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The dangers of neglecting non-financial conflicts of interest in health and medicine

Wiersma, M., Kerridge, I., Lipworth, W. (2017)

Abstract

Non-financial interests, and the conflicts of interest that may result from them, are frequently overlooked in biomedicine. This is partly due to the complex and varied nature of these interests, and the limited evidence available regarding their prevalence and impact on biomedical research and clinical practice. We suggest that there are no meaningful conceptual distinctions, and few practical differences, between financial and non-financial conflicts of interest, and accordingly, that both require careful consideration. Further, a better understanding of the complexities of non-financial conflicts of interest, and their entanglement with financial conflicts of interest, may assist in the development of a more sophisticated approach to all forms of conflicts of interest.

Introduction

The issue of "conflict of interest" (COI) in biomedicine is an enduring one, characterised by ongoing—and often heated—debates about what "counts" as an interest or conflict of interest, what (if anything) causes a COI, who (if anyone) is to blame; and how (if at all) COIs should be managed. Overwhelmingly, these debates have focused on financial interests and the COIs that may arise from them – as evident in a recent issue of JAMA dedicated to COIs in medicine. Of over 24 articles, only two articles addressed non-financial interests in depth (1, 2) – with one article dismissing non-financial COI, and reiterating the significance of bias arising from financial COI. (1, 2) While several articles acknowledged the presence, (3) and potentially problematic nature of non-financial COI, (1) (4) for the most part, the issue focused on financial COI across different medical settings – including biomedical research, medical education and guideline development. (5, 6) (7, 8) This focus on financial COI reflects the wider discourse within medicine – in which financial COIs are granted primacy, while non-financial COIs are merely acknowledged and dismissed as too complex to warrant further investigation, or alternatively defined out of existence. (2, 9)

We believe that focusing solely on *financial* interests and COIs—such as those stemming from pharmaceutical industry sponsorship of research or payments to doctors, and overlooking *non-financial* interests and COIs—such as those stemming from relationships, personal beliefs, and the desire for prestige and career progression, ignores the possibility

that harm may arise from non-financial COIs, discourages exploration of the relationship between financial and non-financial COIs, and impedes the development of appropriate management strategies for all types of COI. Three arguments are fundamental to our claim: first, there are no meaningful conceptual distinctions between financial and non-financial COIs and few practical differences. Second, accepting this does not necessitate abandoning attempts to manage financial COIs; rather, it emphasises the importance of developing management strategies for both financial and non-financial COIs. And finally, acknowledging the complexities of non-financial COI, and their entanglement with financial COI, may assist in the development of a more sophisticated approach to all COIs.

Defining interests and conflicts of interest

In general terms, an 'interest' may be defined as "a value, goal or obligation associated with a social relationship or practice". (10) Values, goals and obligations may stem from social or professional commitments (e.g. a doctor's commitment to improving their patient's well-being); self-interest – which may be financial, physical or psychological (e.g. a clinician's desire for status via appointment as a pharmaceutical company's "key opinion leader"); personal relationships (e.g. concern for the wellbeing of family or friends); or the desire to adhere to one's belief systems (e.g. a Christian opposing abortion on the basis of their religious beliefs). A *duality* of interest arises when two or more interests coexist. A duality may become a *conflict* of interest when a particular relationship or practice gives rise to two or more competing interests. (10)

Understood in this way, neither interests, dualities of interest nor conflicts of interest are necessarily financial or non-financial. This is consistent with the view put forward by Erde, (11) and Kaur and Balan, (12) who refute the notion that economic incentives are the sole cause of COIs. (11) (12) For example, Erde's conceptualisation of COI takes into account non-financial interests, including practical concerns – such as a professional's concern for their safety, emotional resources and time constraints; ideals – such as religious beliefs or professional indoctrination; as well as predilections (that is, the disposition to value something negatively or positively – such as the fear of a particular outcome, or those arising from relationships –for example, friendship or rivalry. (11) Thus, for Erde, COIs exist when a medical professional's motives, financial arrangements or social situation, compromises their ability to act in accordance with the moral requirements associated with their professional role. (11)

Distinguishing financial from non-financial conflicts of interest

Efforts to distinguish financial from non-financial COIs take three forms, focusing on their impact, their management and their very conceptualisation. Each of these, however, fails to provide a convincing reason for distinguishing categorically between financial and non-financial COIs.

The claim is sometimes made that non-financial COIs differ fundamentally from financial COIs, in that the latter have a more significant effect on biomedical research, policy making and practice. Bero, for example, expresses the view that only financial COIs produce bias in research that extends beyond an individual, (2) whereas what she refers to as non-financial "interests" only affect discrete decisions or situations. (9) But while it is true that non-financial COIs may be more difficult to detect, measure and evaluate, (13-15) it does not

follow that they are any less distorting of biomedical research, policymaking or patient care. Indeed, psychological and sociological research suggests that people are as driven to change their attitudes and behaviours by non-financial incentives as they are by financial incentives. (16-18) As noted by Fehr and Falk, non-financial motives, including the desire to reciprocate and avoid social disapproval, exert a powerful influence on human behaviour. (16)

Furthermore, while there is less systematic research into the harms associated with non-financial COIs, it is undeniable that harms may arise from non-financial COIs. For example, in the Tuskegee study, the health of African-American men (and their families) was sacrificed in order to "satisfy scientific curiosity" about the long-term health effects of untreated syphilis.(19, p. 1500) Even where harm to individuals is not as obvious as in the Tuskegee study, there are many circumstances in which non-pecuniary interests, such as faith positions, have determined health and research policies—arguably more extensively than any single industry ever could. As an example, Christian views regarding the moral status of the embryo held by policymakers, legislators and scientists impeded stem cell research in numerous countries, most notably the United States, through the prohibition of public funding of embryonic stem cell research and human somatic cell nuclear transfer. (20) The ubiquity, moral salience and impact of non-financial interests, and potential conflicts of interest, is also clearly evident in the allowances made for conscientious objection in medicine and law.(21)

An additional problem with claiming that only financial COIs have significant effects is that financial and non-financial COIs are frequently entwined. (14, 22) This fact has long been recognised by the pharmaceutical industry, which has sought to create influence through numerous strategies including financial and non-financial incentives. For example, in their strategic selection of key opinion leaders, (23) industry encourages industry-physician collaboration through financial inducements, and through the (non-financial) recognition and endorsement of a clinician's expertise. (24) As this example illustrates, *both* financial incentives, and the psychologically powerful recognition as an "expert", impact upon clinicians' motivations and behaviour. (14) The entanglement between non-financial and financial COIs is also evident in the case of career advancement, which involves not only financial gain, but also non-financial incentives – such as for example, increased status and reputational enhancement.

Another way in which people try to distinguish between financial and non-financial COIs is by claiming that the two require fundamentally different management strategies. It is argued that unlike financial COIs, non-financial COIs cannot be separated from an individual's identity or professional role, and therefore cannot be managed using the same strategies as financial COIs – including disclosure or recusal. (2) Clearly it is not possible to separate certain non-financial interests, such an individual's beliefs, values and desire for professional recognition, from the individual (in contrast to, for example, a relationship with a pharmaceutical company, which can be eliminated). However, this in no way means that non-financial COIs cannot potentially be identified, assessed and managed utilising similar strategies used to manage financial COIs. For example, there is no reason that members of a panel determining the legality of prenatal sex selection couldn't be asked to disclose their views about religion and gender – not in order to change their core values or personal identity, or necessarily exclude them from discourse (i.e. demand their recusal), but rather

to ensure that their influences over decision-making are transparent and appropriately managed.

Similarly, a member of a committee deciding whether to approve the subsidy of a new medicine may reasonably be expected to declare whether they have a health condition that may benefit from the medicine under consideration. If so, they would clearly have a non-financial interest that may influence their recommendation, but there are many options for managing this, including not only recusal, but also discussion and/or limitation of voting powers. This would not necessarily be easy—the significance of non-financial COIs cannot be measured, and can only be determined through discussion. But this applies equally to financial COIs—for example, there is little validity in measuring the significance of financial COI in terms of dollar amounts. (25) We know that even small gifts and other exchanges of value may create reciprocal relationships and have a large impact on attitudes and decisions. (26, 27)

Just as both financial and non-financial COIs can be managed by disclosure and, where necessary recusal, both types of COI can also be managed through structural reform of biomedicine. In the case of the Tuskegee study, for example, the non-financial interests of the researchers could have been prevented from causing harm had there been greater consumer engagement in the research process, including accommodation of voices from the African-American community; ongoing independent external ethical and scientific review; and the institution of systemic requirements to ensure transparency, integrity and valid consent. Similarly, just as the argument is frequently made that medicine should disengage from industry in order to avoid financial COIs, similar arguments could be made about the need for medicine to disengage from powerful political and religious institutions.

Finally, some have argued that there are fundamental conceptual differences between financial and non-financial interests, and that the term "conflict of interest" should only be used in reference to *financial* COI, and that a more appropriate terminology is non-financial "incentives" or "interests". (9, 28) The definition and categorisation of non-financial COIs as merely "interests" or "incentives", (9, 28) is however, logically incoherent, as there is no reason why a non-financial interest cannot compete or conflict with another. It is also argued that financial and non-financial COIs are fundamentally different because they require different management strategies. But even if it were true that financial and non-financial COIs require completely distinct forms of management (which we refute), it does not follow that they are conceptually distinct. (9)

Implications for the management of conflict of interest

It is sometimes argued that giving attention to non-financial COIs will draw attention from financial interests and/or lead to a loss of motivation to manage COIs in general. (2, 9) This concern appears to be based on anxiety rather than evidence. Indeed, the converse viewpoint appears equally plausible: the exploration of both non-financial and financial COIs may increase, rather than decrease motivation for change across the board. In this regard, it is noteworthy that recent efforts to assess whether non-financial COIs have adversely impacted upon biomedical research and clinical outcomes appear to stem from a desire to *strengthen* the management of COI. (22) Viswanathan et al. investigated strategies for identifying and managing non-financial interests in systematic reviews, concluding that

"non-financial conflicts of interest, when ignored, can call into question the impartiality of a review". (22, p1236) Similarly, a qualitative study by Abdoul et al. (29) explored the impact of non-financial COIs in the evaluation of academic grants, and highlighted the need for specific measures to prevent the harmful influence of non-financial COIs on the equitable allocation of health resources. (29) Of course, steps would need to be taken to ensure that any requirements for declaration of non-financial COI don't lead to an influx in which notifications of significant financial COI are lost. But this simply means that care and discretion should be exercised regarding when and how non-financial COIs are declared.

A further concern expressed about giving attention to non-financial COIs is that people from particular cultural groups will be treated unfairly (e.g. excluded without justification from decision making panels), thus limiting the diversity of academic discourse. (2, 9) This claim, however, does not appear to be empirically founded and there is no moral or logical reason to suggest that, just because those with non-financial interests are sometimes treated unfairly, these kinds of COIs should be any less subject to systematic scrutiny. Rather, it means that equal treatment should be afforded to those with financial and non-financial COIs. Indeed, paying more attention to the day-to-day management of non-financial COIs could potentially make it easier for people to declare their interests, discuss possible associated biases and conflicts, and voluntarily recuse themselves or eliminate relationships that they recognise as problematic.

A related concern is that some non-financial COIs are highly personal, and that individuals could face discrimination if required to declare them. (2, 9) But there is no reason why these declarations couldn't be handled with discretion. First, disclosure of personal information could only be required where evidence suggests that it may lead to non-financial COI (e.g. a member of drug regulatory agency who has a medical condition that may benefit from the subsidization of a drug under consideration). This highlights the importance of developing practical strategies to differentiate between circumstances in which "sensitive" COIs need to be declared (e.g. membership of a policymaking panel), and situations where such declarations wouldn't be necessary (e.g. authorship of an article that is clearly an opinion piece). Second, when required, the disclosure of sensitive information could be handled so as to avoid unnecessarily intruding into an individual's privacy, or placing them at risk of discrimination. Mechanisms are commonly put in place to balance the tension between disclosure and privacy, such as controls over documentation and public access to declarations of certain COIs, and these could be applied more broadly.

Learning from non-financial conflicts of interest

Attention to non-financial COIs is not only consistent with simultaneous concern for financial COIs, but also has the potential to teach us important lessons about the complexities and management of financial COIs. As noted in JAMA – "financial interests are used as imperfect proxies for bias", (1, p1727) and it is difficult to determine what sum of money represents an "unacceptable likelihood of bias". (25, p1720) Thus, while it is difficult to determine which *non-financial* interests should or shouldn't be reported, it is equally difficult to determine which *financial* interests should or shouldn't be reported. (27)

Furthermore, the interpretation of declarations of *both* financial and non-financial COI can be enormously challenging. For example, just as single-line declarations of non-financial

COIs can be difficult to interpret (what does it mean to declare that one is a “feminist”), the same is true of single-line declarations of financial COIs (does the phrase “Doctor X receives funding from Company Y” mean that she has received thousands of dollars in personal consulting fees, or that money is being paid to a departmental fund?)

Similarly, the ubiquity and complexity of non-financial COIs can remind us that even financial relationships vary in their acceptability. There is, for example, a moral difference between a doctor receiving a personal financial reward for altering their prescribing practices to favour a particular product, and a doctor accepting industry money for research where this is done without expectation of benefit, where appropriate firewalls are in place, and where the funding contributes to a centralised independent research fund. This in no way creates an argument in favour of industry funding of research; rather it reminds us that there is moral and practical variation when it comes to *any* kind of COI.

Conclusion

Focusing solely on financial COI in biomedicine is insufficient and denies the complexity of medical practice and research, human psychology and social relationship. In addition to being important in its own right, the investigation of non-financial interests and associated COI, may enrich our understanding of COIs in general, and aid in the development of management strategies for all types of COI. Denying, dismissing or defining non-financial COI out of existence is illogical, empirically unfounded, and may have profound consequences for the integrity of research, policymaking and patient care.

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