

POSITION PAPER

Proposal for a graded approach to disclosure of interests in accredited CME/CPD

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Abstract

Disclosing conflicts of interest (COIs) is an important step in the management of COIs and is considered to be crucial to the trustworthiness of presenters. There are significant variations in disclosure procedures regarding the following:

a. How COI is assessed in declaration forms (e.g. type of question, respondent awareness)

b. Type of relationships

c. Detailing of information to program committee members

These variations in procedures have in effect led to

a. Underreporting of COI

b. Reducing the informational value of declared COI to participants

Thus, it has been the aim of the authors to propose a basic formula for a minimum standard declaration of financial COI, with the potential to be applicable to all types of accredited continuing medical education (CME) as well as to all individuals (e.g. speakers, authors) involved in planning and conduct of CME activities. This approach should also serve as basis for more elaborate disclosures as well as strategies for management of conflict of interests adapted to the risk of bias.

Furthermore, we also propose a basic set of items to be declared as nonfinancial interests.

Keywords: conflict of interest, disclosure, CME, CPD, graded approach, bias, unifying disclosure form, score

To access the supplementary material for this article, please see [Supplementary files](#) under 'Article Tools'

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Introduction/objectives

Members of the medical profession frequently pursue multiple personal and professional interests, which form the basis for potential conflicts of interests (COIs), defined by Thompson¹ as “a set of conditions in which professional judgment concerning a primary interest (such as patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest such as financial gain.”^{1,2} There are numerous sources and factors that may contribute to COIs, including economic, financial, professional, scientific, political, and religious. Evidence shows that bias (preconscious and unconscious) is ubiquitous in human reasoning, social interactions, and emotion. Bias influences our social and cognitive motivation, reasoning, and judgment on how we evaluate the actions of ourselves and others^{3–9} and how we make decisions based on these determinations.^{10,11} We can reasonably

conclude that COI factors and the risk of bias are almost inevitable in the life of medical professionals.²

Bias is of particular importance to continuing medical education (CME) and continuing professional development (CPD), which aim to inform and enhance medical decision-making, competence and performance that affect healthcare outcomes in the best interests of patients. Thus, COIs in CME/CPD may directly impact patient care by introducing bias that leads to actions that are no longer impartial, are not aligned with the best patient care, or are based on unreliable scientific evidence.^{12,13} One of the strategies that stakeholders in the CME/CPD accreditation systems implement in order to mitigate COIs is the promotion of transparency in management of COIs.²

Current practices for declaring interests vary widely between CME/CPD systems (accreditors, providers, etc.). Although forms used by different institutions to gather declarations of interests demonstrate many similarities regarding the number and type of items requested, there are still substantial differences in the level of detail in relation to disclosure of interests. For example, some COI processes request disclosure of precise amounts of financial support received by a faculty/educational designer. Some require disclosure of nonfinancial interests, and others require disclosure of past and/or future interests.¹⁴

Transparency is considered to be a shared professional responsibility between organizations, program committee members (or editorial team), individual faculty members (or authors), and participants. Ideally all interests should be disclosed to participants to enable them to identify potential triggers for or sources of bias.² Transparency and COI disclosures in print media have been standardized based on the recommendations defined by the International Committee of Medical Journal Editors (ICMJE).¹⁵ Many journals use the ICMJE declaration form and publish declarations either online or in the printed version. However, in live CME events (group learning activities such as conferences), the most common strategy is the “second slide concept,” where faculty or educational designers disclose COIs with or without providing an explanation to participants before proceeding with the presentation.¹⁶ This strategy has been facing serious problems regarding what is shared and how COIs are displayed.

There is general agreement that the list of interests to be considered for disclosure is increasing. The number of interests pursued by many physicians and the difficulty of anticipating whether bias will be introduced have led CME/CPD providers to request elaborate descriptions of interests to be disclosed. Such a procedure poses no difficulties when time schedules are not tight (e.g. congress program committee or the review process of journals or on electronic media) and the scope of what is to be disclosed is limited.

However, the situation is different for gathering and disclosure of COI for live CME/CPD activities, which constitute the vast majority of all accredited CPD activities (e.g. >95% in Germany; German Medical Association, unpublished data). During the planning phase, it is generally still considered mandatory that COI be fully disclosed

to participants.^{17–19} However, implementing this requirement lacks practicality when the intent is to disclose to participants all conflicts gathered, and it may also raise concerns regarding privacy protection.²⁰ Thus although it behooves all CME stakeholders to ensure participants are aware of and able to make informed judgments about the content presented, in practice there are large variations.²¹ Furthermore, no strategy to mitigate the risk of bias in relation to CME/CPD providers can completely exclude the possibility that COI will lead to bias *during the course* of the event. This judgment is mainly based on the fact that at least part of bias is caused by reciprocity, a largely subliminal process relating to the use of language, where only subtle changes in wording may have substantial influence on the audience.^{22–24} Thus, on-site documentation of physicians’ multiple relationships, either professional or private, may help to identify potential triggers for bias.

Because there is a lack of clear and consistent international standards for COI disclosure, the faculty/presenter and educational designer are often left to their own discretion as to what to divulge. This state has led to the situation, particularly relevant to large congresses lasting several days, where “the second slide” is often shown so briefly that it may not even be read or understood by the audience and is rarely available for review by the participants. This situation is not only unsatisfactory but has the potential to undermine or trivialize the intent of disclosure and damage the reputations of CME/CPD accreditation and of the educational designer.

Thus, it is the aim of this article to promote a dialogue on the issue of COIs and to present a series of proposals for a graded approach to enable presenters in accredited live CME/CPD events to provide participants before, during, and after the event with a meaningful COI declaration. Our goals include the following:

1. To facilitate the review of disclosure statements by program committees/editorial offices, and so on, to identify those declarations that require more in-depth review
2. To examine declarations by faculty or authors to avoid any risks of violating data protection legislation
3. To define a process for timely and sustainable disclosure of meaningful information to participants

Process

The authors of this paper participated as faculty at the Cologne Consensus Conference (CCC) 2014²⁵ organized by the European Cardiology Section Foundation. The goal of CCC was to bring together an interdisciplinary faculty from a broad range of institutions who are active in addressing issues of COI and COI management. This paper was inspired by the processes, dialogue, and discussions held at CCC 2014. The views expressed in this article represent the views of the authors and do not necessarily reflect the official policies of the supporting or participating organizations.

We pursued the following stepwise approach. We reviewed and summarized information from the presentations given during CCC 2014²⁵ and material available on the websites of the organizations and institutions mentioned below, to identify the similarities and differences between current COI declaration forms used by the following:

- Accreditation bodies (Accreditation Council for CME, ACCME²⁶; Royal College of Physicians and Surgeons of Canada²⁷; European Accreditation Council for CME²⁸)
- Medical association journals (*British Medical Journal*²⁹)
- Medical society scientific journals (ICMJE form,¹⁴ which is used by many medical scientific journals)
- Licensing authorities (for pharmaceuticals) (European Medicines Agency, EMA³⁰)

The review summarized the requirements related to the following:

- Type of interest to be disclosed: financial, nonfinancial, others, including any sub-categorization if applicable
- Type of elements requested
- Source of funding
- Inclusion of further details (e.g. amount of money, type of equipment received, etc.)
- Respect for the principle of data economy, as required by privacy protection legislation

We also considered procedural aspects including the following:

- Who is required to declare an interest
- The process for gathering interests
- Descriptions of management practices related to declaration of COI

We developed three criteria by which to evaluate our COI proposals:

1. Concise and easy to grasp
2. Appropriate to the content presented
3. Compliant with applicable privacy protection laws

Comparison of different disclosure forms showed variations in scope and the level of detail required to be declared. A COI form designed to include all items identified from the COI forms reviewed would result in about 50 items to be declared. Such a form would overwhelm participants and would not be concise and easy to grasp (Criterion 1).

Financial interests

Therefore, based on the data abstracted, we developed an approach to the gathering of content for disclosure, based on an index that categorizes risk related only to the disclosure of activities for which an honorarium (Categories I–III) or other financial gains (Category IV) have been received (Form 1).

Built on this basic version we have further designed two augmented versions:

- Version 2 requires in addition disclosure of funding above certain thresholds, received within types of activities declared (Form 2).
- Version 3 requires in addition more detailed disclosure of classes of funding received for activities as described in the basic form. (Comments as outlined in Forms 1 and 2 also apply to Form 3.)

In all three versions we will use structured questions that can be answered by yes or no.

Please declare for the last 5 years and the next 12 months*:

I. I have received (a) research grant (s)/in kind support (to you, your institution or employer)		II. I have been a speaker or participant** in accredited CME/CPD:		III. I have been a consultant/strategic advisor/member of a speakers bureau etc. :		IV. I am a holder of (a) patent/shares/stocks*** or ownership (himself/ spouse/partner/child(ren))****		
	points		points		points		points	
a) from sponsor(s) of current event	yes (2) no (0)	a) sponsored by sponsor(s) of current event	yes (4) no (0)	a) sponsor(s) of current event	yes (8) no (0)	a) of a company active in the field related to the presentation	yes (16) no (0)	
b) from any institution (not only pharmaceutical or medical device industry, but also government, foundations etc.) other than the sponsor(s)	yes (1) no (0)	b) sponsored by any institution (not only pharmaceutical or medical device industry, but also government, foundations(s) etc.)	yes (2) no (0)	b) any institution	yes (5) no (0)	b) of a company active or relevant in medicine, but not active in the field related to the presentation	yes (10) no (0)	
Subtotal								
							Total	
							Score	

To calculate the score, please add up the highest number of points per each category, i.e. a) or b), then take the score from the table "rating scale".

*: in case that arrangements have already been made at the time of declaration
 **: applies only if costs for travel/accommodation/registration have been covered by the sponsor
 ***: Shares in stock fund excluded
 ****: includes part-time employment or that a member of the household is an employee of such company

Please note: Employees of commercial interests in medicine are usually not accepted as presenters in accredited CME/CPD. If they nevertheless should be accepted, they should be assigned 16 points ("very high" on the rating scale).

Rating scale	Score
0: none=	0
1–2: low=	1
3–7: medium=	2
8–12: high=	3
>12: very high=	4

Please declare for the last 5 years and the next 12 months*:

I. I have received (a) research grant(s)/in kind support (to you, your institution or employer)		II. I have been a speaker or participant** in accredited CME/CPD:		III. I have been a consultant/strategic advisor/member of a speakers bureau etc.:		IV. I am a holder of (a) patent/shares/stocks*** or ownership (himself/ spouse/partner/child(ren))****	
	points		points		points		points
a) from sponsor(s) of current event	yes (2) no (0)	a) sponsored by sponsor(s) of current event	yes (4) no (0)	a) sponsor(s) of current event	yes (8) no (0)	a) of a company active in the field related to the presentation	yes (16) no (0)
b) from any institution (not only pharmaceutical or medical device industry, but also government, foundations etc.) other than the sponsor(s)	yes (1) no (0)	b) sponsored by any institution (not only pharmaceutical or medical device industry, but also government, foundation(s) etc.)	yes (2) no (0) yes (9)	b) any institution	yes (5) no (0) yes (9)	b) of a company active or relevant in medicine, but not active in the field related to the presentation	yes (10) no (0)
		c) I have earned >100,000 €/£ by these activities	no (0)	c) I have earned >100,000 €/£ by these activities	no (0)		
Subtotal							

To calculate the score, please add up the highest number of points per each category, i.e. a) or b) or c) (if applicable), then take the score from the table "rating scale".

Total	
Score	

Rating scale

Rating scale	Score
0: none=	0
1-2: low=	1
3-7: medium=	2
8-12: high=	3
>12: very high=	4

*: in case that arrangements have already been made at the time of declaration
 **: applies only if costs for travel/ accommodation/registration have been covered by the sponsor
 ***: shares in stock fund excluded
 ****: includes that a member of the household is an employee of such company
 Please note: Employees of commercial interests in medicine are usually not accepted as presenters in accredited CME/CPD. If they nevertheless should be accepted, they should be assigned 16 points ("very high on the rating scale").

Form 2

The above three levels were constructed based on defining four categories (I–IV) of risk that considered the degree of involvement with a financial interest and/or the potential financial benefit expected from a relationship with a financial interest.

- Level I is focused on receiving research grants from a commercial interest at the disposal of the individual declaring his/her interests, according to the definition by ACCME.²⁶ This level includes the publication of study results, since quality assurance measures (i.e. the editorial process, including declaration as well as management of COIs) are presumed to reduce the likelihood of bias.
- Level II is focused on activities as a speaker in sponsored accredited CME activities. The rationale for speakers in live CME events to be viewed at a higher level is as follows:
 - Choice of wording is significantly more spontaneous (compared to all printed material) and/or volatile and thus more prone to be affected by reciprocity.^{22,23}
 - All the review processes implemented during the preparatory process of a live event cannot anticipate interpretation of the data given during the live presentation.
 - Payment of honoraria and reimbursement of expenses might induce reciprocity, which probably has to be considered as more or less inevitable in particular in accredited activities with only one sponsor.

Form 3

Minimum declaration of interests of presenters in accredited CME/CPD events
Please declare for the last 5 years and the next 12 months:

I. I have received (a) research grant(s)/in kind support (personally, on behalf of my institution or employer) (number of points in brackets)
 - current (1 point)/for <2 years (1 point)/for > 2 years (2 points) in the last 5 years
 - < 50k (1 point)/50–100k (2 points)/100–200k (4 points)/>200k € (6 points)

II. I have been a speaker in previously accredited CME/CPD sponsored by:
 i) sponsor(s) of the current event and received honoraria of <25k (3 points)/25–50k (5 points)/50–100k (8 points)/>100k € (12 points) in the last 5 years
 ii) companies other than the sponsor(s), receiving honoraria with the same categories for amounts of € with 2/3/5/7 points

III. I have been or am a consultant/ strategic advisor/ speaker for industry: same categories of honoraria as defined by speakers
 -with 4/7/11/16 points (from sponsor(s) of the current event)
 -with 3/5/8/10 points (from companies other than the sponsor(s))

IV. I (or a member of my household) own a patent/shares/ stocks of
 a) a company active or relevant in medicine, but not active in the field related to the presentation: 15 points
 b) a company active in the field to which the presentation is related: 30 points

Rating scale ----- Score

0: none	0
1–2: low	1
3–4: medium	2
5–6: medium high	3
7–10: high	4
10–20: very high	5
> 20: maximal	6

Form 3

3. The final two categories of risk (III and IV) were based on the axiomatic assumption that the more the person declaring may think of maximization of profit (starting in Category III), the higher (e.g. as a shareholder, Category IV) and the longer-lasting the personal interest in economic success (e.g. as a patent holder, Category IV), the higher the likelihood that this will distract from the primary interest in patient welfare, and there will not only be subconscious reciprocity, but also consciously controlled processes influencing thought and argument, ultimately leading to bias.

Based on these four levels of risk we arbitrarily assigned points, with the number of points assigned increasing from I to IV (see Forms 1–3).

A feature common to all three versions is the assignment of more points if the sponsor of the current activity has been the funding source.

The maximal number of points across each category enabled us to classify the risk of COIs into *none* (0), *low* (1–2), *medium* (3–7), *high* (8–12), *very high* (>12).

Nonfinancial interests

Although documentation of *nonfinancial interests* also includes a long list of potential factors that may lead to bias, these appear to be of very variable interest.³¹ Thus, we propose that the following nonfinancial interests be documented in every declaration:

- Affiliation of the presenter
- Position in the organization
- Membership in a scientific society, professional union, medical self-regulatory body, this may be amended by: chair of committee, member of the board, president (whatever applies).

Discussion

CME/CPD aims to meet the educational needs of the healthcare participant/learner and should thus scrupulously try to control the risk of undue promotional influence and mitigate the risk of bias, while recognizing that bias cannot be completely eliminated from the human condition.^{17–19} Although the percentage of commercial support of group learning activities may be well below 20% on the national level in selected countries and regions (e.g. North Rhine Chamber of Physicians, Germany, unpublished data), this figure may be substantially higher (up to 60–80%) for international conferences (European Board for Accreditation in Cardiology, unpublished data). Thus, defining independence from commercial influences and mitigating bias to protecting the integrity of the content are key objectives of the accreditation process.

Thus, it has been the primary objective of the authors to propose a process that enables CME/CPD providers to

gather, assess, and disclose COIs. This process would have the following qualities:

- Concise and easy to grasp
- Appropriate to the content presented
- Compliant with applicable privacy protection laws
- Meaningful to participants
- Sustainable
- Adaptable to any type of information or mode of presentation

Many existing COI forms use open questions exclusively or in part to identify items that might not have been addressed by responses to structured questions. However, evidence has shown that open-ended questions miss more than they find.^{32,33} Thus, we have chosen only to use structured questions.²³ In effect this procedure completely shifts judgment, away from the person declaring his or her interests to the CPD provider organization and the participants.

The use of structured questions then necessitates clarity on which items should be declared. Requests for declarations of “COI” have caused confusion, because many presenters focus only on conflicts of which they are aware or where conflict is considered likely. However, since Thompson has defined the mere presence of interests as a “conflict,”¹ we are proposing asking participants to declare their interests, without any predetermination that the interests constitute a COI.

For reasons of practicability, we have chosen to recommend four levels that physicians are required to declare:

1. Research activities
2. Participation in medical specialist education (CME/CPD)
3. Participation in promotional activities
4. Level of personal financial engagement

The quantitative approach to rating personal financial engagement highest and financial contributions to research activities lowest follows the principles and rules established recently in the field of licensure by the EMA and in medical education.³⁴ Calculating a score is just a further step to condense information for the sake of practicability, especially in the context of multiday meetings.

We recommend all faculty or authors in CME/CPD declare *any* financial payment, even if these payments are not related to the particular event.

The requirement for any payment from a third party does not prevent the inclusion of nonfinancial or in-kind support (e.g. equipment, staff, services) into declarations of interests. Furthermore, we have proposed that financial payments be declared over the previous 5 years based on the fact that this is the longest time period in use so far,²⁹ and based on concerns that reciprocity will probably remain a relevant factor even for longer periods of time.²³ In addition, we are proposing that any expected future relations (“next 12 months”), be disclosed since the actual presentation may indeed be the start of a new relationship between speaker and sponsor.²⁹

It is also for reasons of practicability that we have not asked for sources of funding as well as amounts of money in the basic version. However, with this regard version 3 also demonstrates, that the more detailing of precise amounts of money should be included in the basic declaration form, the less will it be possible to display this information in accordance with Criterion #1 (“concise and easy to grasp”). Furthermore, asking for primary public disclosure of more detailed information in category IV would probably have a high chance to violate privacy protection law. Augmenting the *score* by taking into account amounts of money does not automatically mean participants will be provided with more valuable information, because it might imply an evidence base that does not yet exist. Thus, we have chosen to propose the procedure described above, which focuses on a simple calculation of a score, and to recommend the basic version, which might be augmented by presentation of additional data (including amounts of money) as needed.

We do not in any way claim that bias can be completely eliminated by the approach we have proposed.^{35–38} However, it is our goal to strive to quantify bias, fully appreciating the challenge of evaluating the relationship between interests and bias resulting from these interests.³⁹ Although the COI management principles and practices of scientific planning committees are mostly not transparent, some regulators have recently defined criteria based on the type of COI.^{30,34}

Others have claimed a weak relationship between COI and the likelihood of bias because the rates of self-reported perception of bias have been low.^{39,40} However, this approach has neglected to consider concerns related to the existence of a “bias blind spot”² in participants, which underestimates the problem due to flawed awareness of bias in humans in general, and the medical community in particular,^{41–43} thus forming the basis for long-standing behavioral patterns in relation to industry.^{37,44} This factor underlines the necessity of validating this index, not only with regard to practicability and impact on decision-making in management of COIs, but also with regard to whether participants feel empowered to make informed decisions.

In summary, our proposed approach enables a simple, quantitative calculation of a score that can be displayed to participants and used by organizations to facilitate their management of COIs. Because the method of calculating this score is transparent, it may be used in isolation or together with additional information based on algorithms defined by the institution or provider. Furthermore, the use of a score will help to comply with privacy protection rules, because it avoids primary presentation of the following:

- Details of sources and specific amounts of money
- Disclosure of names and/or types of companies/institutions connected with the recipient

Limitations

Regardless of the potential value of our score, this approach is not intended to replace more comprehensive strategies to

mitigate COI (see below “Recommendations for use”). Our approach to disclosure of COI may be associated with adverse effects including “strategic exaggeration” and “moral licensing,”⁴⁵ which in the end may lead to a reduction of trust and (potentially) unwarranted skepticism³⁸ and may reduce the application of evidence-based medicine.⁴⁶ Thus, disclosure of COI should always be considered only as part of a more comprehensive strategy for mitigation of COI.

Second, the score has been designed to provide participants in accredited CME/CPD with a short and easy-to-memorize declaration of interests. It should by no means replace full-version declarations, including the implementation of additional questions arising from a given declaration as well as other management strategies of declaring COI to participants.

Third, the development of the tool was based on a small sample size and may not reflect the full range of organizations or CPD systems. Its limitations may include the following:

- a. There is no mechanism to cross-check the credibility of the items declared or not declared. However, use of the score with extended declarations in parallel offers some opportunity to check for internal consistency.
- b. It contains no data on personal relations (with or without financial benefit), but focuses on corporate relations.
- c. The request for all payments will include payments with only questionable relevance to the event.
- d. Bias resulting from refusal of support in the past is not covered.
- e. Most accreditors do not (or only under exceptionally rare conditions) accept employees of a sponsor as presenter in accredited CME/CPD. This situation is not represented in the calculation matrix of the score. However, since they may be accepted as authors in major journals,⁴⁷ we would rank them *very high* (i.e. 16 points).

Fourth, we have made a proposal for declaration of interests of individuals. Declaration of interests of organizations is beyond the scope of this paper.

Recommendations for use

In the practice of accreditation the results of this calculation may be used in different ways:

1. The rating scale and score should be shared across all faculty, committee members, and learners/participants, (please find further information as well as downloads at supplementary material).
2. The number calculated for the individual presenter/author should be used by the program committee/editorial office to determine if further detailed information is required and what information will be declared to participants. For example presenters with

- a. <2 points (Score 0–1) would only have to inform the participants that they have “no COI to declare”
- b. 3–7 points (Score 2) would have to inform participants of the type and nature of their relationships with commercial interests
- c. 8–12 points (Score 3) would have to inform participants of the level of financial support received
- d. >12 points (Score 4) would have to inform participants how they worked with the organization to mitigate or minimize bias

The mode of presentation of additional data as specified under 2.b–d will be determined by the organization running the event or publishing the article and/or the accreditor, and it will have to comply with applicable privacy protection law.

Even if the program committee or editorial office decides, as a general rule, to get full-version declarations from all presenters/authors prior to the event or publication, the participants' information may follow the principles outlined above. Having fallen into Categories 2. b, c, or d in the past may require full-version declarations in the future. Nevertheless, the data to be presented to participants as well as mode of presentation will follow the same principles.

Conclusion

We have tried to define a simplified, yet highly practicable scoring system with the potential to become more detailed, dependent on degree of COI, always by expanding the same basic approach. This approach, we believe, is applicable to all types of accredited live or blended CME as well as to all individuals (e.g. speakers, authors) involved in planning and delivery of CME activities. In particular, this approach will serve meetings with high numbers of speakers/chairpersons and short presentation times. However, it nevertheless defines a baseline only, which should be exceeded whenever more targeted information is necessary (as outlined in the “Recommendations” section). It now needs to be implemented and evaluated by participants as well as by independent evaluators in order to become evidence based.

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