

Policy on declaring and managing interests for NICE advisory committees

Also includes witnesses, expert commentators and other contributors

Responsible Officer: Chief Executive
Author: Corporate Office
Date effective from: January 2018
Current issue date: September 2022
Next review date: September 2025

Version control sheet

Version	Date	Author	Replaces	Comments
1	January 2018	Corporate office	N/A	New policy specifically for advisory committees, based on the NHS England's managing conflicts of interest in the NHS.
1.1	July 2019	Corporate office	Version 1	Updated after the first year of operation.
1.2	February 2020	Corporate office	Version 1.1	Updated to note the requirement for SMT to review the declared interests of proposed appointees to chair roles (including reappointments)
1.3	November 2020	Corporate office	Version 1.2	Removal of requirement for SMT to review the declared interests of proposed appointees to chair roles (including reappointments).
1.4	December 2020	Corporate office	Version 1.3	Added the requirement for publicly available information to be reviewed when appointing new committee members.
1.5	April 2021	Corporate office	Version 1.4	Updated definition of the commercial sector in paragraph 16, amendment to paragraph 59 and example around indicator committee on p23
1.6	September 2022	Corporate office	Version 1.5	New requirement to declare all paid employment in a role relevant or potentially relevant to the committee. Other minor changes across policy following periodic review. No change to the interests that may be held.

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Introduction

- NICE aims to achieve and maintain high standards of probity in the way
 we conduct our business. These standards include impartiality,
 objectivity, integrity, and the effective stewardship of public funds.
 Managing potential conflicts of interest is an important part of this
 process.
- Effectively managing interests and identifying potential conflicts is
 essential if health and care professionals, and the public, are to maintain
 confidence in our work. It is central to how we develop guidance and
 appoint members to our advisory committees (See also the NICE
 appointments to advisory bodies policy and procedure).
- 3. This policy supports a culture in which we are transparent about the interests of those who are members of, or work with, our advisory committees, so that the effect of interests is known, understood and managed. It aims to ensure that the advisory committees have access to the appropriate expertise on the areas under consideration, while minimising the risks to their perceived ability to objectively consider the evidence.
- 4. The policy provides guidance on:
 - what interests need to be declared and when
 - how declared interests should be recorded
 - when a declared interest could represent a conflict of interest and the action that should be taken to manage this.

Scope

- 5. This policy applies to everyone involved in our advisory committee discussions, including the following groups:
 - advisory committee chairs
 - advisory committee members, including co-opted and topic-specific members or experts
 - those invited to give evidence or advice to advisory committee meetings, including expert witnesses
 - technology appraisal and highly specialised technologies appeal panel chairs and members
 - organisations that are formally represented on, or making written submissions to, advisory committees.

- 6. The principles in this policy also apply to other NICE contributors to products that do not use a formal committee process, for example, peer reviewers who provide a medicines evidence commentary.
- 7. A separate policy applies to:
 - Board members and employees of NICE
 - agency workers and contractors on temporary contracts
 - secondees (people seconded to NICE from other organisations)
 - employees of the external guidance centres and the 'evidence contractors' working directly or indirectly to supply evidence that is used by the advisory committees.

Defining and categorising interests

- 8. Committee members and advisers bring a range of experiences and perspectives to NICE's work. It is likely they will have a variety of interests, arising from different contexts and activities done in a professional or personal capacity. This can include employment and other sources of income, speaking engagements, shareholdings, publications and research, and membership of professional or voluntary organisations.
- Having advisory committee members with varied interests is a positive attribute, but it is vital that interests are openly declared so they can be appropriately managed. Declaring an interest does not mean there is a conflict of interest.
- 10. All interests should be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant, to the work of the NICE committee in question.
- 11. Interests that are not, or could not be perceived to be, relevant to the NICE committee's work need not be declared. This could include, for example, membership of sports and recreation societies, positions in local community groups, and shareholdings in companies unrelated to NICE's work.
- 12. For the avoidance of doubt, a person living with a disease or condition relevant to the matter under discussion, or who has a family member in that position, is not seen as an interest and this does not need to be declared
- 13. It is important to exercise judgement, and if there is any doubt as to whether an interest is relevant to the committee's work, it should be

- declared. This includes indirect interests, such as those relating to family and friends, when they are known. In the case of particular uncertainty, further advice is available from the NICE team. When there are no interests to declare, a 'nil return' should be made.
- 14. The following categories describe the types of interests relevant to the work of NICE. In each case, a benefit may be a gain or avoidance of a loss.

Direct interests

- 15. A direct interest is when there is, or could be perceived to be, an opportunity for a person involved with NICE's work to benefit. This benefit could be financial (a financial interest) or non-financial (a non-financial personal or professional interest). These are explained further below.
- 16. *Financial interests:* When a person gets direct financial benefit. This means anything of monetary value, including: salary and payments for services; equity interests, including stocks, stock options or other ownership interests; and intellectual property rights, including patents and copyrights and royalties arising from such interests.

 Examples of financial interests are:
 - Paid employment in a role relevant or potentially relevant to the committee including in the health and social care sector or commercial sector
 - Work in the commercial sector, including a directorship or consultancy, that attracts regular or occasional payments or benefits in kind such as hospitality. This includes payments for speaking engagements and sitting on advisory boards, and clinicians undertaking private practice.
 - Ownership or part ownership of a healthcare provider, including a GP who is a partner in a practice or a community pharmacist who owns their business.
 - Direct payment from the commercial sector to attend a meeting, conference or event, over and above funding to support reasonable travel, accommodation and attendance costs (as a general guide, this means expenses above a level a public sector body such as NICE would usually offer).
 - Shareholdings or other investments in the commercial sector (unless these are held in a managed fund where the person does not have the ability to instruct the fund manager as to the composition of the fund).
 - Personal payment from the commercial sector to undertake research.

Additional notes: For these provisions, the term 'commercial sector' refers to businesses and trade associations who could be affected by NICE's recommendations and commercial decisions. These include forprofit health and social care providers, life sciences (including pharmaceuticals, medical technology, genomics, diagnostics and digital health) companies, alcohol and tobacco organisations, and companies currently, or seeking to be in, a commercial relationship with NICE.

Membership of a pension scheme from past employment does not constitute an interest that needs to be declared.

As outlined in NICE's <u>statement on engagement with tobacco industry organisations</u>, individuals working for, or holding office in, tobacco organisations cannot be appointed to NICE's advisory bodies. (Tobacco organisations include the tobacco industry, and organisations speaking on behalf of, or funded by the tobacco industry.)

- 17. **Non-financial professional and personal interests:** When a person has a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation. This can include situations where the person:
 - Is an advocate for a particular group or is a member of a lobbying or pressure group with an interest in health or social care.
 - Holds office or a position of authority in a professional organisation such as a royal college, a university, charity, or advocacy group.
 - Is actively involved in an ongoing or scheduled trial or research project aimed at determining the effectiveness of a matter under review.
 - Has published a clear opinion about the matter under consideration.
 - Has authored or co-authored a document submitted as an evidence publication to the relevant NICE advisory committee.

Indirect interests

- 18. An indirect interest is when there is, or could be perceived to be, an opportunity for a third party closely associated with the person in question to benefit. This could be through a close association with another person or organisation that has a financial or non-financial interest (as defined above), and could benefit from a decision the person is involved in making through their work on an advisory committee.
- 19. Indirect interests can arise from people (such as close relatives, close friends and associates and business partners), and also employers (for example with research grants or other funding to the unit in which they work).

20. They can also arise when a committee member is appointed to a committee to represent an organisation, an individual attends a meeting to speak on an organisation's behalf, or an organisation makes a written submission to the committee. These organisational indirect interests would not usually preclude participation in the committee, but should be declared to ensure transparency about the organisation's interest in the matter under review.

Declaring interests

- 21. Committee chairs and members make their first declaration when applying for a specific advisory committee role. Witnesses and other contributors make their first declaration when invited to contribute to a committee meeting. The **initial declaration** covers the preceding 12-month period. Consideration should also be given to any new interests that are not currently held but are known will arise during involvement with the committee (for example a new research project).
- 22. People will be prompted to **update** their declaration:
 - before each meeting, by email
 - at the start of each meeting, orally
 - each year (standing committees), by email.
- 23. Any new information provided before or during meetings, or at the annual update, is added to the original declaration, to give a full picture of the 12 months before beginning work with NICE.
- 24. It is the person's responsibility to identify and declare interests at the earliest opportunity, and to ensure this declaration remains up-to-date.
- 25. A summary of the process for declaring interests is set out in appendix
 A.

Identifying and responding to potential conflicts of interest

- 26. The response to declared interests depends on a person's role within the advisory committee (for example, chair, member, adviser, witness) and what is being considered by the committee.
- 27. Each case is different, and the circumstances must be clarified with the people involved to assess the perceived risk of a conflict of interest.
 When the interest is specific to the topic under discussion, there is

greater likelihood of a conflict of interest (see below). Good judgement is needed to ensure proportionate management of risk. Decisions on managing interests must balance the need for advisory committees to have access to the appropriate expertise on the areas under consideration, while minimising the risks to their perceived ability to objectively consider the evidence.

28. There is a conflict of interest when a reasonable person would consider that an individual's ability to apply judgement or act in the work of NICE is, or could be perceived to be, impaired or influenced by one of their interests.

Responses to declared interests

- 29. There are 3 potential responses following a declaration of interest:
 - No action other than the process of open declaration the person can engage in all aspects of the committee's work. This is usually because nothing is considered to represent a perceived conflict of interest but may in some circumstances be because an open declaration is considered sufficient to mitigate any risk of conflict, or because the interest (and the potential to benefit) has ceased.
 - Partial exclusion the person can engage in committee discussion or provide advice to the meeting (for example, because of their expert knowledge), but is excluded from developing recommendations and decision-making on the matter relating to the interest. Involvement may be limited to answering direct questions from the committee.
 - Complete exclusion the person can have no input to a specific topic, either from the start (non-appointment) or for part of the committee's work relating to that topic. For example, where the person has a financial interest and could financially benefit from the outcome of the committee's discussions. When an interest leads to exclusion for a specific topic, it may be appropriate to withhold any confidential meeting papers for that item especially when the person could benefit from the information.

Interests at appointment

30. Assessment of an applicant's declared interests and application form/curriculum vitae is done by a senior member of the NICE guidance programme, who agrees a final declaration with each applicant. As part of this process, the appointing team should review information in the public domain, such as the Association of British Pharmaceutical Industry (ABPI) Disclosure UK register and published research, to

- identify if any other interests need to be declared. The appointment panel considers whether any interests mean that they cannot be appointed. In the case of doubt, the relevant director or nominated deputy considers the declared interests and, in very unusual circumstances, the decision is referred to the 'conflict of interest reference panel' (see appendix B for terms of reference).
- 31. As part of the appointment process the panel will need to consider whether there are any issues from before the 12 month declaration period that could question the individual's ability to evaluate evidence objectively. For example, where the individual has expressed views on the matters under consideration by the committee, the panel will want to ensure the proposed appointee is open to alternative views and is committed to work impartially.
- 32. NICE recognises that some topics are particularly contentious. If the appointment of people with strong views (and who therefore have a non-financial professional and personal interest) is necessary to ensure the committee has access to the required expertise, then care should be taken to ensure that the committee contains a balance of views.
- 33. Examples of how interests are handled during the appointment process are given in appendix C.

Chairs

- 34. The chairs of advisory committees are in a special position in relation to the work of their committee and have greater scope to influence the outcome of discussions. The chair helps the committee to work collaboratively, ensures a balanced contribution from all committee members and takes decisions about the potential conflicts of interest of their committee members. Chairs are appointed for their expertise and skill in chairing groups, and although they may have some knowledge of the topic, this is not their primary role in the group. Specialist knowledge is provided by other committee members.
- 35. The interests of potential chairs need to be considered in relation to the type of committee. Topic-specific guideline committees cover a defined area, therefore it is possible (and necessary) to identify and exclude possible conflicts of interest before appointment. Standing committees cover a broad range of topics, therefore potential conflicts can generally be handled on a meeting-by-meeting basis. This is explained in the box below.

Appointing chairs

Topic-specific guideline committees:

Chairs cannot have any direct interests (financial, non-financial professional or personal) that relate to the services, interventions, products, or delivery of care to be considered within the scope of the guideline. (This does not disqualify GPs (partner, salaried or locum) with a general interest in the topic through the provision of primary care services, or people employed in publicly funded health and social care services.)

It may also be inappropriate for chairs to have relevant indirect interests, including when a close family member could potentially gain financially from the person's work with NICE.

Standing committees:

Chairs cannot have any direct financial interests that relate to the development, manufacture or marketing of products that may be considered by the committee.

Other financial interests, such as private practice, direct non-financial or indirect interests, can usually be dealt with on a case-by-case basis at the relevant meeting. If these interests cover a significant portfolio of the committee's work, non-appointment may be necessary because the chair may need to be repeatedly excluded from the committee's discussions.

Members and co-optee members (standing and topic-specific guideline committees)

36. Members and co-optees are selected to bring a range of interests and expertise to the committee's discussion. Often these interests need no more than open declaration, but they can result in partial or complete exclusion from the committee discussion when there is a conflict of interest.

Appointing members to all committees

Individual members and co-optees should not be appointed if they have specific interests that mean they are likely to be excluded from more than 50% of the committee's discussions.

Handling interests at committee meetings following appointment (standing committees and topic-specific guideline committees)

Specific interests are those that relate to matters under consideration at a particular meeting, and these interests are where conflicts are most likely to arise. Specific interests include anything that relates to, or informs, a potential recommendation, including all:

products and competitor products

- interventions, including public health interventions and diagnostic tests
- topic areas, such as diagnosis or investigation of clinical issues
- underpinning research papers or economic analyses.

Specific interests do not include having a general interest in the topic under discussion, such as providing NHS, social care, or pharmacy or laboratory services, or through being a salaried employee in a not for profit or commercial organisation that provides these services. t

Income received from consultancy or other advisory services will be treated as a specific interest when it relates to the product under consideration, or the comparator to that product. Advisory services on matters unrelated to these products is not a specific interest. This is explained further in the examples in appendix D.

Before the meeting

- 37. In advance of each committee meeting, the NICE guidance team identifies the issues being considered at the meeting. The NICE guidance team reviews the list of declared interests from the chair, members and co-optees to determine whether there are any potential conflicts of interest relating to these specific areas.
- 38. The NICE guidance team, in consultation with the chair, considers the actions needed and notifies the affected person. In the event of an unresolvable disagreement or uncertainty between the chair and a member of the advisory body, the view of the relevant NICE programme director or authorised deputy must be sought. When uncertainty or disagreement remains, the programme director may decide to escalate the issue to the director. Following discussion with the programme director, the director will either resolve the matter or refer this to the 'conflicts of interest reference panel' for consideration (see appendix B for terms of reference).
- 39. The general approach to handling specific interests at meetings is described below. Whenever the interest leads to excluding the chair, the vice chair will cover that item. Specific examples are given in appendix D.

Approach to handling specific interests at committee meetings

Direct financial interests

40. Any **member or standing committee chair** with a specific financial interest leaves the meeting for the duration of the relevant item, unless

the financial interest has ended and there is no scope to benefit from the committee's discussion; for example, if a person has ceased to hold shares or undertake relevant private practice, or has received sponsorship to attend a past event and has no ongoing relationship with the sponsoring organisation.

- 41. In exceptional circumstances, when a **member** has particular expertise that would otherwise not be available to the committee, they may attend to answer specific questions, but would not usually take part in the decision-making.
- 42. When the interest relates to **private practice** and income in the commercial sector, a **member** can participate if their complete exclusion from the meeting would diminish the committee's access to clinical expertise on the matter under discussion (consideration should be given to whether the relevant clinical experience could be accessed in other ways, for example through written submission). The level of involvement (full involvement or partial exclusion) will depend on the scope for potential benefit (and risk of conflict of interest). For example, full participation may be appropriate if the individual works predominantly in the NHS and the private practice is provided on a sessional basis and mirrors NHS activity. Whereas there is greater scope for a perceived conflict of interest when non-NHS income is directly contingent on the volume of a specific procedure.
- 43. Employment in a voluntary or community sector would not usually lead to exclusion from the meeting. However, if the organisation has expressed a clear opinion on the issue before the committee, this may lead to exclusion on the grounds of a non-financial interest (see below).

Direct, non-financial interests (personal and professional)

- 44. A member or standing committee chair with a specific non-financial interest may need to leave the meeting for the relevant item, if it is felt that the interest (such as publications authored or public statements made) could reasonably be interpreted as prejudicial to an objective interpretation of the evidence. A decision on participation should balance this risk with the benefit of the committee's access to their expertise. Open declaration or partial exclusion will often be sufficient, especially where these views are balanced across the committee.
- 45. When the interest relates to holding office or paid employment in an organisation, it will be important to consider the extent that the organisation has expressed a view on the matters under consideration

- and if this could reasonably be perceived as affecting the individual's ability to objectively consider the evidence under review.
- 46. Involvement in guidelines developed in accordance with international criteria does not usually lead to exclusion from the meeting.

Indirect interests

47. Any **member or chair** with specific indirect interests usually needs to do no more than declare this interest. However exclusion may be needed when a close family member could potentially gain from the committee's work.

Witnesses and other contributors (non-committee members)

- 48. Others contributing to the committee are likely to be either providing expert advice or giving a particular perspective but will not be contributing to the final decision-making.
- 49. Any stakeholder invited to make a written submission to an advisory committee should declare their organisation's interest in the matter under review. This includes any financial interest in the technology or comparator product; funding received from the manufacturer of the technology or comparator product; or any published position on the matter under review. This declaration would cover the preceding 12 months and will be available to advisory committee alongside the stakeholder's submission.
- 50. In the case of oral evidence, every effort will be made to select experts who do not have a conflict of interest that would require a member of the committee to withdraw from the discussion. However, there is discretion to invite an expert with such a conflict when the work of the committee would be seriously compromised without their testimony. For example, in an area where the number of experts is very small and there has been close collaboration between a clinical specialty and the life sciences industry in developing new technologies.
- 51. Where a witness has been nominated by a stakeholder organisation, the individual should declare their own interests and also those of the nominating organisation this includes any financial interest the organisation has in the technology or comparator product; funding received from the manufacturer of the technology or comparator product; or any published position on the matter under review. Where the witness has not been nominated by an organisation, the declaration is limited to their own interests. In both circumstances, the declaration would cover the preceding 12 months and will be available to the advisory committee.

At the meeting

- 52. At each meeting, a copy of all declared interests, including those of the chair, any co-optees, additional invited experts and organisations making written submissions, is made available to the committee.
- 53. The chair asks whether there are any new interests to be added or any potential conflicts of interest specific to the issues being considered at the meeting. This is to confirm, and to potentially add to, the interests that have already been identified before the meeting.
- 54. If a person is aware that a product or service under consideration is, or may become, a competitor of a product or service developed, manufactured, sold or supplied by a company in which they have a current financial (either direct or indirect) interest, this should be declared. (In the technology appraisal programme, competitors are comparator products outlined in the appraisal scope. Potential competitors are products which have been referred by Minsters to NICE for appraisal.)
- 55. The chair informs the meeting attendees of the actions agreed in relation to any specific interests.

Records and publication

- 56. All declared interests that are relevant, or potentially relevant, to the work of the NICE committee are logged on a register of interests for that committee. This is available on the NICE website and at the start of each committee meeting and updated as needed.
- 57. For members and the committee chair, the register will include the interests from the date of appointment plus the preceding 12 months. If there is a reappointment to a standing committee, the register will include the interests from the date of reappointment plus the preceding 12 months.
- 58. For standing committees and topic-specific guideline committees, the interests of those who attended the committee to give evidence or advice will also be published.
- 59. A written audit trail is maintained of the information considered and any actions taken. The committee minutes record the interests declared and action taken in response. Interests are also published alongside guidance publications.

Exceptions

60. If people have substantial grounds for believing that publishing their interests should not take place, then they should contact the Associate Director, Corporate Office to explain why. In exceptional circumstances, for instance when publishing information might put a person at risk of harm or compromise the confidentiality of another person, information may be withheld or redacted. However, this would be the exception and information will not be withheld or redacted merely because of a personal preference.

Wider transparency initiatives

- 61. In keeping with the purpose of this policy, NICE fully supports wider transparency initiatives in healthcare. For example, we strongly encourage people to give their consent for payments they receive from the pharmaceutical industry to be disclosed as part of the Association of British Pharmaceutical Industry (ABPI) Disclosure UK initiative. These 'transfers of value' include payments relating to:
 - · speaking at and chairing meetings
 - training services
 - advisory board meetings
 - fees and expenses paid to healthcare professionals
 - sponsorship of attendance at meetings, which includes registration fees and the costs of accommodation and travel, both inside and outside the UK
 - donations, grants and benefits in kind provided to healthcare organisations.
- 62. Further information about the scheme can be found on the <u>ABPI</u> website.
- 63. As part of the appointment process, publicly available sources of information, such as the ABPI register, should be reviewed to provide assurance that interests are being appropriately declared.

Dealing with breaches

64. There will be situations when interests will not be identified, declared or managed appropriately and effectively. This may happen innocently, accidentally or because of deliberate actions. For the purposes of this policy, these situations are referred to as 'breaches'.

Identifying and reporting breaches

- 65. To ensure that interests are effectively managed, staff, those participating in our committees and stakeholders are encouraged to speak up about actual or suspected breaches.
- 66. Anyone who is aware of actual breaches of this policy, or who is concerned that there has been, or may be, a breach, should report these concerns to the chair of the committee and a senior member of the NICE team.
- 67. NICE investigates each reported breach according to its specific facts and merits and gives relevant parties the opportunity to explain and clarify the circumstances.
- 68. Following investigation NICE:
 - decides if there has been, or is potential for, an actual breach and if so, the materiality of the breach
 - · assesses whether further action is required
 - considers who should be made aware of the breach
 - takes action and clarifies the policy, if necessary.
- 69. A deliberate failure to disclose an interest could in the most serious cases be treated as misconduct and result in referral to a relevant professional body.
- 70. NICE recognises that investigating actual or suspected breaches could potentially be a stressful and upsetting experience for all parties involved. Everyone involved in the process is entitled to be treated calmly, professionally and with respect. NICE will not tolerate abusive or insulting behaviour, nor any attempt to bully someone into not raising a concern. Any such behaviour, if upheld following investigation, could result in disciplinary action. Any staff who feel they are being bullied, or subjected to harassment, because of raising a concern should raise it under NICE's dignity at work policy.

Learning and transparency

- 71. Reports on breaches, the effect of these, and action taken is considered by the executive team and audit and risk committee at least annually.
- 72. To ensure that lessons are learnt and managing interests continually improves, anonymised information on breaches, the effect of these and action taken is published on the NICE website.

Review

73. This policy will be reviewed every 3 years unless an earlier review is needed.

Relevant legislation, guidance and NICE policies

- The Bribery Act 2010, which includes the offences of offering or receiving a bribe
- Freedom of Information Act 2000
- ABPI: The Code of Practice for the Pharmaceutical Industry
- ABHI Code of Ethical Business Practice
- MedTech Europe Code of Ethical Business Practice
- NICE Standards of Business Code of Conduct
- Appointments to advisory bodies policy and procedure
- NICE gifts and hospitality policy
- NICE non-staff re-imbursement policy

Appendix A: process for declaring interests

Committee chairs and members

Declaration of interests submitted with application

Reviewed by senior member of NICE guidance programme to identify whether application can proceed or the candidate is excluded on the grounds of a conflict of interest.



Further declaration of interests submitted when candidate appointed

Interests reviewed by senior member of NICE guidance programme and those relevant, or potentially relevant, to the work of the committee added to the committee's register of interests and published on the NICE website.



Committee members asked to declare any additional interests before a meeting taking account of the items to be discussed

Discussion between chair and guidance team on any declared interests and the position of the committee member at the meeting.



Declared interests available to committee members at the committee meeting

At the start of the meeting, attendees asked to declare any changes to the declared interests and any potential conflicts of interest in relation to the items to be discussed.

Interests recorded in the minutes and added to the register.



Publication of interests alongside final guidance and in committee register of interests



NICE will prompt appointees for annual declaration.

Witnesses and other contributors to committees (that is, non-committee members)

Declaration of interests submitted with application

Reviewed by senior member of NICE guidance programme to identify whether application can proceed, or the candidate is excluded on the grounds of a conflict of interest



Further declaration of interests submitted when candidate appointed

Senior member of NICE guidance programme reviews interest. Interests relevant or potentially relevant to the work of the committee published on the NICE website



Committee members asked to declare any additional interests in advance of a meeting taking account of the items to be discussed

Chair and guidance team discuss any declared interests and the position of the committee member at the meeting



Declared interests available to committee members at the committee meeting

At the start of the meeting, attendees asked to declare any changes to the declared interests and any potential conflicts of interest in relation to the items to be discussed.

Interests recorded in the minutes and published.

Appendix B: conflict of interest reference panel terms of reference

Objectives

- To provide advice to guidance teams, with a short turnaround time, on novel and contentious matters relating to conflicts of interest.
- To help promote consistency in the handling of challenging cases.
- To review decisions made by the reference panel in the previous year on an annual basis, to consider whether any amendments to the policy on declaring and managing interests for advisory committees are needed.

Membership

 Three non-executive directors (including the audit and risk committee chair who will chair the panel) and 2 executive team members from nonguidance producing directorates.

Ways of working

- Email with the option to meet virtually should this be needed. In the case of a meeting, a quorum will be 1 non-executive director and 1 executive team member.
- NICE's Corporate Office will retain a record of referrals to the panel, and the advice given, to inform future cases.

Appendix C: examples of handling interests at appointment

Topic-specific guideline committees: examples of <u>non-appointable</u> chairs

Example 1: Guideline topic - Acute heart failure

Chair not appointable: Cardiologist with specific expertise in managing heart failure, exemplified by a portfolio of research interests and publications in this area.

Rationale: This represents a direct non-financial professional interest (published clear opinion on matters within the scope of the guideline).

Example 2: Guideline topic - Epilepsy in adults

Chair not appointable: Neurologist with private practice that provides specialised epilepsy procedures.

Rationale: This represents a direct financial interest as the areas of work done in private practice are within the scope of the guideline.

Example 3: Guideline topic - Obesity

Chair not appointable: Academic with significant grants for research into diet and obesity from industry bodies.

Rationale: This represents a direct financial interest if they personally receive the grants and a non-financial professional interest in terms of the outcome of the research (published clear opinion).

Example 4: Guideline topic - Physical activity

Chair not appointable: Spouse runs a business providing lifestyle coaching and physical activity sessions.

Rationale: This represents an indirect interest that could be perceived as affecting the judgement of the chair.

Example 5: Guideline topic - Home care

Chair not appointable: Board member of a charity providing home care services.

Rationale: This represents a direct non-financial interest (holds office in a position of authority).

Example 6: Guideline topic - Alcohol interventions in schools

Chair not appointable: Professor of public health at an academic institution, who has research interests in school-based alcohol interventions and has expressed a clear opinion supporting a particular behavioural intervention that is being considered in the guidance.

Rationale: This represents a non-financial professional interest (has published a clear opinion about the matter under consideration).

Topic-specific guideline committees: examples of <u>appointable</u> chairs

Example 1: Guideline topic – Eating disorders in young people

Chair appointable: Adult psychiatrist with a practice focused on anxiety and depression.

Rationale: There are no direct interests in the topic under discussion.

Example 2: Guideline topic - Medicines management in care homes

Chair appointable: Manager of a large care home, which is privately owned and mostly funded by the private sector.

Rationale: There are no direct interests in the interventions covered in the guideline. The manager is salaried so there is no scope for direct personal gain from the committee's work.

Example 3: Guideline topic - Smoking cessation

Chair appointable: Director of public health in a local authority, with no research interests or published opinions on research.

Rationale: There are no direct interests in the interventions under consideration (an expressed opinion that smoking is harmful is to be expected). There is no scope for direct gain from the committee's work.

Example 4: Guideline topic - Asthma: diagnosis and management

Chair appointable: A GP (partner or salaried) who has an interest in asthma, but no recent publications in this area or scope to personally financially gain from the recommendations in the guideline.

Rationale: The GP has a general interest in asthma and primary care services, but there is no scope for direct gain from the committee's work.

Standing committees: examples of non-appointable chairs

Example 1: Committee – Technology appraisal and highly specialised technologies

Chair not appointable: Hepatologist with a significant research portfolio, most of which is funded by the pharmaceutical industry, some as personal payments.

Rationale: The personal payments represent direct financial interests (grants from the commercial sector) that would be perceived as a conflict, and the broad portfolio would probably mean exclusion from more than 50% of the committee's discussions.

Example 2: Committee – Indicator committee

Chair and vice chair: one of these should not be a GP who has income from the Quality and Outcomes Framework (QoF).

Rationale: The committee does not decide which indicators actually enter the QoF, so the ability to influence a direct financial interest is limited. However, should there be a perception that the GP chair is conflicted in a particular instance, the vice chair must be able to step in.

All committees: examples of non-appointable members

Example 1: Technology appraisal and highly specialised technologies

Member not appointable: Member with a broad portfolio of shares in the pharmaceutical industry (unless these are held in managed funds where the person does not have the ability to instruct the fund manager as to the composition of the fund).

Rationale: This represents a direct financial interest and the broad portfolio covering a number of companies would probably mean exclusion from more than 50% of the committee's discussions.

Example 2: Guideline on high blood pressure

Member not appointable: Cardiologist with a broad portfolio of research funded primarily by the pharmaceutical industry, with the funds paid directly to the individual rather than the employer.

Rationale: This represents a direct financial interest and the extent of research portfolio funded by a number of companies would probably mean exclusion from more than 50% of the meetings.

Appendix D: examples of handling specific interests at meetings

Example 1: Consultancy fee received by a committee member from the company producing the product under consideration, or the comparator

Action required: Depends on the nature of the consultancy undertaken.

- Complete exclusion if this relates to the product under consideration, or the comparator, as the interest is a specific direct financial interest.
- Declare and remain if the consultancy is unrelated to the product under consideration or the comparator, as the interest is not specific.

If the consultancy income from the manufacturer of the product under review, or the comparator, accounts for a majority of the person's income then it may be appropriate to exclude the person from the discussion (in the way an employee of the manufacturer would be – see below example).

Example 2: Technology appraisal committee member employed by a company that manufactures a competitor to the product under review

Action required: Complete exclusion –this represents a direct financial interest. It may be appropriate to withhold from the member confidential information in the meeting papers for the topic if these contain commercially sensitive information.

Example 3: Private practice income from the procedure, intervention or delivery of care under consideration

Action required:

- Chairs complete exclusion.
- Members can participate if their complete exclusion from the meeting would diminish the committee's access to clinical expertise on the matter under discussion (consideration should be given to whether the relevant clinical experience could be accessed in other ways, for example through written submission). The level of involvement (full involvement or partial exclusion) will depend on the scope for potential gain (and risk of conflict of interest). For example, full participation may be appropriate if the individual works predominantly in the NHS and the private practice is provided on a sessional basis and mirrors NHS activity. Whereas there is greater scope for a perceived conflict of interest when non-NHS income is directly contingent on the volume of a specific procedure.

Example 4: Publications in which a member expresses a clear opinion about the intervention being considered

Action required: Potential exclusion – this is non-financial professional interest and the response will depend on the nature of the view expressed and the risk to perceived objectivity. In determining the level of involvement, the chair should consider the balance between this risk and the benefit of the member's input to the committee. Open declaration or partial exclusion (i.e. the member to remain in the room to answer questions but not take part in decision-making) will often be sufficient.

Example 5: Grant income received by the member's employer from the company that manufactures the product.

Action required: Declare and remain – this is an indirect interest, because the income goes to the employer.

Example 6: Spouse doing research in the area under discussion.

Action required: Declare and remain – this is an indirect interest with no direct financial gain.

Example 7: Employee of a charity or professional body with an interest in the condition.

Action required: Declare and remain – this is a direct interest, but with no clear financial benefit to the person. However, a person may need to be excluded if they hold a senior position of authority in an organisation that has expressed a clear opinion on the issue, if this could reasonably be interpreted as affecting their objective interpretation of the evidence.

Example 8: Research publications covering epidemiology of the condition.

Action required: Declare and remain –this is not an intervention that might be recommended in the guidance.

Example 9: Previous member of a guideline on the same topic produced by a professional body.

Action required: Declare and remain – the guideline was produced collaboratively by consensus and was not the person's own work. The benefit of their expertise in this topic outweighs a risk of perceived bias.

Example 10: Indicator Advisory Committee member who is a GP

Action required: Declare and remain - while the GP's income could ultimately be affected, the benefit of their expertise in this topic outweighs a risk of bias.

Appendix E: glossary

Interests – examples include employment and other sources of income, speaking engagements, shareholdings, publications and research, and membership of professional or voluntary organisations.

All interests from the last 12 months need to be declared, if in the view of a reasonable person, they could be perceived to be relevant to the work of the NICE committee in question.

A **direct interest** is when there is, or could be perceived to be, an opportunity for a person involved with NICE's work to benefit. Direct interests can be

- Financial where the person gets direct financial benefit
- **Non-financial** where the person gets a non-financial benefit such as increasing or enhancing their professional reputation

An **indirect interest** is when there is, or could be perceived to be, an opportunity for a third party closely associated with the person in question to benefit.

Conflict of interest - when a reasonable person would consider that an individual's ability to apply judgement or act in the work of NICE is, or could be perceived to be, impaired or influenced by one of their interests.

A conflict of interest is most likely to arise when the interest is **specific** – this means it relates to matters under consideration at a particular meeting and/or informs a potential recommendation.