

Spanish Society of Cardiology Ethical Framework (Executive Summary)

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The Spanish Society of Cardiology (SEC) has produced an Ethical Framework Document. This document is divided into two distinct parts that deal, respectively, with the responsibilities of the SEC as an organization and the responsibilities of its professional members. The SEC makes recommendations on how its members should carry out their daily clinical practice, provides a professional perspective on public commitments as a scientific association, and aims to ensure that any views, recommendations, and advice expressed provide the basis for an informed debate on ethical problems in our field of work.

Key words: *Ethical values. Conflict of interest. Management ethics. Publishing ethics. Clinical practice guidelines. Clinical bioethics. Organizational bioethics. Responsibility and the medical profession. Research and bioethics. Medical-industrial relations. Health resources.*

Marco ético de la Sociedad Española de Cardiología (versión resumida)

La Sociedad Española de Cardiología (SEC) ha elaborado su «marco ético». Este documento se estructura en 2 partes diferenciadas que tratan sobre la responsabilidad de la SEC como organización y de los profesionales en tanto que socios. La SEC propone a sus miembros unas pautas de actuación en su práctica diaria, establece un horizonte de compromiso cívico como asociación científica, y desea que las reflexiones, las recomendaciones y los consejos reflejados sirvan para debatir responsablemente sobre los problemas éticos de nuestro quehacer.

Palabras clave: *Valores éticos. Conflictos de interés. Ética de directivos. Ética editorial. Guías de práctica clínica. Bioética clínica. Bioética organizacional. Responsabilidad y profesión médica. Investigación y bioética. Relaciones médico-industria. Recursos sanitarios.*

INTRODUCTION

The Spanish Society of Cardiology (SEC), being conscious of its responsibilities, has created an Ethical Advisory Commission assigned with the task of producing an ethical framework document. Its content is guided by institutional concerns of the SEC and has made free use of hedging it

was expected to be thorough, especially in the full version (www.secardiologia.es), in order to promote dialogue between the SEC and those institutions, organizations, and administrative bodies interested in making their activities transparent. The SEC thus offers itself as a forum.

RESPONSIBILITIES OF THE SPANISH SOCIETY OF CARDIOLOGY AS AN ORGANIZATION

The Ethical Framework of the Spanish Society of Cardiology

Rationale

The SEC is a professional, scientific, nonprofit association that brings together the great majority of Spanish

The full document includes a large glossary of terms and can be found at www.secardiologia.es: the consultants who offered suggestions and comments is listed there. The SEC would like to publicly thank all of them.

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cardiologists and other non-cardiologist professionals involved in cardiovascular problems. At the core of its activities are continuing improvements in further education to help these professionals achieve excellence in their practice and encouraging research in this field.¹

This report is aimed at all members of the SEC. Such members implicitly adopt the official position of the society, although the SEC cannot support all professional actions, especially when in serious conflict with its institutional obligations.

Ethical Values and Excellence

The ethics of any scientific society or company can no longer focus on merely preparing an ethical code, but should encompass a new moral culture of “convinced and shared responsibility” for the entire organization, especially when developing and applying accreditation systems or quality assessment.²⁻⁵

The SEC wishes to make explicit certain ethical values oriented to clinical practice all of which are essential to generating and consolidating confidence in its institutional relationships, in the interests of an ethics based on responsibility^{6,7}:

1. Integrity. Consistency between what is said, written and done.

2. Confidentiality. The obligation to respect confidentiality and privacy in any healthcare relationship, and to protect health data.

3. Trust. This exists by virtue of the credibility and good reputation the SEC merits from third parties when offering good service to the public, quality healthcare to patients and quality of life to users, plus continuing education to its members, honest cooperation with companies from the health sector, as well as promoting respect and consideration toward other scientific associations and social institutions.

4. Independence. Freedom of information and action in the field of cardiovascular disease supported by sound knowledge of the Spanish context, healthcare, and research in this field. Autonomy for managing its resources.

5. Veracity. Transparency regarding actions and activities, declarations of conflicts of interest, and auditing procedures. Providing intelligible and rigorous information on health, as well as supplying the mass media with scientific reports free of bias or deception.

6. Dignity. Respecting and promoting human rights without discrimination regarding any type of condition, or social or personal circumstance.

7. Dialogue. Open and participatory attitude toward its members, other health professionals and the public, official bodies, associations and organizations, in the search for agreement.

8. Civic commitment. Local and regional development of cardiology, and collaboration with national and regional administrations regarding organizing healthcare services

in Spain and improving cardiovascular health among the public. This cooperative responsibility, based on justice and solidarity, involves the ability to respond to the health needs and expectations of the community which, in the context of globalization, goes beyond our borders.

9. Distributive justice. Applying efficiency and equity criteria to action within the framework of the Spanish National Health System.

10. Legality. Complying with the law and current regulations, without impinging on ethical obligations.

Conflicts of Interest

The SEC has articulated and maintained a strict code of conduct regarding its own institutional relationships, which are in line with the guidelines of professional associations,^{8,9} and regulatory bodies in Spain, in addition to following the guidelines provided by reputable scientific societies.¹⁰⁻¹⁶ The SEC reaffirms its position that, while remaining within the framework of mandatory legal regulations, ethical self-regulation can be developed by establishing criteria and standards of excellence.

Individuals often have dual commitments or interests that can converge or diverge, for example, between the patient’s well-being (benefit) and the interest of the institution or company (profit, increased productivity). This should be declared whenever this occurs or when possible conflicts of interest are suspected in healthcare relationships. The mere existence and declaration of conflicts of interest should never be used to prejudge a physician’s professionalism, a researcher’s honesty or the scientific validity of a study.^{17,18}

The term “conflicts of interest” applies to those situations where a secondary, and always personal, interest – economic, ideological, or professional – may be placed before a primary interest – the well-being of the patient, the acquisition of knowledge which is valid and generalizable for research, the interests of science or society – thereby modifying the professional’s ability to give an apparently independent judgment. The secondary interest does not have to be unlawful or bad in itself, it can even be desirable, but what is questioned is the relative effect these interests have on the primary interest.¹⁸

Continuing Medical Education

The Spanish Society of Cardiology as the Protagonist. Role of Industry

The SEC, whose final aim is the patients’ well-being and the general welfare of society, includes the following among its goals¹:

– Promote, coordinate, and develop scientific programs, as well as offer information, and health education to the general public.

– Participate actively in the continuing education of its members and all professionals working in the cardiovascular field.

The SEC is a nonprofit association and thus has to acquire the necessary resources to attain the educational aims society requires from its professionals.¹

On the other hand, the pharmaceutical industry and medical technology companies are important sources of progress in medicine who wish to make known the results of clinical trials related to their own products.¹⁹ They also fulfill important support roles – of a highly diverse nature and value – in the continuing education of physicians and, to a lesser extent, of other health professionals.²⁰ Thus, both parties – companies and industry on one hand, and physicians on the other – need each other.

The SEC will always encourage the independent judgment and professionalism of its members to help them distinguish between promoting these products and providing impartial information and medical education. Thus, it has decided to define its relationship with the pharmaceutical and medical technology companies, and has encouraged its members to embody high levels of professionalism and sensible attitudes at the individual level regarding deontological ethics.^{20,21-24}

Transparency and Responsibility in Sponsoring Activities and Funding

Basically, the SEC has public interests, and the health industry and companies have private interests in potential economic profit. Hence, their relationship should be governed by an ethical framework of transparency and mutual acceptance that guarantees independence regarding the educational content provided to avoid possible conflicts of interest.^{7,20,22,25-27} All sectors involved are urged to encourage more order, rationality, balance, and restraint regarding excessive and repeated activities in this area. This involves very high costs and uncritical acceptance of this situation is no longer possible, even in the context of the competitiveness imposed by a market economy. All activity endorsed or sponsored by the SEC should be in line with the ethical values it has established as an institution. The SEC should assess its degree of dependence on external sources of funding to ensure that its core activity of continuing medical education can be fulfilled even in the eventuality of such economic support decreasing. The independence of the SEC will be based on the diversification of these sources and its ability — scientific and critical — to be impartial and unbiased.²⁸⁻³⁰ To this end, it will implement strategic programs of activities in the medium- and long-term which will be linked to qualitative and quantitative goal-setting.

The Congress on Cardiovascular Disease

Basic Considerations

The main annual event of the SEC is the Congress on Cardiovascular Disease,¹ where current medical knowledge on our specialty is presented. The scientific program of the Congress is divided into two types of educational activity: an official program (round tables, debates on controversial issues, lectures, continuing education, special issues, workshops) and an unofficial program (industry-sponsored round tables).

The Lines of Conduct Governing the Spanish Society of Cardiology

The SEC organizes its annual Congress based on high ethical standards and content, which means that sponsorship and the accreditation of educational activities is strictly regulated.^{20,31} The SEC has developed a detailed code on funding and external relationships for the Congress, as well as suitable and effective mechanisms to achieve compliance.³²

The Spanish Society of Cardiology's Organs and Management Teams

Responsibilities

Maintaining a relationship of trust between members and the SEC administration is vital to preserving its core values and unity, as in any scientific society.¹³⁻¹⁶ Members should be aware that anyone in an administrative position is always motivated by the general interests of the SEC when exercising his/her functions. All such representatives will always act honestly, transparently, and fairly as well as strictly maintaining a scientific-technical approach to their decisions regarding members, without forgetting possible conflicts of interest which can arise.^{1,10-12}

Rules of conduct have been drawn up based on this perspective which are applicable to the following administrative bodies of the SEC:

–Executive committee: President, President elect, previous President, Vice-President, Vice-President elect, Secretary General, Under Secretary, Treasurer, Associate Societies' spokespersons, Editor-in-Chief of the REVISTA ESPAÑOLA DE CARDIOLOGÍA (also including the associate editors), and Executive Director of the SEC.

–Scientific sections and working groups: President, Secretary, and spokespersons.

–Associate societies: President, Vice-President, Secretary, Treasurer, and spokespersons.

Scope of Relationships

Pharmaceutical industry, health technology companies, and others. The administrative officers of

the SEC represent a variety of members that expect effective and transparent management. The administrator should be a model of rectitude in all areas where conflicts of interest can arise and should inspire trust. Collaboration with companies should be based on respect for each party's aims, but both should direct their efforts at increasing the educational level and research skills of all the SEC members.^{22,26,27} There are several fields where conflicts can occur: professional technical consultancy, continuing education courses, scientific meetings, conferences, symposia, round tables, awards, or fellowship panels.

Mass media. The administrative bodies that distribute specialized information to the mass media – general press, radio, television, and Internet – will adhere to the ethical standards established by the SEC.

Public institutions related to the areas of health and education. The Executive Committee of the SEC and its associate societies will promote contacts with the Ministry of Health and the Departments of Health, to implement joint programs and other proposals of interest to the SEC and its members, and to the patients and general public. The SEC will maintain relationships with the Ministry of Education and Culture, central, and regional Administrations and universities to study and develop the academic potential of Spanish cardiologists in graduate and post-graduate teaching.

Research is one of the key areas fostered and promoted by the SEC, which necessarily involves increasing collaboration with Spanish and international scientific institutions at the highest level and becoming involved in several RDI (research-development-innovation) networks.

Scientific societies. The SEC will maintain and expand its relationships with all the Spanish scientific societies it considers relevant and with suitable international societies related to its specialty or related sciences.

Spanish Heart Foundation. The Spanish Heart Foundation is a nonprofit private entity. It is the official social arm of the SEC and fulfills a basic mission of contact with the public, since its aim is to promote and maintain the cardiovascular health of the general population.¹ The SEC will unwaveringly support initiatives proposed by the Foundation which it considers of interest to its institutional aims.

Scientific Publications

A Fundamental Aim of the Spanish Society of Cardiology

The SEC is responsible for distributing scientific information relevant to its field, through continuing

education and all possible media of communication. Likewise, it aims to be a communication channel for current progress in cardiovascular care and research, by publishing works via the REVISTA ESPAÑOLA DE CARDIOLOGÍA, its publishing arm (Agencia Editorial), and the SEC website.

The SEC will ensure the maximum impartiality of their publications' contents such that they fulfill quality and veracity criteria, especially in writings that represent their official position. It will also regulate possible conflicts of interest in all its scientific publications, in line with the recommendations of the International Committee of Medical Journal Editors.^{25,33,34}

Responsibility of the Publishing Team and Referees

The editors and referees of the SEC's publications are not exempt from declaring their possible conflicts of interest, and must abstain from participating in assessing certain manuscripts that may lead to doubt or uncertainty regarding their editorial independence.^{18,34}

Scientific articles should always be assessed on their own merits, without prejudice regarding their origin, authorship, or funding to help detect fraud before their publication.³⁵⁻³⁷ The SEC's publishing policy is clear on these matters and requires from authors a complete declaration of potential conflicts of interest.

Publication Formats of the Spanish Society of Cardiology

Official documents. These represent the official position of the SEC on a specific subject, following the necessary deliberations.

Unofficial documents. These are used by the SEC for the continuing education of its members. They are created both by members of the Society and others and do not express the official position of the SEC.

Articles in the REVISTA ESPAÑOLA DE CARDIOLOGÍA. The original articles published in this Journal solely represent their author's position. The REVISTA ESPAÑOLA DE CARDIOLOGÍA can evaluate the scientific quality of the data and their relevance through a rigorous refereeing process, but does not have the means to check their veracity; this is the sole responsibility of the article's authors.³⁴⁻³⁶

The author must fulfill very specific requirements to be accepted as such, and the person directly responsible for the final manuscript should be clearly differentiated from the person guaranteeing its overall scientific content.³⁵

Clinical Practice Guidelines

Concept and Purpose

The need for creating clinical practice guidelines (CPG) has emerged as a response to the complexity and controversial nature of medical practice.^{25,38} The guidelines are defined as a set of instructions, principles, statements, or recommendations – systematically updated and developed – addressing the diagnostic procedures to be used with each patient presenting a given clinical picture, or the most suitable therapeutic approach regarding a clinical diagnosis or health problem.³⁹⁻⁴⁴ Their purpose is to help physicians and patients make decisions on the most suitable healthcare service for a given clinical condition.⁴⁵⁻⁴⁸

The creation of CPGs is driven by the need to achieve several objectives^{45,49-51}:

- Facilitating the process of reaching correct clinical decisions.
- Promoting the appropriate use of medical technologies.
- Improving quality of care and the proper use of available resources.
- Respecting the recognized rights and obligations of the patients, users, and professionals.
- Increasing the legal protection of physicians and the level of certainty regarding medical issues among judges.
- Decreasing the number of lawsuits and court procedures related to healthcare activity.

The Use and Function of the Clinical Practice Guidelines

The SEC has adopted the CPG from the European Society of Cardiology.⁵² To this end, it has applied certain criteria from experts in its scientific sections and working groups to adapt these CPG, and has added specific observations as footnotes in the version published in REVISTA ESPAÑOLA DE CARDIOLOGÍA.⁵³

It is recommended that all CPG address some basic ethical considerations prior to their scientific or technical development.^{13,15,45} In addition, it is advisable to include cost-effectiveness criteria regarding decisions.^{54,55}

Their Value in Healthcare

The CPG are recommendations on the correct way to proceed, based on the best available current evidence; thus, their value in healthcare should be specified^{45,56}:

- They should always be understood as recommended criteria, not as quality standards.
- They are not equally applicable in all cases, since this varies according to the particular circumstances and various contexts.

– They should not only take into account medical criteria, but should also consider the patients' preferences, according to the current principle of informed consent.

– Once they have been written and disseminated, they should be followed by the professionals during their clinical practice.

– The professionals and the SEC itself should assess compliance with the CPG and their actual impact on public health.

RESPONSIBILITIES OF THE PROFESSIONAL AS A MEMBER OF THE SPANISH SOCIETY OF CARDIOLOGY

The Physician and Professional Practice

The Meaning of the Profession

The dilemma of physicians in view of the purpose of medicine. The true purposes of medicine are⁵⁷⁻⁵⁹:

- Preventing disease and injury, and promoting and maintaining health.
- Relieving pain and suffering caused by disease and disorders.
- Treating and curing patients and caring for those who cannot be cured.
- Preventing premature death or ensuring a peaceful death.

According to the above, it can be stated that currently physicians have multiple social functions^{12,45,60-62}:

- They should uphold the patient's rights and be, in principle, at the service of the ill person.
- They should promote health and act as communicators and health educators for the public.
- They prescribe and use health technology in both clinical research and healthcare.
- They manage resources and are one of the agents within the healthcare system.

All this can lead to a certain crisis regarding professional identity, the development of tension within the healthcare setting, professional burnout, and becoming demoralized.⁶³ This is so because clinical practice is complex and sometimes controversial, and difficult issues have to be resolved: one is always acting in uncertainty, the available scientific evidence has to be weighed up, clinical decisions, and ethical judgments regarding facts, and values, respectively, are continually made, ethical responsibility and legal liability deriving from freedom of clinical action are assumed and, finally, decisions are made between what is optimal for each specific patient and what is optimal for the community.^{45,64,65}

Lex artis. Risks and dangers. At all times, medicine has an obligation to define the general scientific criteria

for action or “good practice,” known as *lex artis*. This involves an assessment criterion to determine the suitability of a given medical action or professional conduct.⁶⁶ Given the diversity of clinical situations, patients and healthcare contexts, it is essential to establish sensible criteria for action according to certain circumstances, *ad hoc lex artis*. Malpractice or poor practice is understood as not conforming to *lex artis*.⁶⁷⁻⁶⁹

Accusations against physicians due to presumed mistakes, carelessness, or negligence have recently increased in Spain. Medical practice involves applying certain procedures and interventions of varying risk, which sometimes have unsatisfactory outcomes for the patient, or do not lead to cure. This can be seen as a failure or even an error due to the creation of false or unrealistic expectations.⁷⁰

Ethical Framework of Professional Practice

A core issue. Ethical responsibility involves respecting the ethical principles that govern the exercise of our medical profession. Legal responsibility will be fulfilled by following the given demands regarding diligence and abiding by civil, penal, and administrative law.^{45,71} Society establishes a certain minimum concerning what it considers maleficent – ignorance, lack of skill, negligence, carelessness – but not regarding professional excellence.^{10,11,13-15,72,73}

Bioethical principles. Since the 4th century C.E. – when the Hippocratic oath was instituted – the medical profession has tried to establish self-regulating systems to prevent or mitigate malpractice.^{71,74-76} The values that play a part in the problems currently discussed in bioethics revolve around four principles⁷⁷⁻⁸²:

- Non-maleficence: no deliberate harm or injury should be done to another person by commission or omission. This relates to the physician’s competence and is defined by *lex artis* and criteria for indication, non-indication, and contraindication.

- Autonomy: the preferences of people able to state these should be respected. This relates to the capacity to make decisions and deal with factors related to our own life and death.

- Justice: burdens and benefits should be equally shared among the members of society. The term “distributive justice” is used when referring to healthcare resources.

- Beneficence: good should be done to people and their vision regarding what a good life is respected.

There is a certain hierarchy within these four principles and none is absolute. This means that there is room for exceptions in all of them, but these exceptions must always be chosen as the lesser evil, and should never

become the norm. The burden of proof, or the obligation to rationally justify such a decision, lies with the person proposing the exception.^{83,84}

Recently, an attempt to define universal “statutes of the medical profession” has been made, based on three fundamental principles⁸⁵:

- Precedence of the well-being of the patient, which is based on trust and altruism.

- Respect for the autonomy of the patient, with special emphasis on providing information.

- Promoting social justice, by establishing and developing just healthcare systems that avoid discrimination.

Conscientious objection. Conscientious objection refers to that which the professional considers immoral and which the law does not prohibit due to not being defined as harmful or unjust. When physicians have a definite conscientious objection this does not mean their obligations cease,^{8,9,14} as they still have the obligation to provide caring medical assistance to the patients affected by the problem, both before and after declaring their objection, and must always provide this in vital emergencies. Similarly, there should be no double standards whereby objections are raised in the public arena but not in the private one, due to profit motives, privileges, or any other unjustifiable circumstance.

Legal Framework for Professional Practice

Assessing medical liability. The law states that a medical intervention is correct if it is medically indicated, has been done in line with *lex artis*, and was done with the consent of the patient. The physician is liable concerning his/her actions when the incriminating facts indicate a voluntary, irresponsible, or negligent offence – with malicious intent or intention – which can be characterized as a minor offence or crime. Civil liability only applies when it can be proved that the physician has failed to perform his/her obligations regarding exploratory, diagnostic, and therapeutic actions, as prescribed by the current state of science, to correctly deal with a specific condition.⁸⁶⁻⁹²

In Spain, the physician’s liability currently falls within three procedural areas: contentious-administrative (public healthcare), civil (private healthcare), and criminal (private and public healthcare) procedures. Several elements have to come together to be able to claim medical liability via criminal or civil procedures:

- That the patient has suffered actual harm.

- That there is a cause-and-effect relationship between the medical action and the harm suffered by the patient.

- That the standards of care have not been complied with.

The burden of proof normally rests with the claimant. However, there is a tendency toward placing it on the physician based on “ease of proof,” since it is easier for the physician to show that he/she has acted in line with *lex artis* than for the patient to demonstrate the opposite.

Team-work. Resident/intern physicians. A working team should not only share knowledge and skills but also attitudes; their relationships should be governed by criteria of hierarchy and coordination. In order to delimit responsibilities within the team, two principles have been put forward⁹³: trust, since a person who acts correctly should trust that the other will also do so; and division of tasks, which results from specialization and scientific progress.

The relationships between physicians and nurses have two dimensions: vertical, involving supraordinate, and subordinate relationships; and horizontal, involving the essential skills exclusive to nursing.

The resident/intern physicians have to actively participate in the process of informing patients and their comprehensive care, in line with the level of knowledge and training indicated by their specialization program, and with the level of monitoring, mentoring, and supervision provided by the acting specialist physician according to the needs of the intern.^{94,95} The relationship between the resident/intern physician and specialist is defined by the vertical division of labor and mutual trust guided by mentorship.

The Physician and the Clinical Relationship

Information and Consent are Ethical and Legal Issues

The clinical relationship between health professionals and patients or users has changed due to the legal recognition of the moral autonomy of people to make decisions regarding their own life, health, and body.⁹⁶⁻⁹⁸ The information and consent processes are basically verbal and should take place in a climate of trust; hence, the professional should develop communication skills specific to the clinical interview and to face emotional situations.^{89,99,100}

Every patient should always know who is the physician responsible for giving suitable information and coordinating clinical decisions. The obligation to inform the patient and obtain their consent constitutes an ethical and legal obligation on the part of the physician. Although there are limits to the obligation to provide information, there will always be exceptions that have to be justified.^{89,99}

Informed Consent is a Verbal Process. Printed Forms

The process of informed consent should not be reduced to a signature on the printed form; rather, this should serve to support previous dialogue. In any case, the information provided should be suitable, truthful, intelligible, understandable, and adapted to the needs and demands of each patient. The physician always has the obligation to describe the risks typical to each procedure and any specific personal risks.^{99,101} The patient's physical or mental disability is one of the exceptions to personal consent; in these cases, the information has to be given to the incapacitated patient, whenever feasible, or to family members or those otherwise related to the patient.^{89,102-107}

The SEC has defined the risks typical to different medical activities in this specialty, identified the procedures that need written informed consent and the requirements of such forms.¹⁰⁸ Similarly, due to the problem of waiting lists, the SEC has established scientific criteria for organizing the scheduling of surgical interventions in cardiovascular disease.¹⁰⁹

Confidentiality, Privacy, and Protection of Health Data

Confidentiality is a fundamental right of the patient which has its counterpart in the following: the obligation of the physician to respect the privacy of the patient in the healthcare relationship.^{13-15,110} Two basic rights can be spoken of: the privacy of the patient and family, and the protection of personal data.^{111,112}

The physician is obliged to exercise confidentiality with each patient because he/she handles sensitive information regarding the patient's body, health, or life. These confidential data are shared with other medical team members – nurses or other professionals – provided they have a direct relationship with the patient's healthcare. The obligation regarding confidentiality can be broken to prevent harm to the patient or third parties, or due to legal requirements, but whenever the physician has to do this the patient affected must be informed.^{113,114}

The Value of the Medical Record

The medical record is a set of documents with ethical and legal value. The physician is responsible for filling in the record correctly, updating and integration, since the record includes his/her subjective assessments as well as those of other healthcare professionals. Health centers should guarantee the protection of health data of all the patients and users included in their records.^{89,114,115}

Access to medical records is restricted to the healthcare personnel with direct responsibility for treating and

caring for the patient; any other personnel are only allowed to verify certain administrative data. The use of computerized health data for statistical or epidemiological analysis, or inspection will be done under due legal guarantees and always anonymously. The patient's access to their own medical record is a recognized right carrying some restrictions – eg, subjective annotations by healthcare professionals – providing the rights of third parties are not adversely affected. In cases of legal action against health professionals, the judge can obtain the medical record as expert evidence, while under the obligation to specify the purpose for requiring this.^{113,114,116}

Biomedical Research on Human Beings

Scientific and technical advances in biomedicine should be at the service of patients and contribute to their health, development, and well-being. Scientific evidence differentiates validated practices from empirical practices. The validation procedure consists in clinical research which should be logically justified even before being ethically justified.^{77,117-123}

Every clinical research ethics committee should analyze the methodological, ethical, and legal aspects of clinical trials in human beings, in line with the principles of bioethics^{18,37,70,77,124-130}:

- Non-maleficence: technical suitability of the trial and competence of the research team, scientific validity, the morality of placebo use.

- Justice: equity regarding patient selection, compensation for possible harm, social usefulness, and economic impact of the trial, conflicts of interest of all parties involved.

- Autonomy: validity and authenticity of the process of informed consent; confidentiality regarding data.

- Beneficence: correct assignment to treatment groups, not unfavorable benefit/risk ratio, protection of vulnerable groups.

The Physician and Society

Conflict-Resolution Scenarios. The Physician As Expert Witness

The first body to address ethical problems in healthcare institutions are the healthcare ethics committees, which are advisory and multidisciplinary.¹³¹ Given the growing trend toward litigation in the healthcare world, an attempt should be made to resolve many minor conflicts within the framework of arbitration tribunals, so that agreements can be reached between the parties in conflict and avoid the customary legal channels.^{132,133}

The SEC, within its field, will support collaboration between expert witnesses in cardiology and forensic

scientists regarding managing risk, evaluating medical errors and assessing physical harm. The SEC notes that the roles of expert witness and medical practitioner are incompatible regarding the same patient and encourages the cultivation of certain attitudes when making an expert witness report: objectivity, impartiality, rigor, truth, restraint, balanced critical judgment, independence, and not going beyond competence, or capability.^{70,92,134-136}

Distributive Justice in Healthcare. Efficiency and Equity

The Spanish National Health System is based on a basic set of values – equity, quality, citizen participation – which aim at coherence.^{90,137} Thus, the Spanish Government has two obligations in its role of promoting social justice, and supporting the public health system: to finance sufficiently validated services and distribute its resources equitably.¹³⁸⁻¹⁴⁵ The SEC calls for the responsible involvement of its members, all healthcare professionals, the general public, society as a whole, and especially public authorities, in order to achieve the greatest efficiency and equity possible.

The debate on efficiency needs to address some core issues:¹⁴⁶⁻¹⁵⁰ the rational and sensible use of drugs, tools, and healthcare technology; the appropriate, inappropriate, or questionable use of diagnostic tests and therapies; the most suitable approach to statements of incapacity to work (sick notes) regarding duration, harm assessment, vital risk and associated comorbidity; or the waiting-list problem.

The SEC supports decisions that encourage equity,¹⁴⁹ given that healthcare resources are finite. However, this involves: demonstrating the effectiveness of every action, considering the opportunity cost of diagnostic and therapeutic choices, affirming that the patient's utilities are the most relevant, emphasizing that "optimal is not maximal" or that "more is not always better," and assessing the different categories of care, since not all are equally effective.^{7,151-154}

Relationship With Pharmaceutical and Medical Technology Companies

Medical prescription. The industry's promotional methods. There is a medical obligation to prescribe both rationally and efficiently. Freedom to prescribe involves selecting, from among the possible and available interventions, the most appropriate one for the patient in his/her specific circumstances. This involves: weighing up its validity, therapeutic usefulness and efficacy, meeting safety criteria, selecting the best option bearing in mind the patient's clinical condition and preferences, obtaining the necessary consent from the patient, and taking into account the economic aspects of the decision, which are

sometimes influenced by incentives deriving from external companies or healthcare administrations.^{21,23,26,155-157}

The industry uses several methods to promote its products – visits to the physician, support services, gifts – that should be put to critical, balanced, and open debate.^{19,20}

The SEC will avoid endorsing promotional campaigns with obvious commercial interests, and will inform the public when messages, or recommendations are disseminated without sufficient scientific evidence, especially if this can generate disproportionate, unjustifiable, or unreal expectations in patients or users, and create distrust towards physicians for not offering them these hypothetical advances.^{12,14,22,27,158-161}

A framework for agreement: self-criticism, transparency and agreement. The physician has the obligation not to accept any type of gift that decreases, or appears to decrease, the objectivity and impartiality of clinical judgment.²⁶ Both individual and institutional self-criticism is required: ethical codes are of no use if they are not accepted and implemented, but neither is their preparation and dissemination sufficient to ensure they are complied with.

All the agents involved need to be brought together and provide the ethical motivation needed to reach an agreement which includes various commitments^{20,21,26,155,157}:

- Stimulate a better culture of relationships between physicians, pharmacists, and industry, based on transparency, honest cooperation, and compliance with the regulations.

- Reform the current model of visits to physicians, to guarantee the added value of the time invested in a dignified atmosphere for both parties.

- Promote changes of attitude in physicians, to prevent certain harmful behavior becoming habitual concerning incentives or influencing prescriptions, as well as giving a bad example.

- Encourage transparency through maintaining collaborative records in health centers, adopted voluntarily by physicians, managers, and health-sector companies.

CONCLUSIONS

Professional Conduct Guidelines

These can provide the members of the SEC with useful pointers concerning their activities in daily practice: some concern actual legal obligations with important ethical implications; others relate to moral obligations that must be fulfilled although they are not laws; and finally, some constitute various pieces of sensible advice. The main aim is to improve quality in the search for professional excellence.

Legal Obligations

- Always take down the case history, do a complete physical exploration and write down everything that occurs regarding the evolution of the patient and their healthcare process in their medical record.

- Request the necessary and sufficient complementary explorations when indicated for correctly diagnosing the disease and aiding clinical decision-making.

- Notify the patient who their assigned doctor is, as the person responsible for passing on information and coordinating clinical decisions.

- Give patients the appropriate information concerning their disease, prognosis and expected treatment or, in the case of disability, to the family or those otherwise related to the patient.

- Always maintain veracity in healthcare practice and clinical research.

- Ask for the patient's verbal consent for implementing specific tests, always explaining the risks typical to each procedure without omitting risks particular to the patient.

- Obtain written informed consent for situations and procedures specified in current legislation, using the procedures and forms required in each case.

- Maximize precautions, monitoring and necessary clinical controls when using experimental drugs or procedures.

- Clearly indicate the established guidelines on medication in writing. Notify patients of the risks and possible unwanted side-effects of the treatment, strongly urging them to report any unexpected adverse effect should this occur.

- Notify the patient about the consequences of refusing the prescribed treatment.

- Respect previous instructions given by patients, as well as the documents where they are recorded, since these specify the patient's wishes.

- Maintain professional confidentiality both within the healthcare context and outside this, as a gesture of respect regarding confidentiality and privacy in the healthcare relationship.

- Notify the patients that interning physicians, student physicians, or nurses in training may participate in their healthcare.

- Ensure that access to the patient's medical record does not compromise the confidentiality of their health data.

- Fulfill all legal requirements, especially in clinical trials, clinical documentation, and other regulations directly related to clinical tasks.

- Cooperate with the law in the capacity of expert witness, when the situations or circumstances require this.

Moral Obligations

- Always respect the basic dignity, confidentiality, and privacy of patients during explorations and tests, both in

the manner of acting and in taking care of the environment where they are done.

- Develop specific communication skills for the clinical interview and for managing emotional situations, with the aim of maintaining a correct and good relationship with the patient and their environment.

- Notify the patient affected by a breach of confidentiality in specific cases of need, and minimize any possible harm that could be caused by this.

- Offer advice concerning quality of life and guidance on how to prevent cardiovascular problems and develop healthy habits, while also respecting the patient's or user's wishes and preferences.

- Prescribe the treatments offering greater safety and efficiency when choosing among those whose proven efficacy and effectiveness is similar.

- Encourage attitudes of altruism, respect, and co-responsibility in the patients and users regarding the donation of organs, tissues, or cells from their own body.

- Try to keep up with continuing education in the specialty, regarding knowledge, technical skills, and the development of attitudes in line with the ethical principles of the profession.

- Maintain veracity in biomedical publications and in relationships with the mass media.

- Obtain the support and advice of the healthcare ethics committee in cases of ethical conflict requiring dialogue outside the framework of the clinical relationship.

- Oppose inequality, above all in the use of healthcare technologies, avoiding unfair discrimination in the use of resources.

- Maintain honest relationships with the pharmaceutical industry and medical technology companies.

Sensible Advice

- Non-delegation to nurses or auxiliaries of the obligation of passing information on to the patients and obtaining their consent which always remains the physician's obligation; such healthcare personnel can only pass on information regarding their own clinical activities.

- Avoid requesting too many tests, unless required in specific cases. This could unjustifiably delay diagnosis or treatment and perhaps expose the patient to inadmissible risk.

- Cooperate with the nursing personnel to improve interdisciplinary work.

- Ensure that human relationships within the team do not give rise to conflict.

- Always maximize daily performance and efficiency during working hours.

- Give a full report, preferably in writing, to the head of the service or the unit's acting physician, regarding any healthcare problems caused by a lack of organization,

or failures in the operation of medical-surgical instruments or technical equipment.

- Promote autopsy studies to improve diagnostic and therapeutic accuracy.

- Develop a culture of reporting medical errors, as a guarantee of good faith on the part of the professionals, for the sake of patient safety and to avoid legal action.

Proposals of the Spanish Society of Cardiology

Given its civic commitments, several proposals are set out within the framework of the SEC:

1. The education of healthcare professionals should be promoted and encouraged concerning bioethics as well as the socioeconomic aspects and management of healthcare, with the aim of improving their knowledge and skills in decision-making regarding these issues. Attitudes that promote human values in line with authentic medicine aims should be reinforced, especially to prevent the professionals involved becoming demoralized. In this sense, the SEC will promote education and raising awareness in relation to medical ethics.

2. Committed and collective responsibility should be encouraged in everyone in the socio-healthcare world, regarding both achievements and failures, especially because the public's expectations should not grow beyond the real chances of meeting their demands. In this line, awareness of costs should be gradually introduced:

- In patients and users, without compromising access to the health services and their resources.

- In physicians, nurses, and other healthcare professionals, without interfering with the personal relationship due to the patient or the institutions where they work.

- In the mass media, because of its obligation to practice honesty and restraint in all matters relating to providing information and opinions on the immense field of healthcare.

A deep and transparent political, economic, social, and professional debate should be encouraged regarding:

- The healthcare models promoted in Spain.

- The present and future of the Spanish healthcare professions, their needs, problems, and possible solutions.

- Healthcare cover from public funds and the potential to maintain and improve them.

- The quantity and quality of the social services available to serve real needs in the present and future.

- The new moral culture of the professionals and healthcare institutions, and organizations, which is

essential to responsibly fulfilling their respective functions and tasks.

These points are extremely relevant – in micromanagement (clinical management ethics), mesomanagement (organizational and institutional ethics), and macromanagement (healthcare policy ethics) – and cannot be achieved in the short term, although the demands and needs are strong and pressing. Hence, it is neither ethical to forget them nor to be satisfied with less.

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