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COMMENTARY

Information transfer in medicine: modus vivendi out of paradise*

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Abstract

Medical communication constitutes the backbone of acquisition and maintenance of professional competence for physicians. The fact that during recent decades, the vast majority of medical innovations has either been developed by commercial companies or at least been marketed on a commercial basis represents a huge challenge to the freedom of medical communication from commercial bias. This article summarises the current situation regarding bias in medical information transfer and focuses on international CME/CPD activities from the point of view of a European accreditor, the European Board for Accreditation in Cardiology (EBAC).

Keywords: communication rules, evidence-based medicine, independence; transparency, information transfer in medicine

Introduction

Information transfer in medicine, which in this article we restrict to information transfer to physicians, is essential for the maintenance of high-quality patient care. Medical communication has come to a crossroads with an ill-defined "mood of suspicion" spreading throughout the medical community, such that priority is given to the funding source, instead of considering how the evidence in the data will impact on decision-making of the individual physician.[1] This hinders implementation of evidence-based medicine as the basis for discussion and decisions in medical diagnosis and therapy. Thus, keeping medical communication free from undue influences of third parties seems to be a challenge not yet fully met.[2–4] This article outlines the current situation from the perspective of a European accreditation body, the European Board for Accreditation in Cardiology (EBAC), one of the specialty accreditation boards of the Union of European Medical Specialists (UEMS).

Background

At national level, medical professional practice is regulated by law, but similar legislation is lacking at European level. Thus, at the European level, we have to rely on the declarations of commitment by the profession as expressed in the Declarations of the World Medical Association (WMA), which represents all national medical associations.

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History

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The following citations describe the framework for the medical profession:

In the introduction to the WMA Declaration of Helsinki, two previous WMA Declarations are cited as follows:

1. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration" and the International Code of Medical Ethics declares that, "A physician shall act in the patients' best interest when providing medical care."[5]
2. The WMA Declaration of Seoul on Professional Autonomy and Clinical Independence says:

   The central element of professional autonomy and clinical independence is the assurance that individual physicians have the freedom to exercise their professional judgment in the care and treatment of patients without undue influence by outside parties or individuals.[6]

   Last, but not least, the profession makes a commitment in the Declaration of Madrid that:

   Any system of professionally led regulation must ensure

   a) The quality of the care provided to patients,
   b) The competence of the physician providing that care and
   c) The professional conduct of physician.

   To ensure the patient quality continuing care, physicians must participate actively in the process of Continuing Professional Development in order to update and maintain their clinical knowledge, skills and competence.[7]

It is the strength of the contemporary cardiovascular medicine that concepts and strategies in diagnosis and therapy have been truly internationalised in recent decades. This has been achieved by the activities of international organisations like the European Society of Cardiology (ESC) and has made a substantial contribution to the harmonisation of quality of healthcare, not only in European countries but also abroad. In order to achieve such internationally harmonised concepts in diagnosis and therapy, exchange of ideas and discussion on an international level are needed. This applies not only to the groups of principal investigators of international randomised clinical trials (RCT), but also includes all those delivering healthcare on the regional or local level, with the intention of facilitating and shortening the time needed for dissemination and implementation. This is because health care systems vary from country to country, and recommendations may not be comprehensive.

In this context, international CME/CPD activities form an integral part of our contemporary concept for the delivery of patient care in cardiovascular medicine at a uniformly high level throughout Europe.

Aspects of information transfer

Nowadays, most of the medical community has adopted the philosophy of evidence-based medicine[8] as the basis for clinical decision-making and the classification and grading of evidence have become integral parts of our thinking and communication.

Highest ranking evidence is based on RCTs. There are estimates that 70–80% of the recent RCTs have been funded by industry.[9,10] This is because there is political consensus in industrialised countries that the development of innovations in medicine can be organised on the basis of commercial business. It must be in the public interest to make the results of this research publicly available. This means, in the context of CME/CPD, that communications within the medical profession will have similarities to communications from the manufacturing companies, since both refer to the same data. This makes it even more important that the medical community not only defines, but also follows strict rules for the conduct of high-quality clinical trials[11] and their presentation.[2,3]

On the other hand, evidence derived from RCTs, although contributing to many of our contemporary therapeutic strategies, does not provide all the answers to questions in clinical decision-making. Significant co-determinants like age, sex, and comorbidities have usually not been studied in specific RCTs, but are dealt with on the level of subgroup analysis. Furthermore, there are systematic deficiencies in research such as the study of long-term effects, safety, adherence and considerations about the nature of the health care services.[12] This is demonstrated by an analysis of the American Heart Association/American College of Cardiology clinical practice guidelines:[13] strong recommendations (class I) based on more or less firm evidence (level A: multiple RCTs or meta-analysis, or level B: at least one RCT) form only one-third of all "positive" recommendations (classes I and II). In other words, clinical decision making must still rely largely on expert opinion or personal experience and preferences.

Furthermore, the definition of who can be considered as an expert has become somewhat vague over the years. Depending on how the health care system is organised on the national level, we are increasingly facing more or less fragmentation of clinical experience; for example, in Germany, many of the university departments are no longer allowed to treat outpatients with common diseases like arterial hypertension or diabetes, and now lack experience in the long-term management of such patients. The increase in super-specialisation is another reason for the decline in broad clinical experience. Thus, the limitations of relevant evidence in clinical problem-solving along with the decline in clinical experience at the level of the individual physician must have an impact on the design and conduct of CME/CPD activities. These will have to change from "educational" activities, with an expert "teaching" the audience into opportunities for exchange of views and open discussion (including aspects of off-label use as well as therapeutic freedom), especially when it comes to the discussion of the aspects of cost/effectiveness, health economics or medico-legal issues. This, in turn, makes it necessary that not only

speakers and moderators, but also the other participants must declare potential conflicts of interest.

Commercial business has to maximise profit.[14] On the other hand, medical decisions are always based on a determination of the benefit/risk ratio. But transparency about risk, not only in scientific papers but also in all types of CME/CPD activities, may threaten maximisation of profit, or in other words, our professional principle of "primum non nocere" may be at odds with strategies to maximise profit. We are not aware of any means by which this conflict of interest may easily be resolved. Therefore, every piece of information has to be examined as to whether it favours the maximisation of profit or whether it supports down-to-earth analysis of the benefit/risk ratio. The situation is further complicated by the fact that medicine is not practised on an altruistic basis throughout Europe. In other words, there is no single person or institution, who or which can claim to be neutral in the strict sense of the word, that is, to have no personal or institutional interests whatsoever, which may be described as "bias, which may be scientific, political, economic or financial, religious, gender-related, ethnic, racial, cultural or geographical".[15]

It is our impression that economic and/or financial bias in particular, resulting from financial constraints in the practice of medicine, challenges the clinical acceptance of evidence in decision-making. This may well be, at least to some extent, the reason why physicians assess the quality of evidence for decision-making in large part in the light of the funding source and not solely on the robustness of methodology used to produce the evidence.[1,16] Since there is political consensus in most of the industrialised countries that the organisation of healthcare may be, at least partly, on a commercial basis, and also that funding of research is dependent on competition, including the acquisition of industry funds,[4] such factors constitute a systematic bias for all parties involved in the generation, dissemination and implementation of evidence and make demands for impartial judgments, a difficult goal to achieve. From our point of view, the only way to create a reliable basis for clinical decision-making, and at the same time maintain credibility with patients, will be to define and follow strict rules, not only for the generation and terminology of evidence in CME/CPD activities,[2–4] but also for the demonstration of absolute transparency regarding conflicts of interest.

Terminology remains an issue, and we still lack clear-cut understanding of how terminology quantitatively translates into clinical decision-making. Thus, the clinical meaning of differences between the classes of recommendation remains to be determined (class I = indicated, class IIa = should be, and class IIb = may be considered). Given the high number of class I/C recommendations in current clinical practice guidelines (where C indicates the level of expert opinions or case studies and which still are considered as the "historical gold standard" by many members of our profession), it is important to keep this class of recommendations free of subjectivism.[17] In general, all these difficulties are more pertinent to oral communication compared to CME/CPD in print or electronic media. Thus, imprecise terminology may result in overuse of diagnostic and/or therapeutic methods.

International CME/CPD activities result in another problem in relation to information transfer and accreditation: since participation in an international event generates high costs for travel, accommodation and congress fees for individual participants, this may be one of the main reasons that at the European level (in 2011) 71% of EBAC-accredited events were supported by industry, while at the national or regional level, this percentage varied between 30 and 40% over the last ten years (in more than 20,000 accredited events per year, Chamber of Physicians, Northrhine, Germany, unpublished data). This percentage increases to 84%, if only events with fewer than 50 participants are considered (EBAC, unpublished data). Since "closed shop" events offer the ideal environment for biased presentations, selection of those supported by industry for participation in an international event is an issue both for information transfer and for accreditation. Besides the fact that access to up-to-date information, from our point of view, constitutes something like a "human right" for the medical profession, EBAC, along with other accreditors, has clearly stated in its accreditation rules that CME/CPD activities must be open to the entire medical community.[18]

Conclusion

The medical profession is committed to act in patients' best interests by delivering healthcare on the basis of impartial judgments without undue influence of third parties or persons, and to take measures to maintain and improve professional competence. CME/CPD activities are an integral part of such strategies, and international CME/CPD activities have become increasingly important in establishing patient care at a uniformly high level of quality throughout Europe. However, it should also be recognised that CME/CPD is the last part of a chain starting with medical school followed by postgraduate training and which functions to implement and maintain knowledge, skills and general principles of professional conduct. Thus, CME/CPD cannot be expected to compensate for problems arising from the political approach to the funding of clinical research or inadequate knowledge of the principles and methodology of evidence-based medicine. That said, in order to meet the objectives outlined above, the medical profession needs to define strict rules not only for the generation of evidence, but also for its communication, based on the principles of a well-defined terminology, impartiality, professional honesty as well as transparency. Accreditation of CME/CPD activities has to contain measures to facilitate and ensure the implementation of such standards.

Declaration of Interest

R.G. has disclosed that he has no relevant financial relationships.
L.M. has disclosed that he has no relevant financial relationships.
D.S. has disclosed that he has no relevant financial relationships.
R.S. has disclosed that he has no relevant financial relationships.
H.W. has disclosed that he has no relevant financial relationships.

Peer reviewer

The Peer Reviewer has disclosed that he has no relevant financial relationships.

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