

*Editor*

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# Malpractice and Medical Liability

European State of the Art and Guidelines



Springer

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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, Caplinskiene 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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# Contents

## Part I Overview

<b>1 Present and Future Perspectives for Medical Malpractice, Responsibility, and Liability</b> . . . . .	3
S. Davide Ferrara, Guido Viel and Rafael Boscolo-Berto	
References . . . . .	9

## Part II Historical Background

<b>2 Historical Overview of Medical Liability</b> . . . . .	13
Maurizio Ripa Bonati and Fabio Zampieri	
2.1 Introduction . . . . .	14
2.2 Cases . . . . .	17
2.2.1 Case I. The Doctor–Patient Relationship Between “Ethics” and “Cunning”: Gabriele Zerbi . . . . .	17
2.2.2 Case II. Melchiorre Guilandino and the Strange Cure . . . . .	25
2.2.3 Case III. A Healthcare Commission and Reason of State: Even Luminaries Make Mistakes . . . . .	29
2.2.4 Case IV. The Cynical Doctor: Alessandro Knips Macoppe . . . . .	37
2.3 Conclusion . . . . .	46
References . . . . .	47
<b>3 Praxis et Mala-Praxis Medica</b> . . . . .	51
Ivone Cacciavillani	
3.1 Introduction . . . . .	52
3.2 Primary Sources . . . . .	53
3.2.1 Law and Norms . . . . .	53

- 3.3 Secondary Sources . . . . . 54
  - 3.3.1 Consuetudo (Customs) . . . . . 55
  - 3.3.2 Behavioral Codes . . . . . 55
  - 3.3.3 Practice . . . . . 56
- 3.4 The Medical Profession . . . . . 57
  - 3.4.1 The Professional Work Contract . . . . . 57
  - 3.4.2 The Therapeutic Protocol . . . . . 57
  - 3.4.3 The Work Contract and Employment Relationship . . . . . 58
- 3.5 Medical Practice . . . . . 59
  - 3.5.1 The Structural Practice . . . . . 60
  - 3.5.2 The Professional Practice (Publicity) . . . . . 61
- 3.6 Function of Healthcare Practices . . . . . 62
  - 3.6.1 Worker’s Exemption . . . . . 62
  - 3.6.2 The User’s Trust . . . . . 62
- 3.7 Bad Healthcare, Bad Practice, and Insurance Coverage . . . . . 63
  - 3.7.1 In Private Healthcare . . . . . 63
  - 3.7.2 In Public Health . . . . . 64
  - 3.7.3 Bad Healthcare and Bad Practice . . . . . 64
  - 3.7.4 Lack of Responsibility of Insurance Companies . . . . . 65
- References . . . . . 66

**Part III Legislative and Juridical Background**

- 4 European Legislative and Juridical Overview . . . . . 69**
  - Paola Frati and Matteo Gulino
  - 4.1 Introduction . . . . . 70
  - 4.2 Medical Liability in Western Europe Between Civil Law and Common Law . . . . . 72
    - 4.2.1 Fault . . . . . 74
    - 4.2.2 Contractual and Extra-Contractual Responsibility . . . . . 74
    - 4.2.3 Standard of Care . . . . . 76
    - 4.2.4 Burden of Proof . . . . . 77
  - 4.3 The Key Role of Mediation in Medical Responsibility . . . . . 78
    - 4.3.1 Court Systems . . . . . 79
    - 4.3.2 Administrative Systems . . . . . 79
  - 4.4 Scandinavian Countries: Models . . . . . 80
  - 4.5 The French Experience and the “Loi Kouchner”: *The Aléa Thérapeutique* . . . . . 82
  - 4.6 The English Experience of the NHS Authority Litigation and the Key Role of Mediation . . . . . 86

- 4.7 Medical Responsibility in Eastern Europe: Bulgaria, Czech Republic, Slovakia, Russia, and Lithuania . . . . . 87
- 4.8 Conclusion . . . . . 88
- References . . . . . 91
- 5 Causal Value and Causal Link . . . . . 93**
  - S. Davide Ferrara
  - 5.1 Principles of Truth and Cause . . . . . 94
  - 5.2 Juridical Construction, Evidence, and Medicine . . . . . 97
  - 5.3 “Conditio Sine Qua Non” and Scientific Laws. . . . . 99
  - 5.4 From the Theory to the Practice of Specific Causality. . . . . 101
  - References . . . . . 106

**Part IV Major European Countries and/or Areas**

- 6 Medical Responsibility and Liability in German-Speaking Countries: Austria, Germany, and Switzerland . . . . . 111**
  - Thomas Bajanowski, Walter Rabl and Tony Fracasso
  - 6.1 Judicial and Normative Overview . . . . . 112
  - 6.2 Judicial and Extra-Judicial Institutions and Operative Roles . . . . . 113
  - 6.3 Ascertainment Methodology. . . . . 115
    - 6.3.1 Living . . . . . 115
    - 6.3.2 Fatalities . . . . . 116
  - 6.4 Evaluation Criteria . . . . . 119
    - 6.4.1 Identification of any Injury, Dysfunction, Invalidity, or Cause of Death . . . . . 120
    - 6.4.2 Analysis of Medical Treatment. . . . . 121
    - 6.4.3 Relationship Between Injury/Death and Medical Malpractice . . . . . 124
  - 6.5 Future Perspectives . . . . . 125
  - References . . . . . 126
- 7 Medical Responsibility and Liability in the United Kingdom . . . . . 129**
  - Peter Vanezis
  - 7.1 Overview . . . . . 130
    - 7.1.1 The Medical Acts and the General Medical Council . . . . . 130
    - 7.1.2 The Common Law System. . . . . 131
    - 7.1.3 Type of Enquiries . . . . . 131
    - 7.1.4 Recent Trends in the Number of Claims Made. . . . . 132
  - 7.2 Judicial and Extra-Judicial Institutions and Operative Roles . . . . . 132

- 7.2.1 Doctors and Others Undertaking Assessment of Alleged Medical Negligence Cases . . . . . 134
- 7.2.2 The Judicial System Procedures . . . . . 135
- 7.2.3 No-Fault Compensation . . . . . 136
- 7.2.4 Civil Procedure Rules 1998 . . . . . 137
- 7.3 Ascertainment Methodology . . . . . 137
  - 7.3.1 Living and Deceased Persons . . . . . 137
- 7.4 Evaluation Methodology . . . . . 138
  - 7.4.1 Standard of Care, Causation and the Development of Clinical Guidelines . . . . . 138
  - 7.4.2 Causation . . . . . 139
- 7.5 The Future . . . . . 142
- References . . . . . 142
  
- 8 Medical Responsibility and Liability in France . . . . . 145**
  - Eric Baccino
  - 8.1 Introduction . . . . . 146
  - 8.2 Epidemiological Data . . . . . 146
  - 8.3 Juridical Procedures . . . . . 147
    - 8.3.1 Penal Jurisdiction . . . . . 147
    - 8.3.2 Civil Jurisdictions . . . . . 148
    - 8.3.3 Administrative Jurisdictions . . . . . 150
  - 8.4 Non-Juridical Procedures Intervening in Medical Responsibility . . . . . 151
    - 8.4.1 Council of the Order of Medical Doctors . . . . . 151
    - 8.4.2 Commission Régionale de Conciliation et D’Indemnisation des Accidents Medicaux . . . . . 152
  - 8.5 Nomination of Experts . . . . . 154
  - 8.6 Expertise Regarding Medical Responsibility . . . . . 155
    - 8.6.1 Premise . . . . . 155
    - 8.6.2 Phases of Expert Examination . . . . . 156
    - 8.6.3 Access to Medical Documentation . . . . . 157
  - 8.7 How is Medical Error Evaluated? . . . . . 158
  - 8.8 Conclusions and Prospects . . . . . 159
  - References Suggested by the Editors . . . . . 160
  
- 9 Medical Responsibility and Liability in Spain . . . . . 161**
  - María Castellano Arroyo and Ricardo de Ángel Yáguez
  - 9.1 Judicial and Normative Overview and Judicial and Extra-Judicial Institutions and Operative Roles . . . . . 162
    - 9.1.1 Introductory Note on the Terminology . . . . . 162
    - 9.1.2 The Complex Regime of Healthcare Liability in Spain . . . . . 163

9.1.3	Mala Praxis is Attributed to a Doctor or Other Healthcare Professional Acting as “Free Professionals” . . . . .	163
9.1.4	Mala Praxis is Attributed to a Doctor, or Other Healthcare Professional, Who Acts in a Private Healthcare Institution . . . . .	164
9.1.5	The Defendant is a Healthcare Centre . . . . .	165
9.1.6	Events Occurring in the Framework of Healthcare Provided by a Public Authority . . . . .	165
9.1.7	Out-of-Court Settlement of the Claims . . . . .	166
9.1.8	General Considerations . . . . .	166
9.1.9	Criminal Medical Liability . . . . .	169
9.1.10	Statistical Data . . . . .	171
9.2	Ascertainment Methodology . . . . .	173
9.2.1	Cases Calling for Expert Ascertainment in Professional Liability . . . . .	173
9.2.2	Ascertainment Methodology . . . . .	176
9.3	Evaluation Criteriology . . . . .	184
9.3.1	Evaluation Criteria in Living Patients . . . . .	184
9.3.2	Evaluation Criteria in Cadavers . . . . .	185
9.3.3	Evaluation of the Sequelae . . . . .	186
9.4	Future Perspectives . . . . .	186
	References . . . . .	187
<b>10</b>	<b>Medical Responsibility and Liability in Portugal</b> . . . . .	<b>189</b>
	Vera Lúcia Raposo and Duarte Nuno Vieira	
10.1	Introduction . . . . .	190
10.2	Epidemiological Data . . . . .	190
10.3	Judicial and Normative Overview . . . . .	191
10.3.1	Civil Medical Responsibility . . . . .	193
10.3.2	Criminal Medical Responsibility . . . . .	198
10.3.3	Judicial and Extra Judicial Institutions and Operative Roles . . . . .	200
10.4	Ascertainment Methodology . . . . .	201
10.5	The Medico-Legal Council . . . . .	205
10.6	Conclusions . . . . .	206
	References . . . . .	206
<b>11</b>	<b>Medical Responsibility and Liability in Italy</b> . . . . .	<b>209</b>
	Pietrantonio Ricci, Francesco Ausania and Paolo Arbarello	
11.1	Introduction . . . . .	210
11.1.1	The Physician’s Responsibility as “Contractual Liability” . . . . .	210

- 11.1.2 Liability for Healthcare Defects Outside the Professional Activity of a Doctor or Other Health Professional. . . . . 210
- 11.2 Epidemiological Data . . . . . 211
  - 11.2.1 Increase in Professional Liability Cases in Italy . . . 211
  - 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. . . . . 212
- 11.3 Normative and Judicial Overview . . . . . 213
  - 11.3.1 Criminal Medical Responsibility . . . . . 213
  - 11.3.2 Civil Medical Responsibility . . . . . 215
- 11.4 *Nomofilattica* and Professional Medical Liability . . . . . 217
- 11.5 Methods of Ascertainment and Evaluation Criteria . . . . . 219
- 11.6 Future Perspectives . . . . . 225
- References . . . . . 226

- 12 Medical Responsibility and Liability in Lithuania, Latvia and Estonia . . . . . 227**
  - Alvydas Pauliukevičius, Marija Caplinskienė, Romas Raudys, Ojars Teteris, Grigorijs Vabel and Marika Väli
  - 12.1 Medical Responsibility and Liability in Lithuania. . . . . 229
    - 12.1.1 Judicial and Normative Overview . . . . . 229
    - 12.1.2 Judicial and Extra-Judicial Institutions and Operative Roles . . . . . 229
    - 12.1.3 Ascertainment Methodology . . . . . 230
    - 12.1.4 Evaluation Criteria . . . . . 231
    - 12.1.5 Future Perspectives . . . . . 232
  - 12.2 Medical Responsibility and Liability in Latvia . . . . . 233
    - 12.2.1 Legislation Governing the Medical Practitioner’s Liability . . . . . 233
    - 12.2.2 Extra-Legal Activity in Latvia . . . . . 235
    - 12.2.3 Ascertainment Methodology . . . . . 237
    - 12.2.4 Evaluation Criteria . . . . . 237
    - 12.2.5 Future Perspectives . . . . . 238
  - 12.3 Medical Responsibility and Liability in Estonia . . . . . 239
    - 12.3.1 Judicial and Normative Overview . . . . . 239
    - 12.3.2 Judicial and Extra-Judicial Institutions and Operative Roles . . . . . 240
    - 12.3.3 Ascertainment Methodology . . . . . 241
    - 12.3.4 Evaluation Criteria . . . . . 242
    - 12.3.5 Future Perspectives . . . . . 242
  - References . . . . . 243



**Part V Consensus Document: European Guidelines**

**13 Medico-Legal Methods of Ascertainment and Criteria of Evaluation in Medical Responsibility and Liability . . . . . 247**  
 S. Davide Ferrara, Eric Baccino, Thomas Bajanowski,  
 Rafael Boscolo-Berto, Maria Castellano Arroyo,  
 Ricardo De Angel Yagüez, Alvydas Pauliukevičius,  
 Pietrantonio Ricci, Peter Vanezis,  
 Duarte Nuno Vieira, Guido Viel and Enrique Villanueva

13.1 Itemisation of Guidelines . . . . . 251

13.2 Expert Definition and Essential Expertise . . . . . 252

13.3 Methods of Ascertainment on Living Persons. . . . . 252

    13.3.1 Step 1: Collection and Examination of Clinical  
             and Documentary Data . . . . . 253

    13.3.2 Step 2: Consultation with Specialist . . . . . 256

    13.3.3 Step 3: Clinical Examination . . . . . 257

    13.3.4 Step 4: Further Instrumental Diagnostic Exams. . . . . 257

    13.3.5 Step 5: Clinical Synthesis. . . . . 258

13.4 Methods of Ascertainment on Cadavers. . . . . 258

    13.4.1 Step 1: Collection and Examination  
             of Clinical and Documentary Data . . . . . 258

    13.4.2 Step 2: Consultation with Specialist . . . . . 259

    13.4.3 Step 3: Pre-Autopsy Examinations . . . . . 259

    13.4.4 Step 4: Autopsy . . . . . 259

    13.4.5 Step 5: Choice and Execution of Further  
             Diagnostic Procedures . . . . . 262

13.5 Evaluation Criteria . . . . . 262

    13.5.1 Step 1: Comparative Evaluation of Data . . . . . 262

    13.5.2 Step 2: Identification of Pathological Features . . . . . 263

    13.5.3 Step 3: Damage Identification. . . . . 263

    13.5.4 Step 4: Reconstruction of Physiopathological  
             Pathways and Ideal Medical Conduct . . . . . 263

    13.5.5 Step 5: Reconstruction of the Real  
             Medical Conduct. . . . . 264

    13.5.6 Step 6: Reconstruction and Verification of Real  
             Conduct of Medical and Healthcare Personnel . . . . . 264

    13.5.7 Step 7: Identification of Error/Non-Observance. . . . . 266

    13.5.8 Step 8: Classification of Error/Non-Observance . . . . . 267

    13.5.9 Step 9: Error Evaluation—Ex-Ante: Possible  
             Causes of Justification . . . . . 267

- 13.5.10 Step 10: Causal Value and Causal Link Between Error and Event . . . . . 268
- 13.5.11 Step 11: Universal Law, Statistical Law or Criterion of Rational Credibility . . . . . 268
- 13.5.12 Step 12: Identification of the Degree of Probability of Causal Value and Causal Link . . . . . 268
- 13.5.13 Step 13: Damage Estimation . . . . . 269
- 13.6 Conclusions . . . . . 270
- Appendixes: Flow Charts . . . . . 271
- References . . . . . 275

**Part VI Final Statements**

- 14 Requirements and Final Recommendations . . . . . 279**
- S. Davide Ferrara, Rafael Boscolo-Berto and Guido Viel
- 14.1 Recommendation 1: Essential Expertise and Competence of the Medico-Legal Expert . . . . . 280
- 14.2 Recommendation 2: Essential Expertise and Competence of the Consultant . . . . . 280
- 14.3 Recommendation 3: Collection and Examination of Clinical Data . . . . . 281
- 14.4 Recommendation 4: Clinical Examination of the Living . . . . . 281
- 14.5 Recommendation 5: Instrumental Diagnostic Exams in the Living . . . . . 282
- 14.6 Recommendation 6: Ascertainment on Cadavers. . . . . 282
- 14.7 Recommendation 7: Identification of Pathological Features. . . . . 282
- 14.8 Recommendation 8: Reconstruction of the Ideal Medical Conduct . . . . . 283
- 14.9 Recommendation 9: Reconstruction of the Medical Conduct . . . . . 283
- 14.10 Recommendation 10: Identification and Classification of Error/Non-Observance . . . . . 284
- 14.11 Recommendation 11: Evaluation of the Error/Non-Observance . . . . . 284
- 14.12 Recommendation 12: Evaluation of the Causal Value of the Error . . . . . 284
- 14.13 Recommendation 13: Damage Estimation . . . . . 285

**Part VII Iconography**

**15 Historical Iconography from the “Vincenzo Pinali”**  
**Antique Medical Library** . . . . . 289  
 S. Davide Ferrara, Guido Viel and Rafael Boscolo-Berto

**Glossary** . . . . . 351

**Index** . . . . . 359

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# Part I Overview



Herman Boerhaave—Hermanni Boerhaave ... Methodus studii medici, emaculata, & accessio-  
nibus locupetata 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.

### Contents

References..... 9

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

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