Managing conflicts of interest in the EAU Guidelines

GO Policy

To avoid criticism say nothing, do nothing, be nothing (Aristoteles)

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1. Rationale

The ultimate goal of this Policy is to protect the integrity and credibility of all activities related to the production of the EAU’s Clinical Guidelines. To safeguard public trust and confidence in the EAU Guidelines Office (GO), their output, and all those involved in the development and promotion of their Guidelines and any derivative products. Conflict of interest (COI) disclosure and management is an integral part of the ethical foundation of clinician/patient, and other third party interactions, and as such, vital for all those involved in the development of clinical practice Guidelines.

Disclosure alone will not suffice; any management of COI must be transparent, fair and sustainable. A Committee assigned by the EAU GO shall be responsible for reviewing disclosures and ensuring adequate management of all types of COIs. Assessment of disclosure information in the course of Guidelines development will require active involvement of the Panel chair.

Whilst the EAU GO aim to establish Guidelines Panels involving members that ideally have no or only very limited COI, it is recognised that as opinion leaders in their fields, Panel members will likely have conflicts. “The only person who does not have some vested interest in a subject is somebody who knows nothing about it” (Smith R. Conflict of interest and the BMJ. BMJ. 1994 Jan 1;308(6920):4–5. PMID: 8298354).

An added consideration may be that once clinicians are involved in Guidelines development they may be more likely sought out for speaking engagements and positions on advisory boards, etc. In recognition of this, the aim is to balance existing COI within the EAU Guidelines Panels, and to manage COI transparently.
The GO recognises that COIs are ubiquitous, yet intends to assure that these interests do not adversely influence the work of the GO.

2. General Policy
The development and upkeep of EAU Guidelines, as overseen and directed by the EAU GO, cannot be adversely affected by either financial or intellectual COI of the clinicians and others involved in this programme.

All those participating in EAU clinical Guidelines development, are expected to fully disclose both financial and intellectual relationships, in detail, to the EAU GO. Failing to comply with this Policy will result in sanctions as provided herein. All COI information provided related to EAU Guidelines development will be assessed based on its relevance in relation to the activities the submitter is involved in.

All relationships over the previous two calendar years and the current year (including future commitments which are foreseen over the coming year) must be disclosed. COI of all participating in EAU Guidelines development will be published online: www.uroweb.org/guidelines/. The Methodology sections of the individual Guidelines will include a link to the relevant online repositories.

3. What needs to be disclosed?
3.1 Definition
A COI is defined as ‘A set of conditions in which an individual’s objectivity, professional judgement, professional integrity and/or ability to perform his/her responsibilities may be unduly influenced by a secondary interest (such as personal or financial gain), or which may be perceived by others to bias an individual’s judgement, conduct, or work’. This will include situations where a family member or a close personal relation has financial interests, personal relationships, or professional associations with an outside individual or organisation, which could appear to create a source of bias such that his/her activities within the GO could appear to be influenced by that interest or relationship.

3.2 Types of COI
Conflict of Interest may be either financial or intellectual. All COI should be disclosed, not just those that are considered relevant by the Panel member.

Financial COI: exists when an individual is, or may reasonably be perceived to be, in a position to gain or suffer financial loss as a result of an action, deliberation or recommendation.

Intellectual COI: exists as a result of competing scientific beliefs, strong moral convictions, competing academic institutions, societies or publications. Such COIs may be self-declared (e.g. competing beliefs) or be evident when COI is disclosed.

As determined by the COI Committee, COI is deemed to be either low- or high risk. Declared COI will be judged with regards to a possible relation to the topic in which the GO member is active.
3.3 Termination used

Low-risk COI
- Honoraria for speaking at company sponsored meetings or events.
- Support in the form of fellowships, travel grants, in-kind donations, etc.
- In case any enumeration is paid to the department (and not to an individual): pharma/medical device company – investigator.
- Participation in clinical trials.
- Officer or board member of another medical society.
- Editorial positions with publications.
- Programme oversight of meetings (e.g., program organiser or guidelines publications).

High risk COI
- Research grants, partial or full salary support from a commercial organisation for self or employees for whom you are managerially responsible (i.e. laboratory technical/research fellow).
- Consultant or advisor to pharma/medical device company including positions on medical or scientific advisory boards.
- Equity interests (or entitlement to same) of stocks, stock options, royalties, etc, including income from patents or copyrights. Or a family member (first degree/spouse), holding stock, etc.
- Service as a director or employment by a commercial organisation, whether or not remuneration is provided for such service (or a close family member holding this position/stock etc.).
- Sole ownership, partnership, or principal of a commercial enterprise (idem for a close family member holding this position).
- In case a salary is paid to the individual for: research grants, partial or full salary support from a commercial organisation for self or employees for whom you are managerially responsible (i.e. laboratory technical/research fellow).
- Investigator initiated trials, sponsored by company.

4. Who are to disclose COI
This Policy applies to all those involved, directly, or indirectly, in the development of EAU clinical practice Guidelines:
- EAU GO Board and Committee Members
- EAU GO Panel members (which includes all those partaking in Panel meetings; the Panel (vice)chair, full senior Panel members, junior clinicians/Guidelines Associates, Patient Advocates, collaborators, advisors and specialists non-Panel members participating in discussions – during Panel meetings, or otherwise, i.e those linked to any aspect of EAU Guidelines development)
- EAU Staff and consultants (including temporary staff)
5. **When to disclose COI**

5.1 **New candidates for EAU GO positions**

All candidates considered for any position within the EAU GO will be asked to submit COI information prior to being appointed. A standard COI form, supplied by the EAU GO, is to be used requesting full disclosure of all COI covering the actual and the previous two years. Failure to do so within the time frame set will result in expulsion. COI information can be provided online, through the EAU website: [www.uroweb.org](http://www.uroweb.org).

All Panel member disclosures provided will initially be assessed by the Panel chair (and/or Vice-chair) (see Table 1). In case a second opinion is required, the COI Committee can be called upon. COI disclosure of a new Panel Chair or vice-Chair will be assessed by the COI Committee.

In particular, candidates applying for a GO Associate position should be free of any high-risk COI.

Assessment of new candidates for all EAU GO positions, COIs may result in:

- Appointment;
- Conditional acceptance, acknowledging that management of COI will be required;
- Rejection.

Rejection criteria for new candidates will include any COI which cannot be managed within a Guidelines setting.

**Table 1. Assessment of COI prior to appointment of GO Board members, GO Panel (vice) Chairs and Panel members**

<table>
<thead>
<tr>
<th>Candidates</th>
<th>COI assessed by</th>
</tr>
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<tbody>
<tr>
<td>GO Board Chairman</td>
<td>COI Committee (during office term, the EAU General Assembly ratify candidates proposed by the EAU Search and Nomination Committee)</td>
</tr>
<tr>
<td>GO Board members</td>
<td>GO Board Chairman/COI Committee</td>
</tr>
<tr>
<td>GO Panel Chairs</td>
<td>GO Board Chairman and GO Board members/COI Committee</td>
</tr>
<tr>
<td>GO Panel members</td>
<td>Panel Chair and vice-Chair</td>
</tr>
<tr>
<td>GO Associates</td>
<td>GO Associate Committee/COI Committee</td>
</tr>
<tr>
<td>GO Committee members (e.g. Methods Committee, Associates Committee)</td>
<td>GO Board/COI Committee</td>
</tr>
<tr>
<td>Reviewers</td>
<td>GO Staff /COI Committee</td>
</tr>
</tbody>
</table>

5.2 **All those already involved in the GO (Table 2)**

- As a minimum, COI information is to be updated annually, to be assessed by the COI Committee.
- COI should, as a standard, be on the agenda of each Panel meeting, to allow for discussion and management.

*For an appeals procedure, see below.*
Table 2. Submission and updating of COI information

<table>
<thead>
<tr>
<th></th>
<th>Prior to being involved</th>
<th>Annual declaration</th>
<th>At meetings and/or to coincide with a scientific publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>GO Board &amp; Committee members</td>
<td>Yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Panel members</td>
<td>Yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Staff and consultants</td>
<td>Yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Peer-reviewers</td>
<td>Yes</td>
<td>n.r.</td>
<td>n.r.</td>
</tr>
<tr>
<td>Institutional COI</td>
<td>Yes</td>
<td>yes</td>
<td>n.r.</td>
</tr>
</tbody>
</table>

*n.r = not relevant.*

6. Management and review of COI disclosure (high-risk COI)
Meeting minutes are to record any decisions made. This information is to be made available annually online upon publication of the final Guidelines documents (as part of the supporting documents).

6.1 Panel Chair – vice-Chair
In case the Panel Chair has a particular COI in one area, the Panel vice-Chair cannot have an identical conflict (or vice versa). During Panel interaction, when topics arise for a discussion which touches on the Panel Chair’s particular COI, the Panel vice-Chair (without COI in this area) is to:
- Lead the discussions (Panel Chair can partake);
- Lead the drafting of recommendations;
- Lead Panel voting (if relevant).

6.2 Panel members and all those partaking in Panel meetings:
- Can take part in the discussion on a topic related to their area of COI;
- Cannot take part in any voting or development of recommendations related to their area of COI.

6.3 GO Board and Committee members
- Cannot take part in any discussion/voting/decision related to their area of COI.

6.4 EAU Executive- and Board members
- Cannot have direct influence on appointment of Panel participants, nor on Guidelines content.

6.5 Expulsion
COI which cannot be managed within a Guidelines setting (high-risk, but as defined below) will result in direct expulsion from all Guidelines activities. An appeals procedure may apply (see below)

7. Appeals
7.1 New candidates
Upon rejection based on COI information provided, new candidates may, in some cases, be given the opportunity to divest of a relationship(s) instead of being disqualified. Divesting must be done prior to starting any Guidelines activities, and for a minimum duration of one year post-publication.

7.2 All those involved already in the GO (with, or without management)
In case a new COI arises which is deemed unmanageable, the Panel member will be requested to step back, unless they are willing to divest of this particular COI.

While COI provision relies on good faith, in case information becomes available that full disclosure has not been provided, the member in question will be contacted by the COI Committee requesting clarification. Failure to respond in a timely manner (within 3 months after receiving a request to provide COI information), or providing incomplete information will result in dismissal from all GO activities.

Organisational COI
Collaboration with other societies/organisations: A basic Memorandum Of Understanding/agreement (MOU) defining responsibilities and expenses, as well as the conditions for publication, authorship, the management of COI, endorsement, profits, and termination will apply. Such a memorandum is, as a minimum, to contain all requirements considered essential to safeguard the independence and credibility of the EAU Guidelines. Assessment of organisational COI will be the remit of the GO Board and the EAU COI Committee.
All financial support of Guidelines projects must be unrestricted and paid out to the EAU Central Office (not to the EAU GO). Any external (financial and in-kind) support of the EAU guideline development must be independent of the guideline process. Contributing industries or other entities may not have representation on Panels or systematic review groups. In case of industry support, multiple sponsors are sought.

8. **Role GO Staff**
- For all those already involved in the GO: Ensure currency of COI information;
- Collect COI information for new members;
- At every panel meeting, provide COI information of all Panel members to the (vice)Chair;
- Standard agenda point: inquire into changes;
- Link available COI to agenda points: will people be asked to leave the room during discussions/voting;
- Recording of procedure: including processing of new/changed COI (website/database), record which Panel members were excluded from decision making/discussions. This record is to be part of the minutes. A compilation will eventually need to be part of the supporting material (to be posted online).

9. **Examples of COI:**
1. A Panel member provides COI information which is deemed high-risk within the context of guidelines development, but for Guidelines topic A. However, he/she is a panel member in Guidelines topic B, which is entirely unrelated. In this case, there will be no restrictions on his/her participation.
2. A panel member provides COI information which is deemed high risk within the context of guidelines development. This COI relates to his/her own panel. In such a case, they cannot take part in any decisions regarding development of recommendations, and they will be asked to leave the room in case this discussion is held.
3. Within one panel, a group of panel members share (close to) identical high-risk COI within the context of that particular guideline. In this case, no restrictions apply for their participation. In the case that the Chair and vice Chair also share the same COI: a rigorous external review process is to be ensured.
4. A Chair provides COI information which is deemed low-risk within the context of guidelines development, but this COI relates to the guidelines topic that he/she Chairs. In this case, they need to disclose this information at the start of the meeting. He/she can still Chair the discussions pertaining to this particular area of COI.
5. A Chair, or vice-Chair, provides COI information which is deemed high-risk for an area (possibly a particular systematic review question) within their own guideline. In this case neither the Chair, nor the vice-Chair can lead a discussion related to that topic, or take part in any decision making. If it applies to both the Chair and the vice-Chair, they must appoint a senior panel member to take over for this particular task.
6. Panel member A has been involved in the development of product X. In a SR performed by the panel product X does not perform as well as all other comparators. Panel member A is unwilling
to support a low level/negative recommendation for product X. If panel member A will not inform the panel that he/she led this trial, in general (hopefully), other panel experts may be aware of panel member A’s involvement. If that is not the case and Panel member A is the only, persistent, dissenter, the Chair should have a private discussion with panel member A first asking him/her – in view of the evidence – what the motives are. If he/she will not state the reasons for this point of view, since they are the sole outlier, a note will be made in the meeting minutes. The majority vote will decide. If the information regarding product X comes to light at a later stage, this would be reason to expel panel member A.

Other similar scenarios may apply: partner/spouse of panel member A is a major stock holder in a pharmaceutical company. Panel member A can only do open surgery and dislikes anything involving robotic/laparoscopic...). Key message is that when this is found out later, the Panel member will likely have to be asked to leave the panel. When it comes to COI, submission and management, one has to rely on honesty of all parties involved.

‘balanced’ COI – definition:
Proposal: In case a Panel Chair has a high-risk COI in one area, the vice-Chair cannot have an identical conflict (and visa versa).
Panel members can have a high-risk COI, but across the Panel COIs cannot be identical (this has to be taken into account when renewing the Panel).