Identifying and managing conflicts of interest

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NHMRC Standards
The following Standards apply to the Identifying and managing conflicts of interest module:

4. To identify and manage conflicts of interest guideline developers will:
   
   4.1. Require all interests of all guideline development group members to be declared
   
   4.2. Establish a process for determining if a declared interest represents a conflict of interest, and how a conflict of interest will be managed.

Overview
A trustworthy guideline should contain recommendations that are based on high-quality evidence, and be as free of bias as possible (Institute of Medicine 2011).

Bias, resulting from conflict of interest or sponsorship, can be evident at any stage of the guideline development process, including in the source evidence on which the guideline is based.
Conflicts of interest, including those stemming from relationships with industry, may bias guidelines disproportionately in favour of new, expensive and less effective treatments and products, often to the detriment of under-resourced health systems and the public (Williams, Kevat et al. 2011). They can promote over-diagnosis, over-treatment and lead to the medicalisation of normal human states and behaviours (Moynihan, Cooke et al. 2013). For example, dietary guidelines may be influenced by the conflicts of interest of companies (and groups lobbying on their behalf) whose profits could be adversely affected by recommendations in the guidelines (Nestle 2013). If conflict of interest is not appropriately anticipated, recognised and managed, it can bias guideline recommendations; if bias comes to light it can discredit guidelines and cause serious reputational damage to guideline developers (Coyne 2007).

While other forms of bias will be discussed elsewhere, management of the conflicts of interest of the guideline development group is the primary focus here. This module covers conflicts of interest related to sponsorship of the guideline development process and individual guideline development group members. Key terms around conflict of interest are described in Table 1.

Conflicts of interest related to sponsorship of the guideline development process
Sponsorship of the guideline development process by a single commercial entity is a clear conflict of interest because the sponsors could potentially bias the development of recommendations and benefit from recommendations made in the guidelines.

Conflicts of interest of individual guideline development group members
While conflict of interest is only one possible source of bias, it can be contentious and is frequently misunderstood. It is poorly managed in Australia, with studies showing that between 79 and 85 percent of national guidelines are published without statements about conflicts of interest (Buchan, Currie et al. 2010; Williams, Kevat et al. 2011). Poor disclosure rates have also been reported in North American and Danish guidelines (Neuman, Korenstein et al. 2011; Norris, Holmer et al. 2012; Bindslev, Schroll et al. 2013; Campsall, Colizza et al. 2016).

With reference to the Institute of Medicine definition (2009), a conflict of interest arises when the primary interest of guideline development (the need to develop unbiased guideline recommendations) is undermined by and conflicts with the secondary interest (financial gain for guideline development group members).

Having a conflict of interest does not in itself imply improper motivation or individual wrongdoing. However, it is widely understood that conflicts can directly influence decision-making in health care (Robertson, Rose et al. 2012; Dunn, Coiera et al. 2016), and this is often an unconscious act (Collins 2006; Cain and Detsky 2008).

Guideline development group members will have a wide variety of interests ranging from personal values to intellectual commitments, professional ambitions and financial ties, and these interests will shape the guideline development process. The development group members are in a position to influence decision-making, and because of that, some of these interests may be in conflict with the aim of developing the guidelines (see Step 2).

Development group members may also be influenced by organisational conflicts of interest because they sometimes serve as representatives of organisations. Examples include a consumer member
who represents an advocacy organisation vulnerable to pressure to represent the views of organisations that fund it (Moynihan and Bero 2017; Rose, Highland et al. 2017), or a member of a nutrition guideline development group who represents the processed food industry and may feel pressure to represent industry views.

Table 1. Key terms around conflict of interest

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<th>Term</th>
<th>Description</th>
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| Interest           | For the purposes of this module an interest can be described as a commitment, goal or value arising from personal beliefs, past experience, intellectual commitments, personal or professional relationships, financial ties etc. (adapted from Bero and Grundy 2016). It is inevitable that most people involved in guideline development will have an interest or stake in the process. This is typically the basis for why they were selected to participate in the first place. While some interests may be inherently problematic in specific circumstances, many are not, and they could reasonably be viewed as essential components of character, personality and life experience (Bero and Grundy 2016). Examples of the latter include:  
• published opinions on the effectiveness of a clinical, public or environmental health intervention which is considered in a guideline  
• publishing research that may be used in a guideline  
• being an acknowledged expert or opinion leader on an intervention considered in a guideline  
• personal experience of a disease or condition considered in a guideline, and  
• holding positions and convictions (political, intellectual, religious, ideological or other) relevant to the clinical, public health or environmental health guideline being developed. |
| Conflict of interest| A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest (such as the health of the community) will be unduly influenced by a secondary interest (such as personal interest or financial gain) (Institute of Medicine 2009). Commonly, conflicts of interest arise when committee members have financial ties to commercial entities with an interest in the guideline recommendations. Examples include:  
• fees paid for service to a for-profit company (consultancy payments, speaking fees, panel memberships)  
• indirect payments (funding of travel, accommodation, professional development, hospitality)  
• stock  
• royalties  
• directorships  
• support for a researcher’s clinical or research infrastructure (e.g. funding of data managers, scientists, equipment and clinical staff), and  
• personal relationships with those who may have the above interests. |
| Organisational conflict of interest | Conflicts of interest may arise if guideline development group members also serve as representatives of organisations with an interest in the guideline recommendations. Examples include if members:  
• represent or have roles in organisations with financial links or affiliations with industry groups which stand to benefit from or be affected by guideline recommendations, and  
• represent or have roles in organisations which advocate known ideological, industrial or policy positions. |
| Sponsorship        | Sponsorship refers to organisations, entities or agencies providing funding support to develop a guideline. Conflicts of interests may exist where the guideline development group’s interpretation of the evidence conflicts with the aims of the guideline’s funder. The financial support provided by the funder or the participation of a funding agency in guideline development, even as an observer, can have an influence on the working of a development group and may bias a guideline. |
What to do

1. Develop a declaration of interests policy
Guideline developers should develop and operate under a declaration of interests policy that everyone involved understands and adheres to.

The key components of a declaration of interests policy include:

- identification of the scope of the declaration of interests policy and to whom it applies
- guidelines for accepting sponsorship for the guideline development process
- a process for appointing chairs and development group members
- a process for disclosing interests
- a process for identifying conflicts of interest, and
- a process for managing conflicts of interest.

Examples of existing policies and disclosure forms are provided in the ‘Useful resources’ section below.

2. Determine if an interest is a conflict of interest
There are many ways to determine whether an interest poses a conflict of interest. It may help to consider the following rules of thumb whenever interests are declared (Bero and Grundy 2016).

First, consider whether it is theoretically possible to eliminate the interest, which might indicate that it is a conflict of interest. For example, consulting fees are a conflict of interest because they can be eliminated, whereas someone’s intellectual commitments (e.g. theoretical approach, academic background or training) or personal beliefs cannot be eliminated. Note that the issue of eliminating conflicts of interest in this rule of thumb is theoretical rather than about practical strategies to manage them, which are discussed in Step 6.

Second, consider whether the interest would produce a consistent direction of bias in the context of guideline development, such as if financial sponsorship were to influence decisions consistently in favour of an intervention or product preferred by the sponsor.

Third, consider whether the scope of influence extends beyond an individual. For example, financial ties with companies whose products may be affected by or recommended in a guideline are conflicts of interest because multiple development group members could have such ties (and they would consistently favour interventions being considered for the guideline). Development group members’ unique intellectual commitments are not conflicts of interest because they will be different for each member and are unlikely to consistently bias the recommendations in one direction.

3. Appoint a chair who is free of conflicts of interest
The chair’s primary qualification should be expertise in chairing and facilitating groups (NICE 2014). The role of chair is critical as they are ultimately responsible for directing the development group’s determination of conflicts of interest in its meetings. For this reason the chair should be independent, meaning having no conflicts of interest. The chair does not need to be an expert in the content area of the guideline but should have a general understanding of the content to be able to participate in the discussion and deliberations. The guideline developers should document and make public all efforts made to identify a chair who is free of conflicts of interest.
If it is not possible to appoint a chair who is free of conflicts of interest, particularly financial ties that would preclude full participation in all meetings, strategies used to manage the conflicts of interest of the chair should be documented and implemented at the start of each meeting. For example, another member of the development group who has no conflicts of interest in the relevant topic could be nominated to act as chair for a particular discussion and deliberation, and the chair would not be involved in drafting or approving any recommendations related to that discussion.

It is prudent to appoint an independent chair prior to appointing other development group members as the chair can then assist in selection and screening of prospective members.

Co-chairs can be used where guidelines are likely to be complex or leadership is required to be shared amongst different disciplines (Institute of Medicine 2011). In this case, both co-chairs should be free of conflicts of interest as described above.

A chair may require expert assistance in identifying and managing conflicts of interest of the guideline development group members. Therefore, some guideline developers appoint dedicated conflict of interest advisors, analogous to a company secretary servicing a board of management, whose role is to advise and support the development group chair.

4. Select development group candidates
Organisations planning guidelines should aim to appoint a guideline development group whose members have no financial or other links with relevant industry groups. If this is not possible then attempts should be made to limit the number of members who have these types of conflicts so that they form a minority of members.

When considering prospective candidates for the guideline development group, a review of their declarations of interests against the agreed conflict of interest management policy should occur.

While it is inevitable that many people being considered for involvement in guideline development will have interests because of their skills and expertise, potential members with certain conflicts of interest should not be accepted as members of a guideline development group. This may include employees of pharmaceutical or device manufacturer companies or people with a direct financial interest in the potential recommendations of the guideline.

5. Disclose interests throughout development
The business of guideline development groups should be conducted with all members of the group being aware of other members’ conflicts at all times. These conflicts should be published in the final guideline.

Disclosure of interests is an ongoing process. Members must update their disclosures and advise fellow development group members as they change.

A disclosure process should include:

- a structured checklist of possible interests to be disclosed (e.g. financial ties or other affiliations through consulting, stock or shares, grants, honoraria, travel support, patents)
- an open-ended option to disclose any other interests not covered by the structured checklist
- the amount of each financial interest (which should not be limited by monetary thresholds), and
- the timeframe of each interest (for example, ongoing, current, or past, e.g. within 3-5 years)

6. Manage conflicts of interest

If there are areas where a guideline development group member has a conflict of interest, or could reasonably be perceived as having a conflict of interest, they should not take part in any discussions or decision making related to that specific area or issue.

In an area where the potential for bias exists, the conflicted individual should not be present when a decision or recommendation is made and should not be involved in writing or approving recommendations.

The guideline development group chair should ensure that any decision to exclude members from discussion and decision making is made in full consultation with all members of the group. This decision should be recorded in the final guideline.

7. Publish declarations of interest in the guideline

The final guideline should include a statement for each member noting whether they had conflicts of interest or not. For each member with conflicts of interests, the final guideline should describe what the conflicts were and the strategy used to manage each of them.
NHMRC Requirements

Guidelines approved by NHMRC must meet all requirements outlined in the Procedures and requirements for meeting the NHMRC standard. The following requirements apply to the Identifying and managing conflicts of interest module:

- A.1 The organisation/s responsible for developing and publishing the guideline is/are named.
- A.2 Sources of funding for guideline development, publication and dissemination are stated.
- A.3 A multidisciplinary group that includes end-users, relevant disciplines and clinical experts is convened to develop the purposes, scope and content of the guideline, and the process and criteria for selecting member are described.
- A.4 Consumers participate in the guideline development, and the processes employed to recruit, involve and support consumer participants are described.
- A.5 A complete list of all the people involved in the guideline development process is provided, including the following information for each person: name, profession or discipline, organisational affiliation and role in the guideline development process.
- A.6 Potential competing interests are identified, managed and documented, and a competing interest declaration is completed by each member of the guideline development group.
- A.7 A list of organisations formally endorsing the guideline is provided.

Additionally, subsection 29(1) of the Public Governance, Performance and Accountability Act 2013 requires that:

“An official of a Commonwealth entity who has a material personal interest that relates to the affairs of the entity must disclose details of the interest.”

If the NHMRC or other Commonwealth entity were to appoint a committee to develop a guideline under their legislation, and where under their legislation a committee member is an official for the purposes of the PGPA Act, appointed members of the committee would be legally required to disclose details of the interest not just in relation to the scope of the guideline, but in relation to the affairs or activities of the Commonwealth entity. Further information on the scope of this provision is provided in the Finance Resource Management Guide No 203 available at: http://www.finance.gov.au/resource-management/accountability/officials.

Useful resources

Examples of existing forms for disclosure of interests are provided below:

- NHMRC form for disclosure of interests (guideline development)
- Cochrane Collaboration disclosure of potential conflicts of interest form

Examples of existing declaration of interests policies are provided below:

- 2012 Identifying and Managing Conflicts of Interest of Prospective Members and Members of NHMRC Committees and Working Groups Developing Guidelines
- 2014 UK National Institute for Health and Care Excellence Policy on Conflicts of Interest (currently under review)
References
Glossary

**Interest**: A commitment, goal or value arising from personal beliefs, past experience, intellectual commitments, personal or professional relationships, financial ties etc. (adapted from Bero and Grundy 2016).

**Conflict of interest**: A set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest (Institute of Medicine 2009).

**Primary interest**: A commitment to the principal goals of an activity, such as the health of patients, the integrity of research, or the duties of a health professional.

**Secondary interest**: An interest that could detract from or conflict with the primary interest, such as personal benefit including financial gain, motivation for professional advancement, or the wish to do favours for family and friends.