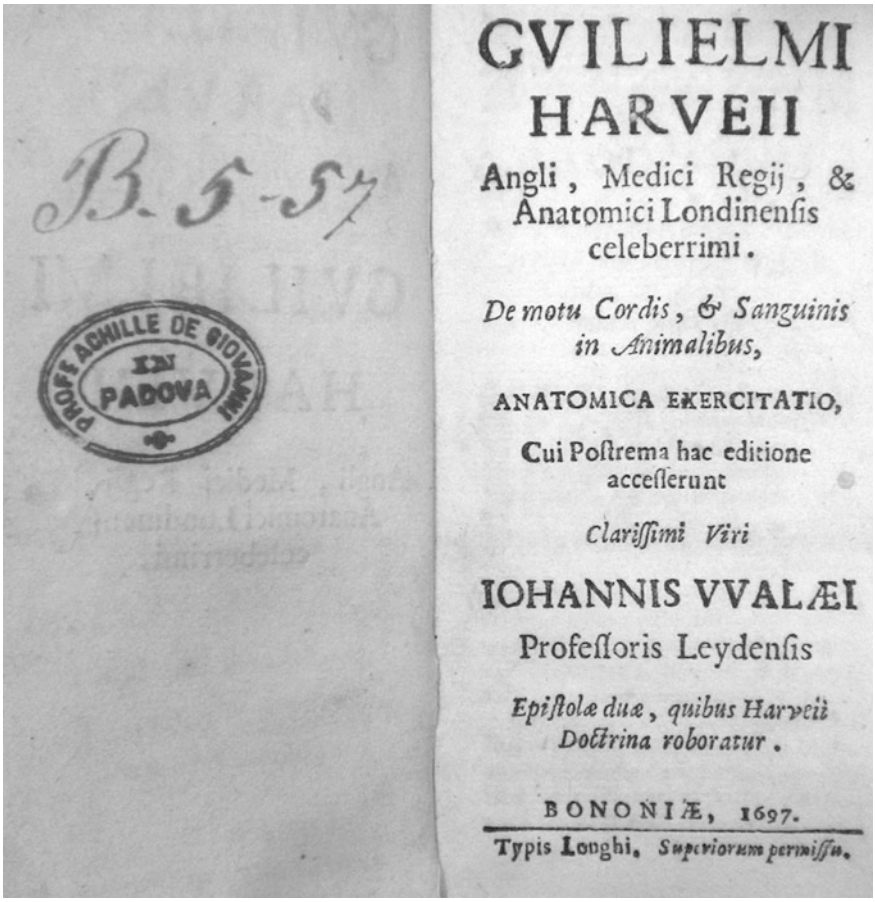
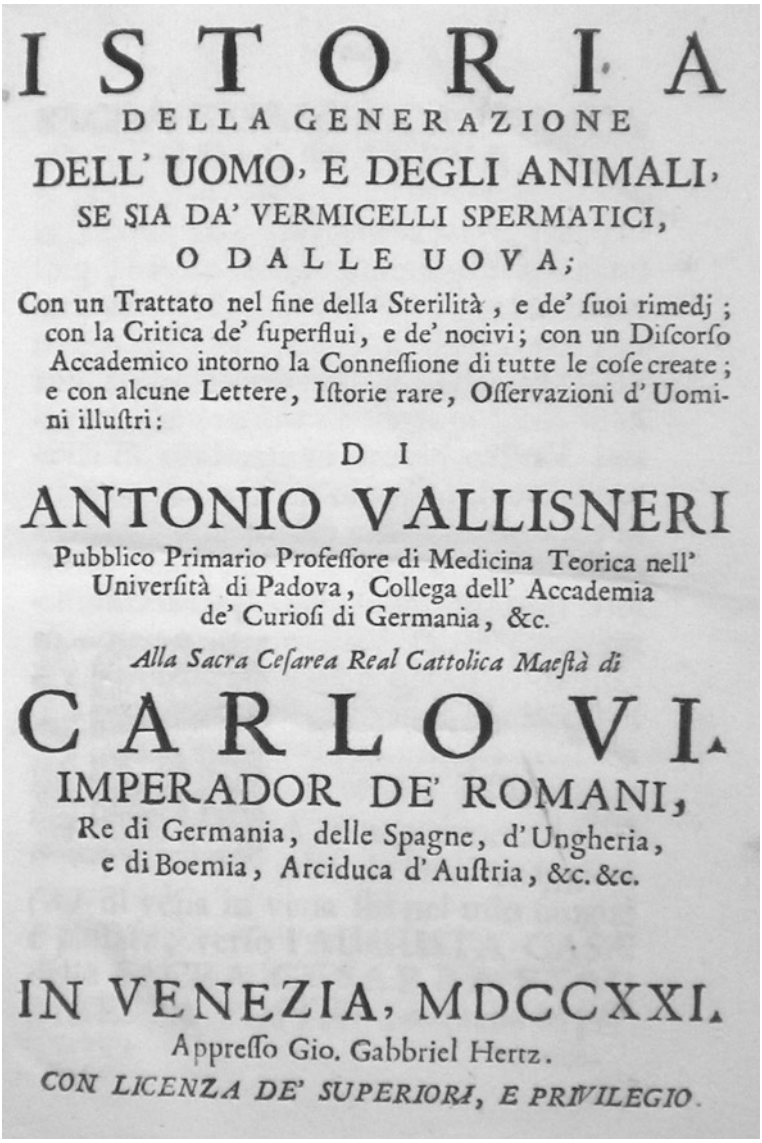


Fig. 15.56 William Harvey–Guilielmi Harveii… "De motu cordis, & sanguinis in animalibus, anatomica exercitatio, cui postrema hac editione accesserunt clarissimi viri Iohannis Walaei professoris Leydensis epistolae duae, quibus Harveii doctrina roboratur Bononiae: typis Longhi", 1697. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

Fig. 15.57 William Harvey–Guilielmi Harveii… "De motu cordis, & sanguinis in animalibus, anatomica exercitatio, cui postrema hac editione accesserunt clarissimi viri Iohannis Walaei professoris Leydensis epistolae duae, quibus Harveii doctrina roboratur Bononiae: typis Longhi", 1697. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova



ISTORIA
DELLA GENERAZIONE
DELL' UOMO, E DEGLI ANIMALI,
SE SIA DA' VERMICELLI SPERMATICI,
O DALLE UOVA;
Con un Trattato nel fine della Sterilità, e de' ſuoi rimedj; con la Critica de' ſuperflui, e de' nocivi; con un Diſcorſo Accademico intorno la Conneſſione di tutte le coſe create; e con alcune Lettere, Iſtorie rare, Oſſervazioni d' Uomini illuſtri:
D I
ANTONIO VALLISNERI
Pubblico Primario Profeſſore di Medicina Teorica nell' Univerſità di Padova, Collega dell' Accademia de' Curioſi di Germania, &c.
Alla Sacra Ceſarea Real Cattolica Maeſtà di
CARLO VI.
IMPERADOR DE' ROMANI,
Re di Germania, delle Spagne, d'Ungheria, e di Boemia, Arciduca d'Auſtria, &c. &c.
IN VENEZIA, MDCCXXI.
Appreſſo Gio. Gabbriel Hertz.
CON LICENZA DE' SUPERIORI, E PRIVILEGIO.

Fig. 15.58 Antonio Vallisneri—"Istoria della generazione dell'uomo e degli animali se sia da'vermicelli spermatici o dalle uova; con un trattato nel fine della sterilità, e de' suoi rimedj; con la critica de'superflui, e de'nocivi; con un discorso accademico intorno alla connessione di tutte le cose create; e con alcune lettere, Istorie rare, Osservazioni d'uomini illustri: di Antonio Vallisneri… In Venezia: appresso Gio. Gabbriel Hertz", 1721. Courtesy of historical section of the "Vincenzo Pinali" Medical Library of the University of Padova

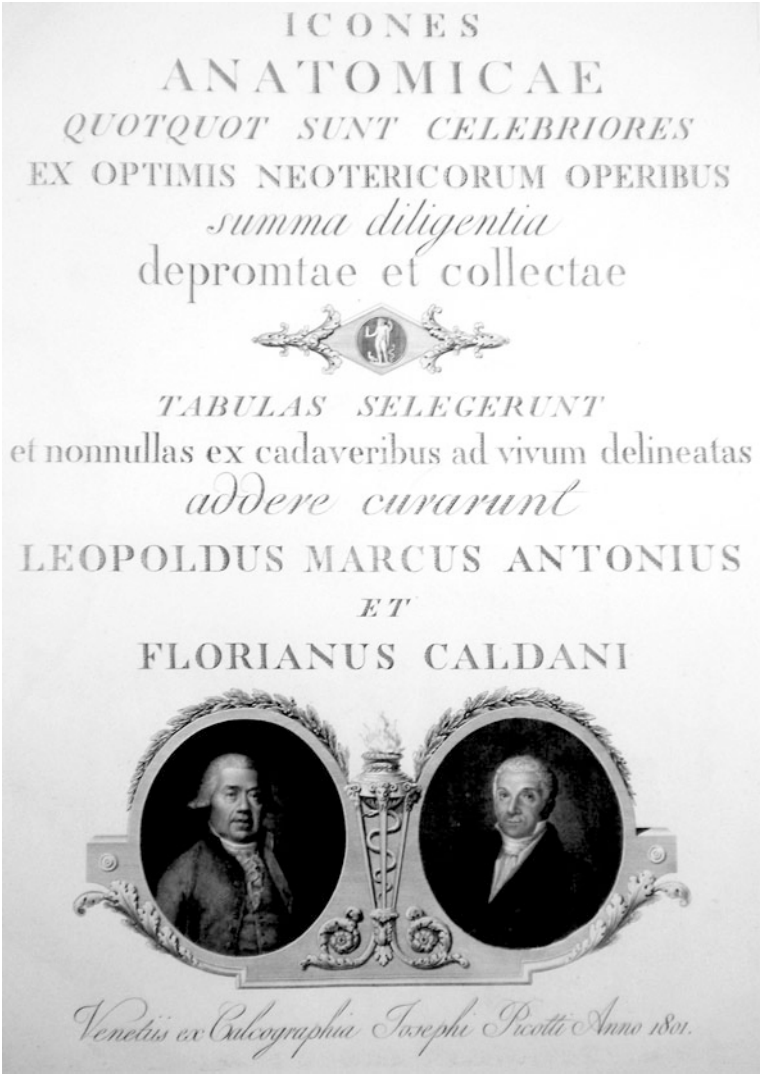


Fig. 15.59 Leopoldo Marco Antonio Caldani, Floriano Caldani Icones anatomicae quotquot sunt celebriores ex optimis neotericorum operibus summa diligentia depromtae et collectae. Tabulas selegerunt et nonnulas ex cadaveribus ad vivum delineatas addere curarunt Leopoldus Marcus Antonius et Florianus Caldani Ve-netiis: ex calcographia Josephi Picotti, 1801–1814. Courtesy of historical "Vincenzo Pinali" Medical Library, University of Padova

Glossary

Ascertainment Methodology This is the methodology for ascertaining presumed error/inobservance in healthcare treatment on Living Persons and/or Cadavers, involving the examination of clinical and documentary data, specialist consultation, autopsy (external and/or internal examination) and further diagnostic procedures carried out by a medico-legal expert.

Anaesthesia Report This report comprises all the information about the physiopathological state of the patient during anaesthesia and surgery. It is very important in lawsuits for death during surgery or anaesthetic accidents.

Anamnesis and physical examination This is the prior step for diagnostic and therapeutic accuracy, the omission of which indicates inadequate medical conduct.

Authorisation for Admission Consent form signed by patient or patient's legal representative if the patient is physically or psychologically incapable of doing so.

Autopsy This is the examination of a cadaver to determine or confirm the cause of death.

Capability of Causing Harm (Ex-Ante Criterion of**)** This is the capability of a specific action/event to cause harm or disease. Such a capability must be ascertained by comparing the nature and strength of the action/event to the effects observed.

Causal Link/Causal Value This is the connection between error/inobservance (a possible *cause*) and an injury (the *effect*), where the second event is understood to be a consequence of the first.

Cause for Justification of Error/Inobservance The situation where an error/inobservance may be justified under the circumstances of the harm caused. A medico-legal expert must supply technical reasons for cases of justifiable error, since a final decision will be made by a judge of the court.

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Chronological Criterion This indicates the possible correlation between the moment of action of the causal factor (which may involve the omission of an action) and the moment when the injury becomes manifest.

Clinical Discharge Report This is issued when the patient is discharged, from the medical point of view, and goes home or to another hospital. It summarises the period in which the patient was hospitalised and should be a complete document, which includes the cause of hospitalisation, with precise diagnoses, treatments administered, evolution, the state of the patient when discharged and treatment(s) to be followed, with indications of any future examinations and whether the family doctor should carry out monitoring.

Clinical Synthesis This is the summary of the clinical, documentary and objective data before the phase of analysis and evaluation in Ascertainment Methodology on Living Persons.

Conditio Sine Qua Non In Legal terms, this is the juridical theory concerning the essential requisite existing between a specific antecedent and the fact in the case where the fact would not have occurred without the antecedent. It is also known as the *but-for* rule and is the minimum indispensable for the objective imputation of harmful events in Criminal Law.

Consent Documents These have to demonstrate that the patient was properly informed and that he has fully understood the implications of the given medical intervention and has agreed to it. They are generally compulsory by law.

Consultation with Specialist This takes place if preliminary evaluation of the clinical and healthcare documentation reveals the need/suitability for 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, as the specialist may profitably contribute to the clinical ascertainment phase and to the choice of any further examinations to be carried out.

Counterfactual Reasoning This is a type of hypothetical reasoning in which, regarding the causal link, one tries to answer the question as to whether, without the conduct of the actor—contrary to the facts—a certain event would have taken place in any case. If the ascertainment indicates a negative answer (the event would have taken place), one may conclude that the action, or omission, is a necessary condition for the event to take place. If instead the answer is positive (the event would have taken place in any case), the behaviour of the actor was not a necessary condition and there is no causal link.

Criterion of Exclusion of Other Causes The cause of juridical relevance may act alone or together with other pre-existing or simultaneous causes (co-causes) that took place later which, if they are true co-causes, do not interrupt the causal link. Instead, the criterion of exclusion of other causes, if satisfied, leads to the opposite consequence, i.e., interruption of the causal link. In order for

interruption of the causal link to occur, "other causes" must be identified, either alone or necessary and sufficient to produce the event, or producing it completely autonomously.

Criterion of Phenomenological Continuity This indicates the possible correlation between the moment of action of the causal factor (which may involve the omission of an action) and the moment when the injury becomes manifest.

Criterion of Rational/Logical Credibility This is the criterion that refers only to the average experience and expertise of a particular medical category and is used for evaluating the causal value of error and the relationship of an actual causal link between error/non-observance and damage.

Damage Identification This covers death as well as possible bodily and/or biological damage or incapacity, which can be classed as temporary or permanent.

Degree of Probability of Causal Value and Causal Link The ascertainment of the causal value and causal link between error/inobservance and injury, which is identified by applying counterfactual reasoning and then medico-legal criteria, expressed in terms of certainty, high probability/near-certainty, average probability, low probability, possibility or exclusion of the causal value- causal link between error/non-observance and injury.

Emergency Room Assistance Sheet or Emergency Room Report This is compiled when the patient has requested care in the Emergency Room, including the reason for consultations, the results of any examinations and tests that have been requested, clinical opinion and diagnosis.

Error This is the violation of a rule shared by the national and/or international medical community as regards an aspect of professional practise, 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 an error not due to incompetence or ignorance on the part of a medical doctor or a member of the healthcare personnel, but is *apparent*. It may be caused by erroneous or unknown scientific knowledge at the time of the event, by the unpredictability or inevitability of the event, by chance, or by *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.

Ex-Ante Evaluation/Judgement This is used in establishing error in which the medico-legal expert must imagine being in the same space–time circumstances of the medical and/or healthcare personnel involved (training, age, qualifications and professional experience) and the technical and instrumental equipment at their disposal, thereby drawing a comparison between ideal and real conduct.

Explanatory Law This expresses regularity in the succession of events observed in nature, from which it is possible to infer a known or still unknown fact (in which case it is predicted). The applicable laws are subdivided into universal and statistical laws.

Ex-post Analysis This is the subsequent analysis of the conduct of medical and healthcare personnel, taking into account the existence of the patient's consent, the diagnostic tests, prognosis, treatment and care of the patient.

Falsificationism This is the theory that falsifiability is an essential characteristic of any scientific hypothesis, which must be capable of being falsified by scientific observation and empirical experiments.

Force Majeure This is the occurrence of an extraordinary event or circumstance that is beyond the control of the physician.

Highly Complex Medical Interventions The nature and complexity of the medical intervention must always be evaluated when an error/inobservance in the healthcare conduct has been identified. If such an intervention involves highly complex technical challenges in cases of error/inobservance, the physician is liable only if the fault was extremely serious or intentional.

Ideal Medical Conduct This is the conduct which a physician should have followed during diagnosis, prognosis and treatment/therapy. Ideal standards of medical conduct are dictated by medical ethics and by medical conduct as regulated by law, which may overlap. Ideal Medical Conduct is established by reference to scientific sources, such as *Guidelines* (national and international), *Consensus Documents* (national and international), *Operational Procedures* (local, national and international), and *Scientific Literature* (national and International *Treatises* and *Journals*).

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 taken into account.

Medical Orders Sheet This is the sheet on which doctors attending the patient are obligated to record their decisions.

Medical Responsibility/Liability This may be separated into two categories, the first of which is the positive responsibility of the physician for curing the patient. The second type is the negative responsibility not to cause harm to the patient. If harm is caused or the patient dies, then the physician may be liable under criminal law or civil law, depending on the nature of the medical conduct and of the judicial proceedings that are taken.

Necessary Condition A necessary condition is a single condition that must be satisfied in order for an event to take place. The necessary condition is examined through counterfactual reasoning.

Non-Observance of Rules of Professional Medical Conduct This is the non-observance of rules of conduct as referred to in National Laws, National/Local regulations, Hospital codes of conduct or those rules deriving from scientific medicine as taught in degree courses and specialisation schools, permanently updated through the scientific literature, congresses and training courses. The rules are mainly orientative and must be applied according to the diagnostic and therapeutic features of each single case.

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

Obligation of Means In medical malpractice, this is a burden on the physician who owes such an obligation to perform a given treatment in accordance with appropriate standards of care.

Observance of Minimum Quality Requirements/Important Rules of Conduct These are the minimum standards of conduct, understood as a set of duties incumbent on the physician and other health professionals when carrying out their work in the healthcare context.

Obligation of Result In medical malpractice this is a burden on the physician who owes such an obligation to attain a precise result when treating a patient. However, it is normally only applied in a small number of specific medical specialities, i.e. plastic surgery, orthodontic surgery, etc.

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 a simple drawing 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.

Pathological Features These are features of the disease recognised in living persons/cadavers, divided into *initial*, *intermediate* and *final* clinical pictures, resulting in restoration to health, death, chronic pathological state or permanent injury.

Patient's Journal This document records daily changes in the hospitalised patient's condition, response to treatment, recommended tests and their results, and clinical evaluation of the patient's state until discharged.

Physiopathological Pathway This is the actual chain of events which took place and links the initial pathological features with the intermediate and final ones.

Post-Surgery Evaluation 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 healthcare in this phase (early detection of complications, early and correct actions to avoid them, etc.).

Pregnancy Monitoring Sheet In cases of pregnancy this document 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.

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.

Real Medical Conduct This is the actual conduct of a physician during diagnosis, prognosis and treatment. Evaluation of the correctness of these various diagnostic, prognostic and therapeutic phases is carried out by comparing them with the ideal conduct.

Record of Assistance at Birth This is a clearly compiled record of the phases of the birth clarifying problems, the time when they are detected and at which moment each professional intervened.

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, neuro-physiological, psychological tests, etc.

Source Hierarchy This is the gradation of scientific sources of non-equivalent importance into (1) Guidelines, (2) Consensus Documents, (3) Operational Procedures, (4) Literature (Treatises), (5) Literature (Journals).

Standard of Care This is a medical treatment guideline, which can be general or specific and may vary between healthcare centers. It specifies appropriate treatment based on up-to-date scientific evidence and collaboration between medical professionals involved in the treatment of a given condition. The

medical malpractice plaintiff must establish the appropriate standard of care and demonstrate that the standard of care has been breached, with expert testimony.

Statistical Law This is limited to stating that the occurrence of an event is accompanied by the occurrence of another event in a certain percentage of cases and with relative frequency.

Sufficient Condition This is a single condition which, if verified, guarantees that a particular occurrence will take place.

Topographic Criterion This describes the correlation between the injury and the anatomo-functional location at which the hypothesised causal factor acted; it takes on importance mainly in the framework of the injuriousness of physical energy, i.e. mechanical, electrical, radiating or chemical energy, or due to bacterial or viral agents. The criterion may be deemed to be satisfied in the case of direct topographic correspondence (e.g., fracture of the skull due to a fall), indirect (counter-coup) or at a distance (pulmonary embolism after contusion of lower limbs).

Universal Law This law derives from consolidated and unanimously shared scientific knowledge.

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Page numbers followed by '*f*' indicate figures and '*t*' indicate tables respectively.

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