



How can the European Society of Cardiology ensure compliance with ethical standards?

Maarten L. Simoons*, Jean-Pierre Bassand, Jeroen Bax, Michel Bertrand, Günter Breithardt, Roberto Ferrari, Kim Fox, Paul Hugenholtz, Michel Komajda, Fausto Pinto, Lars Rydén, Michal Tendera, and Panos Vardas

Department of Cardiology – Thoraxcenter, Erasmus Medical Center Rotterdam, Room Ba 593, 's Gravenijskwal 230, PO box 2040, Rotterdam 3000 CA, the Netherlands

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Physicians, allied health professionals and scientists, should act according to the highest professional standards in patient care, research and relations with others, including medical industry. Guidelines for prevention, diagnosis, and management of disease are provided by professional organizations, such as the European Society of Cardiology (ESC). Furthermore, the ESC, as well as other medical organizations, provides a forum for presentation of the newest research findings at congresses and in scientific journals, and offers programmes for training and continuing medical education (CME). Many advances in patient care—diagnostic tests, medication, equipment, and devices—have been developed and were introduced by industrial companies, often in close collaboration with universities and hospitals. Therefore, the relations between industry and individual physicians, scientists, universities, and medical professional organizations are of particular interest. Promotion of new developments that may improve healthcare is in the interest of patients and physicians, provided that conferences, educational materials, and programmes organized by the ESC are unbiased by commercial interests. The Board of the ESC emphasized this in a policy statement, which included strict recommendations for transparency and disclosure of relations between representatives from the medical profession and industry, concerning scientific communication and education.¹

Nevertheless, in recent years, some members of the European Society of Cardiology (ESC) have been discharged or suspended by their universities because of scientific or financial misconduct. Furthermore, the relations between ESC and industry have been questioned.²

To address these issues it has been suggested that the ESC and similar professional organizations should appoint an 'Ethical and Oversight Committee' to oversee the conduct of its members and to take appropriate action if professional misconduct or biased relations with industry are suspected or apparent. To further this discussion and to assess the possible role of an 'Ethical and Oversight Committee', in this report we herewith review the ethical

standards, which apply to the members of the ESC and to the ESC itself, indicate how the ESC can ensure compliance with ethical standards and discuss which organization may be expected to investigate and act upon possible violations.

Patient care

Hippocrates first summarized the ethics of patient care. Nowadays physicians promise to obey an updated version of the oath of Hippocrates, i.e. commit to offer the best possible care to each patient and to keep information related to the patient confidential. Similar rules apply to nurses and other healthcare workers. Medical professionals who deliver sub-standard care, breach professional confidentiality, or develop inappropriate relations with patients or their relatives will be investigated and possibly prosecuted by medical legal courts in the respective countries.

The ESC has no specific responsibility in these matters. However, the ESC may consider whether actions are required when a member or fellow is suspected of inappropriate behaviour. Furthermore, the ESC may get involved in or initiate general discussions on the ethical standards that govern patient care. For example, the ESC has contributed to the discussion about deactivation of ICDs at the end of life.³

Research

Clinical research should be conducted according to the rules for Good Clinical Practice based on the Declaration of Helsinki. Similarly, experimental research should follow Good Laboratory Practice and avoid unnecessary harm to laboratory animals. Each research programme should follow a well-designed protocol, approved by the local or national Medical Ethics Committee or Committee for Animal Welfare. The protocol should state the purpose of the study and summarize the relevant existing knowledge and the new information that is expected to be gained. Furthermore, the protocol must describe the study procedures in detail and provide a statistical analysis plan.

* Corresponding author. Tel: +31 10 704 0 704, Fax: +31 10 463 5258, Email: msimoons@xs4all.nl

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Deviations from these rules, including sloppiness, falsification, or even fabrication of data, may be detected and corrected by collaborators of the investigator, but may also become apparent after presentation of the results at a meeting organized by the ESC, from a submitted manuscript or from a publication. The integrity of science as well as scientific fraud has been discussed recently in this journal, with recommendations to prevent such misconduct.⁴

While these issues remain within the responsibilities of national or local authorities, the ESC should consider how to react to such misconduct when persons involved are members or fellows of the ESC or otherwise actively involved in ESC matters.

Publications

The results of scientific investigations should be presented at scientific meetings, and published, usually in a peer-reviewed journal. A research publication should state the questions that are addressed, describe the study protocol in sufficient detail, present the patients, animals, or other study materials, and accurately describe the results that were obtained. The implications of the study should be discussed, with proper references to previous work by other investigators as well as to earlier publications from the authors. The authors should be transparent with respect to possible conflicts of interest.⁵ Duplicate publications of the same study are generally not acceptable. Editors, reviewers, or other investigators may suspect or even detect inaccurate data, unwarranted conclusions or plagiarism, including self-plagiarism. If inaccuracies, falsifications, or plagiarism are suspected, appropriate action should be taken by the Editor of the journal. The *European Heart Journal*, *Cardiovascular Research*, and the other ESC journals have created an Ethical Committee that can investigate suspected fraud or other misconduct.

Clinical practice guidelines include an overview of the relevant scientific literature. If part of these references appears faulted, the guideline should be revised. During the revision process, a note should be added to the guideline.

The journal editors as well as reviewers should adhere to high standards as specified by the International Committee of Medical Journal Editors.⁶

If improper research conduct, scientific fraud or plagiarism is confirmed, the editor of the journal will take appropriate action, including retraction of a publication with falsified data. Additional actions may be taken by ESC, when the misconduct is confirmed.

Medical education

Continuing medical education is essential to keep physicians and other healthcare workers up-to-date. It is also in the interest of medical industries to inform physicians on new developments, and to promote the use of their products to the advantage of better patient care. Over the years, scientific conferences, CME programmes, or programme attendees have been supported by industry either directly or indirectly through medical education companies. Guidelines to ensure unbiased presentations and transparency of any relations between lecturers or organizers of educational meetings and congresses and industry have been detailed.¹ Furthermore, rules have been formulated in many countries restricting the level of

support by industry, although it must be appreciated that these rules may differ between countries.

If biased presentations or other misconduct occur, the ESC Education Committee, the European Accreditation Committee for Continuing Medical Educations (EACCME) and the European Board for Accreditation in Cardiology (EBAC) should take appropriate action regarding the persons or organisations involved.

Finances at hospital/university

Heads of departments, leaders of research groups, and also individual investigators often carry responsibility for funds for research projects, education, or patient care. These funds must be used for the designated purposes and be accounted for. Financial misconduct, for example, use of research funds for private travel or other inappropriate purposes, may be detected during the accounting process and will often be followed by measures against the perpetrator, including discharge from his/her responsibilities or even expulsion from the university.

During the investigation of alleged misconduct by local authorities, ESC may ask the persons involved to temporarily suspend their ESC responsibilities. If the misconduct is confirmed, the ESC should take appropriate action.

Finances related to the European Society of Cardiology

Similar to the above, officers of the ESC or the staff might make use of ESC funds inappropriately. This should be dealt with in a similar fashion as inappropriate use of other funds. The ESC may request the return of such money.

During the investigation of alleged misconduct, ESC may ask the persons involved to temporarily suspend their ESC responsibilities. If the misconduct is confirmed, the ESC should take appropriate action.

The Secretary of the Board and the CEO shall keep a registry of such occurrences.

Governance and use of European Society of Cardiology position for private purposes

Members of the Board and other officers of the ESC have been elected or appointed to foster the interest of the ESC and related organizations, including the Associations, Working Groups, and Councils. They may hold influential positions in or on behalf of the ESC. It is understood that they perform their duties in agreement with the mission of the ESC, and with the instructions from the Board, the General Assembly, or other relevant bodies in the ESC. These officers of the ESC should not misuse their influence to promote any private interests nor to favour friends or relations. An independent body under direct supervision of the CEO and the Board should take decisions with potential commercial interests. If, for example, certain tasks must be outsourced, these should not be delegated to an organization in which the officer has financial interests.

Officers of the ESC should be transparent about their relations with other organizations and industry. This holds also for the period

before their election or appointment. It is recognized that under the current system of election of Board Members and in particular the President-Elect, candidates may organize extensive campaigns by mail and or visits to ESC-related meetings or constituent bodies. The candidates should disclose such visits and how they were financed during the preceding 2 years.

The ESC is constituted by 56 National Societies in Europe and the Mediterranean area. This is the strength of the Society. However, it should also be appreciated that these countries have different cultural backgrounds including different political, and governmental styles and habits. Officers of the ESC from different countries will be influenced by their background and may act accordingly, also in ESC matters. The Board of the ESC and the relevant committees should be sensitive to differences in style and culture and discuss these in a transparent manner, when appropriate, in order to ascertain that ESC matters are handled according to a common high ethical standard as agreed upon within this organization.

The ESC Audit Committee or the future Ethics and Oversight Committee should be assigned to oversee the governance in ESC. If inappropriate behaviour during a campaign or misuse of an ESC position is detected, the ESC will take appropriate actions.

Industry relations

By its nature, as a medical professional organization, with members involved in patient care, research, and education, the ESC has various contacts with the medical and healthcare industrial companies and their employees. The ESC Board has described these relations, and the relevant rules for conduct, in particular concerning education, ESC congresses and development of clinical practice guidelines, research programmes, and journals in detail.¹ Officers of the ESC should comply with these recommendations and declare any relations with industry including possible conflicts of interest. This holds, in particular, for the ESC President-Elect, President, Past-President, the Presidents of the Associations, the Editors of the journals and the Chairpersons of the Working Groups, Councils and the congress-, education-, guidelines-, and observational research programme committees.

Furthermore, members of the ESC Board, other officers, and staff should ascertain that one specific company is not favoured, nor perceived favoured, or otherwise excessively promoted in publications, presentations, and congress-related activities. The ESC should only accept unrestricted grants from the industry.

More rigorous rules were proposed by Rothman *et al.*,⁷ banning all financial relations between professional medical associations and industry, apart from payments for space in a congress exhibition or journal advertisements. Overall, we believe that these proposals are too strict. Nevertheless, the Board of the ESC might consider whether some of these can be applied in the current European setting.

The ESC Audit Committee or the future Ethics and Oversight Committee should be assigned to oversee the ESC–industry relations and to take appropriate action.

Funding of research or education programmes

Research and education programmes at the institutions of members of the ESC may be supported by the respective Governments, by

grants from Heart Foundations or other private funds and by the medical industry. Similar support may be provided for travel related to research or education. Such support should be detailed in scientific publications and in the announcements and programmes of meetings. Officers of the ESC should openly disclose any support received during their period of office and the two preceding years.

The ESC-Audit Committee or the future Ethics and Oversight Committee should be assigned to oversee these disclosures and to take appropriate action.

Appropriate actions

Cases of possible misconduct should be investigated. Most often, such investigations should be carried out by local authorities, particularly when it considers patient care (Section 1), research (Sections 2 and 3), and financial issues (Section 5).

The ESC may inform local authorities, the Head of a department, the Director of a hospital, or the Dean of a University, of suspected misconduct by one of their employees, and request an investigation. Some allegations may be investigated by, or on behalf of the ESC, particularly when related to education (section 4) and ESC related activities (sections 6, 7, 8, 9).

During investigation of suspected misconduct, an officer of the ESC may be asked to step down from relevant ESC committees or other positions. Once misconduct has been confirmed, the ESC may permanently remove the person(s) involved from ESC positions, including ESC membership or fellowship, exclude the person(s) from participation as lecturer in educational programmes, or take other actions when deemed appropriate.

From this review of ethics related to the ESC, it is apparent that structures are in place to oversee compliance with ethical and governance rules of conduct by ESC members, officers, and related physicians and scientists. Local and national authorities oversee the conduct of patient care and research as well as management in hospitals and laboratories. The Editors and the *European Society of Cardiology Journals Ethics Committee* assess appropriateness of publications and submitted manuscripts. The ESC Education Committee, EACCME, and EBAC could ensure that education programmes are unbiased. Finally, the Board and the Audit Committee oversee financial management of ESC and its organizations, governance, the election process, and the relations of ESC members with medical industry.

We believe that the creation of an *Ethics and Oversight Committee* is essential to an organization such as the ESC to strengthen the adherence to ethical standards. Indeed, the Board may decide to delegate (part of) its role related to ethics to this committee. The committee should further define the issues indicated in this overview and develop in more detail the processes required to deal with possible misconduct. It should act independently and have the appropriate support to develop its activities. The brief of such a committee should be defined clearly, in particular relative to the brief of the Audit Committee and the Board of the ESC.

Authors' contributions

M.L.S. conceived and designed the research. M.L.S., L.R., and G.B. drafted the manuscript. J.-P.B., J.B., G.B., P.H., K.F., R.F., M.K., M.T., and P.V. made critical revision of the manuscript for key intellectual content.

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