

## Editorial

## Professional Liability in Cardiology

## La responsabilidad profesional en cardiología

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Currently, patient safety and the risk of litigation for alleged malpractice are a major concern for everyone. In 1999, the US Institute of Medicine in its publication *To Err Is Human: Building a Safer Health System*,<sup>1</sup> was of the opinion that medicine was not as safe as it should be. The article reviewed 4 studies on the topic, which reported rates of adverse events of between 2.9% and 3.4% during hospital admissions. Of these, between 53% and 58% could have been prevented. If these data were extrapolated, between 44 000 and 98 000 US citizens died each year due to adverse events during hospital admission, and the scale of the problem could be even larger if adverse events outside the hospital setting were taken into account. The alarming figures highlighted by that report triggered an international debate on the importance of adverse events and medical errors and have definitively aroused general interest in patient safety in health care.

In line with the concept of the Institute of Medicine, patient safety is defined as the absence of avoidable errors or complications arising as a result of interaction between the patient and the health system and its professionals when receiving health care.

In 2002, the World Health Organization (WHO) adopted resolution WHA55.18, which urged member states to pay as much attention as possible to patient safety and established and reinforced evidence-based measures to improve patient safety and the quality of health care.<sup>2</sup> In 2004, the WHO Alliance for Patient Safety was born with the objective of coordinating, disseminating, and accelerating improvements in patient safety throughout the world. This body was to serve as a vehicle for international collaboration between member states, the WHO, experts, consumers, and health care professionals.<sup>2</sup>

The increasing concern and interest for patient safety has prompted positive changes in health care, and rates of adverse events continue to decrease. In Spain, Law 16/2003, pertaining to Cohesion and Quality of the National Health System, placed patient safety at the center of health policy and made it one of the key elements in improving the quality of care, as reflected by strategy number 8 of the Quality Plan for the Spanish National Health System.<sup>3</sup> Patient safety, understood as a marker of quality of care, looks to decrease and prevent the risks associated with health care, and thereby contribute to the excellence of the system.

Likewise, for years now, several scientific societies such as the American Heart Association/American College of Cardiology, the European Society of Cardiology, and the Spanish Society of Cardiology have increased their efforts in the field and have published consensus instruments such as checklists, protocols, and clinical practice guidelines.<sup>4</sup> An indication of the widespread acceptance of these clinical practice guidelines among cardiology specialists is that these articles are among the most read articles in the history of *Revista Española de Cardiología*, with a total of 9 clinical practice guidelines among the 10 most read articles.<sup>4</sup> Worthy of special mention is that compliance with clinical practice guidelines has had a positive impact on patient safety,<sup>5</sup> and often provides a certain legal protection,<sup>4,6–10</sup> as they mentioned in sentences on professional medical liability (Table).

Paradoxically, the improvements in patient safety have been accompanied by an increase in claims related to professional medical liability. In the last 5 years, claims made against physicians have increased considerably in Spain, without reaching the levels seen in countries such as the United States, which is experiencing a malpractice crisis and making continual legislative reforms.<sup>6,7,11</sup>

This increase has occurred in the context of highly specialized medicine in constant scientific flux, and has inevitably been influenced by important sociocultural changes.<sup>6,7</sup> The enactment of Law 41/2002, which essentially regulated patients' autonomy, rights and obligations in terms of clinical information and documentation, was a significant change in the physician-patient relationship. The physician's role was no longer the traditionally paternalistic one and new emphasis was placed on information, while informed consent became much more important. As indicated by current legislation in Article 8.2, consent, in general, will be given verbally. However, it should be given in writing in the following cases: surgical procedures, invasive diagnostic and therapeutic procedures and, in general, application of procedures with notable risks and drawbacks and a foreseeable negative impact on the patient's health.<sup>12</sup> The role of patients has changed and their expectations have increased, at times unreasonably, due to greater access to medical information. Thus, in 2007 Gaultier<sup>13</sup> warned that death due to acute myocardial infarction was no longer assumed to be an unavoidable event. The author indicated that the rate of deaths due to myocardial infarction had decreased dramatically, stenting had improved coronary artery treatment, and the media often reported impressive improvements in the area of cardiology. The high expectations derived from these advances are offset by the increase in iatrogenic risk from the use of increasingly sophisticated techniques by professionals faced with

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**Table**

Examples of Sentences Citing Clinical Practice Guidelines of the Spanish Society of Cardiology

Sentence	Clinical Practice Guideline
Sentence 690/2006 dated 20 November, Section 11, Provincial Court of Barcelona: “[...] the clinical practice guidelines of the Spanish Society of Cardiology state that serial echocardiography may be useful for detecting incipient systolic dysfunction and establishing the tolerated dose [...]”	Evangelista Masip et al. <sup>8</sup>
Sentence 6211/2005 dated 23 November, Section 4, High Court: “[...] that according to the Clinical Practice Guidelines of the Spanish Society of Cardiology for pericardial disease, moderate or severe cardiac tamponade ... is a Class I indication for performing pericardiocentesis [...]”	Sagristá Sauleda et al. <sup>9</sup>
Sentence 751/2009, dated 1 October, High Court of Catalonia: “[...] for this it is sufficient to take note of a study of the expert panel in the Clinical Practice Guidelines of the Spanish Society of Cardiology... the lack of symptoms until diagnosis is no guarantee that the accessory pathway is innocuous, Clinical Practice Guidelines for cardiac arrhythmias [...]”	Almendral Garrote et al. <sup>10</sup>

ever more complex information. Professionals must try to adequately transmit this complexity to their patients, following the requirements of the current legislation concerning patient autonomy and respecting their rights, thereby minimizing the risk of professional liability.<sup>6,7,13</sup>

Warnings of the negative consequences of the increased number of claims for professional liability against physicians have been issued all over the world. It has been reported that a litigious environment encourages the practice of defensive medicine, increases health costs, generates dissatisfaction among professionals, and, in subspecialties at particular risk of claims, even forces physicians to stop practicing.<sup>6,7,11</sup> The harm of such an environment to patients is undeniable, and it has even been reported to that it may limit access to health care in certain areas of medicine.<sup>11</sup>

In this new context, it is essential that physicians be aware of the medical-legal issues involved in health care, and studies or articles that analyze claims or rulings on professional liability, such as that by Santiago-Sáez et al.<sup>14</sup> published in *Revista Española de Cardiología*, are a valuable source of information. The article provides an indication of the reality of medical liability in Spain, where there is limited literature on the topic. Beyond Spanish borders, Oetgen et al.<sup>15</sup> underline the need to be aware of data on claims in cardiology and indicate that dissemination of the findings among specialists could improve the quality of patient care and decrease the rate of adverse events and the number of claims for professional medical liability.

Santiago-Sáez et al.<sup>14</sup> classify cardiology as a low-risk specialty, in agreement with Claudot et al.<sup>16</sup>, who concluded that cardiology remains “relatively protected from claims.” According to data from the *Servei de Responsabilitat Mèdica* published by the Barcelona Medical Association, which currently includes 7535 claims between 1986 and 2011, the percentage of claims pertaining to cardiology is 1.4%.<sup>17</sup> This percentage is well exceeded by specialties such as traumatology and orthopedic surgery (15.7%) or obstetrics and gynecology (12.5%), which face much larger maximum damage awards.

However, the seriousness of diseases treated by cardiology and the complexity of certain approaches underline the importance of professional medical liability in our specialty. Oetgen et al.<sup>15</sup> reported that diagnostic error was the most common cause for complaints in cardiovascular disease, and coronary arteriosclerosis the most frequent diagnosis implicated in claims. The authors highlighted the relevance of events such as aortic dissection or aneurism in terms of the percentage of cases brought and the extent of the damages awarded. Twenty years ago, Kuehm et al.<sup>18</sup> had already identified diagnostic error as the main reason for professional liability in cardiology-related claims, and noted the importance of a lack of documentation or poor dialogue between the physician and patient. The findings of Santiago-Sáez et al.<sup>14</sup> are in agreement with these previous studies. For their part, Claudot et al.<sup>16</sup> highlight the importance of nosocomial infections.

Their duties as practitioners notwithstanding, physicians can be held liable for exercising their profession in criminal courts (public law: criminal code) and civil courts (private law: civil code); when the health care administration in which the physicians work is held liable, this is an administrative process.<sup>7</sup> The legal procedure for alleged malpractice varies according to the jurisdiction where the claim is made. Criminal procedure, which transpires in the framework of the Law for Criminal Justice (LECr in Spanish), is initiated by a claim or complaint filed when an alleged case of malpractice is brought before the legal authorities in a magistrates' court. The investigation (instruction) is performed by the court itself, whereas the plenary or oral phase will transpire in a criminal court or a provincial court. Civil procedure is regulated by the Law for Civil Justice (LEC in Spanish). Any citizen who feels harmed can claim damages by lodging a complaint with the court of first instance, where the trial will be held after the evidence has been presented. The provincial courts should decide on possible appeals against decisions issued by the court of first instance. Claims against the administration will be presented to administrative law courts in provincial capitals.

Professional medical liability is said to arise in the case of damage or injury to a patient when deficient practice existed, and also when a relationship between the 2 could be demonstrated.<sup>6</sup> Deficient practice corresponds to the term malpractice, which according to the etymology of the word means bad practice, that is, when the practice of medicine does not follow what in legal terms is known as *lex artis* and what in Anglo-Saxon spheres is known as the standard of care.<sup>6</sup> Strictly speaking, clinical practice guidelines may imply a legal guarantee that clinical practice follows *lex artis* and that scientifically proven practices are what are practised by most physicians in the same circumstances<sup>6,7</sup> (Table). *Ad hoc lex artis* constitutes a legal criterion used to assess the appropriateness of a specific medical act.<sup>6</sup> Today, legal experts define a medical act as appropriate if it is medically indicated, has been performed according to *lex artis*, and the patient has been correctly and specifically informed. This information can, in certain circumstances, be formalized in an informed consent document.<sup>6</sup> Particularly in cardiology, which deals with potentially life-threatening diseases, we should remember that, for curative medicine, the legal precedence of the high court clearly establishes that medical professional liability derives from an obligation of the means, not the outcomes.<sup>6</sup>

Cardiologists, like all physicians, are subject to legal and ethical frameworks in their practice, and it is essential that medical-legal aspects of care form part of their training. Claims against physicians are a reality and are usually the result of a poor outcome or an unexpected and/or avoidable complication of the disease, the diagnostic procedure used, or the treatment, rather than medical negligence. The practice of medicine affects one of an individual's most prized assets, his or her health and life; therefore it is understandable that patients and their families make legal and nonlegal complaints when events occur that have a negative effect

on their health, and the person responsible for these events in their eyes, whether rightly or wrongly, is a physician. We therefore believe it is essential to analyze the reasons for claims by specialty and to assess which procedures are subject to the greatest number of claims. Articles such as the present article contribute to such an analysis and have a positive impact on health care professionals and patients.

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## CONFLICTS OF INTEREST

None declared.

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