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Awareness and management of conflicts of interest

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Abstract: Aim: To discuss conflicts of interest and their impact on health care practice, policy and science.
Methods: Selective literature review and own empirical studies.
Results and conclusions: There is growing pressure on medical practitioners, researchers and policy makers to face up to the subject of conflicts of interest which is a very topical and controversial one in different areas of the health care system. Conflicts of interest are often unavoidable but there is nothing dishonourable about this and it does not in itself either detract from the value of the research and clinical work being done or impugn the integrity of the people doing it. However, the issue becomes critical when possible conflicts of interest are ignored. Inadequate awareness and transparency may cause substantial damage, both to the quality of research and clinical practice, and also to the reputations of individuals and of the medical profession and the scientific community as a whole. Therefore, to deal constructively with conflicts of interest we particularly need to enhance the awareness and transparency.

Response to Reviewers: Thank you very much for the reviews. The manuscript was thoroughly revised to take account of your comments. (New and additional text is marked in red.)

Reviewer 1:
The focus on non-financial conflicts of interest was strengthened to make the original aspects of the paper more explicit (please also see the response to reviewer 2).

Reviewer 2:
The focus on non-financial conflicts of interest was strengthened and broadened, and a personal example is given to illustrate the problem (page 6/7).

Thank you very much for the reference. Now the paper refers to Martinson et al. (pages 6 and 8).

Examples for different kinds of publication bias are given on page 3/4 together with additional references (Dickersin 1990, Dwan et al. 2008).

The spelling mistakes were corrected.

*Title Page

Awareness and management of conflicts of interest

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Abstract

Aim: To discuss conflicts of interest and their impact on health care practice, policy and science.

Methods: Selective literature review and own empirical studies.

Results and conclusions: There is growing pressure on medical practitioners, researchers and policy makers to face up to the subject of conflicts of interest which is a very topical and controversial one in different areas of the health care system. Conflicts of interest are often unavoidable but there is nothing dishonourable about this and it does not in itself either detract from the value of the research and clinical work being done or impugn the integrity of the people doing it. However, the issue becomes critical when possible conflicts of interest are ignored. Inadequate awareness and transparency may cause substantial damage, both to the quality of research and clinical practice, and also to the reputations of individuals and of the medical profession and the scientific community as a whole. Therefore, to deal constructively with conflicts of interest we particularly need to enhance the awareness and transparency.

Key words: conflicts of interest, health services research, public health, transparency

Text

The subject of conflicts of interest is a very topical and controversial one in a number of different areas of the health care system. Examples of such areas are in-service training events for doctors that are sponsored by the pharmaceutical industry and visits to hospitals and doctors' surgeries by industry representatives (Moynihan 2008; Carney et al. 2001; Wazana 2000). Links between medical research and related sectors of industry are also increasingly giving rise to critical debate both among professionals and in the public domain (Agnell 2000; DeAngelis 2006). There is growing pressure on medical practitioners, researchers and policy makers to face up to these issues.

In the theoretical discussion within the sector, a distinction is made between primary and secondary interests. Primary interests relate to the fundamental concerns and objectives involved in the exercise of a profession (Thompson 1993). These vary, depending on what area of professional activity is involved in each case. For physicians engaged in clinical practice, for example, the primary interest as defined from this point of view is to provide the individual patient with the best possible treatment; for researchers it is to produce valid new results; while for politicians concerned with the organisation of health care it is to create a system providing the best possible framework of conditions. Secondary interests, on the other hand, relate to circumstances which have material or social consequences that might influence people's judgments. This may express itself in many different ways, for example in the form of taking only one side of an argument into consideration, or of avoiding asking awkward questions, or else of not pursuing the search for scientific insights to sufficient depths (Klemperer 2008).

Such secondary interests do not automatically imply negative consequences. The quest for academic success (as measured by reputation, the number of publications and the ability to tap into new sources of funding) is a secondary interest among researchers which may initially be assumed to exert a positive influence on the primary scientific interest of gaining valid new findings. Practising physicians for their part draw a large proportion of their social status from the doctor/patient relationship; the enhancement of this status represents a secondary interest that is capable of influencing positively the basic concern of the medical practitioner to provide his patients with the best possible care. These examples show that primary and secondary interests are closely interlinked, and in the ideal case represent important drivers of progress, development and the quality of care.

However, secondary interests may also have substantial negative consequences, and one essential aspect of the matter is the fact that we are often not aware of, or prefer to close our eyes to, this problem (DeAngelis 2006; Klemperer 2008; Schneider 2008).

Lobbying activities

As mentioned above, among the problematic areas is the influence of the pharmaceutical industry on research. For example, studies sponsored by the industry produce results favourable towards a particular product and a particular diagnostic or therapeutic procedure more frequently than do studies that are not sponsored by the industry (Bekelmann et al. 2003; Bell et al. 2006; Lexchin et al. 2003). This may be due, among other factors, to the choice of study design, the questions asked of the data collected or publication bias. Publication bias occurs when the publication of results depends on their nature and direction (Dickersin 1990). For example, positive

or statistically significant results are more likely to be published than negative or inconclusive findings (Dwan et al. 2008).

Where researchers are heavily dependent on acquiring outside funding, this fact fosters a tendency to reach conclusions or publish results that will be popular with whoever is providing the funding. If the researcher receiving the funds knows what results will best suit the sponsor making them available, his desire and need for further finance and for follow-up projects may create dependencies which – consciously or unconsciously – influence the scientific work (Klemperer 2008).

Another critical point is the closeness to the industry of those who write clinical guidelines. Choudry et al. (2002) showed that four out of five authors of such guidelines had links to the pharmaceutical industry; and of these four, two were even employees or consultants of companies whose preparations they recommended in their guidelines.

Although the pharmaceutical industry is at the focus of the debate on conflicts of interest, these may also be triggered by other players such as the medical technology industry, professional associations, health insurance funds or government authorities. In view of the all-pervasiveness of lobbying activities in the health care sector, there are plenty of temptations at all levels – whether it is the clinical, the scientific or the political/organisational level – to succumb to influence or accept inducements.

It will never be possible to avoid conflicts of interest. Cooperation between researchers and the pharmaceutical industry, for example, is unavoidable, and indeed in many cases is even desirable and necessary – e.g. for the acquisition of

research funding or to foster the transfer of research findings into clinical practice and the development of new products.

Awareness and transparency

There appears, however, to be a need for a cultural shift with regard to how to deal with this issue, a shift in the direction of an enhanced awareness of possible conflicts of interest and of transparency in respect of them.

Awareness means above all that both clinicians and researchers should give real consideration to the problem of possible conflicts of interests and should not, as can still frequently be observed, dismiss it with a superficial, knee-jerk reaction. It is an element of good academic practice to consider one's own position self-critically and to monitor the extent to which one is capable of forming independent judgments. It is up to researchers and practitioners to be aware of their responsibilities and to live out this awareness on the basis of the understanding they have of their own professional positions. It would be a dreadful thing if they were to be forced into giving the matter more serious consideration only by increased pressure from outside (from government, the media or the courts).

Transparency can be enhanced by the disclosure of any potential conflicts of interest. In the academic world, the arrangement whereby publications are accompanied by a conflicts of interest statement is an important instrument pointing in this direction. The International Committee of Medical Journal Editors (ICMJE) has issued internationally recognised recommendations with regard to the criteria to be applied; these provide for information to be given not only on possible financial conflicts of interest, but on non-financial ones such as personal relationships, intellectual passion or scientific competition as well.

Even though an increasing number of scientific journals nowadays expect their authors to provide such details, the actual implementation is often still less than ideal. Martinson et al. (2005) found out that not properly disclosing involvement in firms whose products are based on one`s own relationship belongs to the top ten misbehaviours of scientists. Schneider et al. (2007) investigated the practice of disclosing conflicts of interest in German publications concerning health services research: a mere 9% of the articles investigated (11 out of 124 publications) provided the reader with information on possible conflicts. This was due to the fact that only 58% (18 out of 31) of the journals concerned expected their authors to disclose conflicts of interest when submitting manuscripts; while even those magazines that expected such details from their authors often did not publish them, and so did not make them transparent to the reader. Furthermore, it was noticeable that where information on conflicts of interest was given, this related first and foremost to financial relationships, whereas non-financial conflicts of interest were largely ignored.

This is doubtless due among other things to the fact that, compared with financial ones, intellectual and social conflicts of interest are more difficult to define, and also to the fact that they may impinge particularly closely to the personality and personal sphere of the scientist concerned. This may be illustrated by the following example: Recently, I reviewed a manuscript on new models of care for a specific group of patients. The authors had carried out a survey with physicians who were potential collaborators with the specific services to examine barriers, incentives, and the physicians` professional self-image regarding the new models of care. Some of the authors have participated in the establishment of the services which were subject of

the study and act as well known pacemakers in the field. In the manuscript they stated that there were no conflicts of interest.

However, I wondered if possibly there were conflicts of interest due to intellectual or social reasons. In their response to my review the authors negated this and explained: “We surely have conducted our research with a high level of personal commitment and intellectual passion – for us a method to ensure the quality, profundity and complexity required for a scientific approach of the (medical) world.”

It becomes clear how difficult it is in particular cases to decide if there were non-financial circumstances that should be mentioned – or not – in a conflict of interest statement. On the one hand, obviously, non-financial conflicts can occur for a reason such as intellectual passion (ICMJE 2008); it might influence the researchers` judgments in planning and conducting a study and interpreting the results, e.g. in the form of avoiding asking awkward questions or taking only one side of an argument into consideration. On the other hand, however, a high level of intellectual passion is the basic motive for research; it is inherent to the scientific system. Is there any benefit if intellectual passion was declared in a conflict of interest statement? How to define standards?

Overall, compared to financial relationships, demands for the disclosure of intellectual and social conflicts of interest are more likely to run into obstacles - although this is no grounds for not making the attempt to achieve a greater degree of awareness and openness. Self-critical and balancing consideration of these factors ought to be inherent in the academic process. This is particularly important as the modern scientist faces intensive pressure resulting from factors such as competition,

regulatory, social and managerial demands which result in various possibilities for the compromise of scientific integrity (Martinson et al. 2005).

Dealing constructively with conflicts of interest

In dealing constructively with the issue of conflicts of interest, it might be helpful to take the following to heart: conflicts of interest will often be unavoidable, both in the academic sphere and in clinical practice, but there is nothing dishonourable about this and it does not in itself either detract from the value of the work being done or impugn the integrity of the people doing it. But the issue becomes critical when possible conflicts of interest are ignored. Inadequate awareness and transparency may cause substantial damage, both to the quality of research and clinical practice, and also to the reputations of individuals and of the medical profession and the scientific community as a whole.

Conflicts of interest

The author declares that he has no conflict of interest.

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