Policy on declaring and managing interests for advisory committees

Frequently asked questions

The following questions reflect the issues that have been raised during implementation of the policy in guidance development. It is not meant to be exhaustive, and the <u>policy</u> itself should be checked in the case of any query.

General

1. What is the relevant time period for the declaration to cover?

The 12 months preceding appointment (or re-appointment) to an advisory committee and at any time during the period of membership of an advisory committee, if a new interest arises. Consideration should also be given to any new interests that are not currently held but are known will arise during involvement with the committee (e.g. a new research project). Where a member is re-appointed to an advisory committee for further terms, the register of interests will include the interests from the date of reappointment and the preceding 12 months.

2. Can chairs of topic specific guideline committees have ANY interests?

Chairs of committees have greater influence over their committee's work. Therefore, chairs of topic specific guideline committees cannot have **any** direct interests that relate to the services, interventions, products, or delivery of care to be considered within the scope of the guideline. This does not include 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.

3. Can chairs of standing committees have ANY interests?

Chairs of standing committees 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 interests or indirect interests, can usually be dealt with on a case by case basis at the relevant meeting. If these interests cover a significant portion of the committee's work, then non-appointment of that individual as chair must be considered as they may need to be repeatedly excluded from the committee's discussions.

4. I am a member of an advisory committee. Does a conflict of interest arise if I have ANY interest in the commercial sector?

Only interests that are relevant, or could be perceived to be relevant, to the work of the NICE committee in question need to be declared. Therefore, a conflict of interest could only arise if the interest relates to the matters you are involved with on the committee. Care should be taken to consider whether your involvement is with the "commercial sector" as defined in page 6 of the policy, and whether the involvement relates to the business under consideration.

5. What constitutes a close associate?

A third party closely associated with the person in question who could potentially benefit. This could be through close association with another person or an organisation. Indirect interests can arise from close relatives, close friends, business partners. Also, through organisations such as employers.

A common sense approach should be adopted - it would be unrealistic to expect chairs and committee members to know of all the interests that third parties in these classes might hold. This declaration is intended to cover interests that an individual could reasonably be expected to know about, and where the third party has scope to materially benefit from the individual's work at NICE.

6. Do indirect interests have to be sub-categorised in the register as being financial or non-financial?

It is helpful to be specific about whether indirect interests are financial or non-financial. This will allow the committee chair and developer to agree how the interest should be handled at a committee meeting. It also provides full transparency.

See also Qu32 which requires consideration to be given to the individual's role on the committee and the potential for exclusion where a third party closely associated with the NICE appointee could stand to materially gain from the committee's work.

7. I am a clinician who undertakes private work. Can I still take part in meetings?

There is not a 'blanket exclusion' of people who undertake private practice.

Full participation will be possible where the private practice does not relate to the committee's discussions.

Where the private practice relates to the committee's discussions, then a committee member can participate if their complete exclusion would diminish the committee's access to clinical expertise on the matters under discussion. The level of involvement (full involvement or partial exclusion) will depend on the scope for potential benefit and the risk of the 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 undertaken.

8. I have co-authored academic papers and books on the matter under consideration and my name is on conference abstracts which are published or will be published in the future. How should this be managed?

This should be declared as a non-financial professional and personal interest. In these circumstances you would need to discuss this with the chair of the meeting who will consider the nature of the views expressed and the risk to your perceived objectivity, balanced against the benefit of the committee's access to your expertise on this matter. You may need to leave the meeting for the discussion or remain in the room to answer questions but not take part in decision-making. Alternatively, open declaration may be sufficient especially where views are balanced across the committee.

9. Do I need to declare membership of professional or voluntary organisations or advocacy groups (this includes royal colleges)?

Membership of a lobbying or pressure group with an interest in health and social care should be declared. Membership of a royal college would not usually need to be declared unless you hold a specific office or position of authority in these bodies and it is relevant, or potentially relevant to the committee's work.

The most likely scope for a potential conflict of interest to arise is where a person may be inclined to, or be seen as likely to, 'promote' the line of a professional body or advocacy group irrespective of the evidence, or where their reputation as an office holder may be affected if the committee decision is not in accordance with the line taken by their professional organisation.

This would be a non-financial professional and personal interest. In these circumstances you would need to discuss this with the chair of the committee to decide on the most appropriate course of action.

10. What sort of organisation may give rise to a conflict of interest in NICE's public health guidance?

Work with companies involved in products that might affect the public's health, including the food and alcohol tobacco industries could represent a conflict of interest.

NB: As part of NICE's commitments under the WHO Framework Convention on Tobacco Control, individuals working for, or holding office in, tobacco organisations cannot be appointed to NICE's advisory committees. (Tobacco organisations include the tobacco industry, and organisations speaking on behalf of, or funded by the tobacco industry.) Further information is contained in NICE's <u>statement on engagement with tobacco industry organisations</u>.

11. I held shares in a life sciences company which I sold last year. Does this preclude me from joining a committee?

This should declared as a direct financial interest which occurred in the last 12 months. An open declaration is sufficient and you are able to become/remain a committee member as the shares are no longer held and there is no scope to benefit from the committee's work.

12. Are all declared interests entered onto the register of interests that is uploaded to the NICE website?

All interests that are relevant, or potentially relevant, to the work of the NICE committee are entered on the register that is available on the NICE website and updated as new interests arise. Interests that are declared but are not potentially relevant to the committee's work do not need to be included on the register.

The published register should include those who attend standing committee and topicspecific guideline committees to give evidence or advice. It should be available alongside guidance publications.

13. Why do committee members have to make an annual declaration of interest when they make a declaration at every committee?

This is to provide a prompt to ensure that interests are kept up to date, and also to enable NICE to identify if there are any interests that are so significant the committee member could not reasonably be expected to undertake any committee work without a conflict arising.

14. A committee member works freelance/self-employed. How should this be handled?

Any work in the commercial sector should be declared if it is relevant, or potentially relevant, to the committee's work.

Income received from consultancy or advisory services will be treated as a specific interest (and require exclusion) only when it relates to the product under consideration, or the comparator to the product.

Advisory services on matters unrelated to these products is not a specific interest and would not usually require exclusion from the meeting. However, 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 them from the discussion (in the way an employee of the manufacturer would be).

15. Can chairs of NHS England's Clinical Reference Groups join a NICE guideline committee?

No. NHS England's Clinical Reference Groups are responsible for writing the NHS service specifications covering wide areas of NICE guideline scopes therefore a conflict of interest would exist. NICE's policy on appointments to advisory committees therefore excludes NHS England appointees to the roles of National Clinical Director / National Specialty Lead / Specialty Adviser (or equivalent) or Clinical Reference Group chair. It also excludes employees of the Department for Health and Social Care, and NHS England staff who are employed in the organisation's national commissioning functions.

16. A committee member is chair or member of another non-NICE committee in a health area related to the topic under discussion, but they are not receiving any payment. How should this be handled?

This would be a non-financial professional and personal interest and action is at the discretion of the chair in discussion with a senior member of the guidance team. Particular care is needed around any reputational interest related to positions held in other organisations, and publications authored or public statements made, which could reasonably be interpreted as potentially 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 the person's expertise.

Involvement in guidelines developed in accordance with international criteria does not usually lead to exclusion from the meeting.

17. Over 70% of social care services are provided by the private sector. Does the policy mean no one from the private sector can be a member of an advisory committee as this would represent a direct financial interest?

Having a general interest in a social care topic as a salaried employee in a commercial organisation that provides social care services is not treated as a specific interest, and will not usually require exclusion from a topic. This is because the individual is salaried and has no scope to directly gain from the committee's work. If the individual is an owner or director of a private organisation and there is greater scope to directly benefit from the committee's recommendations, partial or complete exclusion is more likely to be required. A decision on participation should take account of the risk to perceived objectivity with the benefit of the committee's access to the individual's expertise.

18. Do I have to declare research grants paid to my employer?

Yes. Research grants paid to an employer are an indirect interest and need to be declared. As an indirect interest, this would not lead to exclusion and open declaration will usually be sufficient.

Where research funding is paid to an employer and the individual holds a position in the trial (eg investigator), this should be declared as a direct non-financial professional and personal interest.

19. I work at a university for which I am paid and my university department now has a contract with NICE, albeit with a different work programme. Does this need to be declared?

This should be declared as an indirect interest. However, if it does not relate to the committee's work it does not represent a conflict of interest. Open declaration will usually be sufficient.

Financial interests

20. Do I need to declare the number of shares I hold?

No. You only need to declare the company/companies in which you hold shares where these are relevant, or potentially relevant to the work of the NICE committee. Shares held in managed funds (i.e. where you do not have the ability to instruct the fund manager on the composition of the fund), do not need to be declared.

21. Can committee members accept hospitality (travel and accommodation) from the commercial sector to enable them to attend a conference? Do such expenses need to be declared?

Sponsorship within the last 12 months from the commercial sector to attend a meeting, conference or event should be declared as a direct financial interest when this exceeds funding to support reasonable travel, accommodation and attendance costs (i.e. expenses above a level a public sector body such as NICE would pay).

If the sponsorship took place in the last 12 months and there is no ongoing sponsorship relationship with the commercial organisation, then open declaration is likely to be sufficient as the scope to benefit has ceased.

If the sponsorship was significant, or remains ongoing, then this would likely require exclusion from the committee's discussion if the interest is specific – for example when it relates to a product manufactured by the company that provided the funding. This is because of the greater risk to the individual's perceived objectivity.

Note: if a speaker's fee is paid this would be a direct financial interest (even if travel and accommodation is in line with the level NICE would pay).

When acting in their NICE role, committee members must follow the provisions in the gifts and hospitality policy.

22. Do direct financial interests relate to the manufacturer/owner of the product being appraised or do they relate to the product itself?

This depends on the type of interest.

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.

For other financial interests, an interest is specific when it relates to the manufacturer of the product under review or the comparator.

23. A committee member is employed in a role related to the topics being discussed in the guideline, do they have to declare it?

All paid employment in a role relevant to the scope of the guideline should be declared, including in the health and social care sector, or the commercial sector. If the role is salaried and involves providing NHS, social care, or pharmacy or laboratory services (including in a commercial or not-for-profit organisation that provides these services) which relate to the topics under discussion (e.g. if it's a NHS diabetologist working on a diabetes guideline), this is not a conflict of interest and they will be able to participate fully. The interest will be categorised as direct and financial, but it will not be treated as specific because the role is salaried and there is no scope for the member to personally financially gain from the committee's recommendations.

Similarly, employment in a voluntary or community sector providing these services would be categorised as direct and financial, but not specific. 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 specific non-financial interest. There will need to be consideration of the individual's role within the organisation, and the extent to which the organisation's publicly expressed opinion could affect the individual's ability to objectively consider the evidence under review.

Employment in the commercial sector providing private services, or income received from consultancy or advisory services, will be treated as a specific interest (and require exclusion) only when it relates to the product or services under consideration, or the comparator to the product/services.

24. A committee member is commissioned by the commercial sector to write articles or a book on a matter under consideration. Is this a conflict of interest?

Any published articles and books relevant, or potentially relevant to the committee's work should be declared if published in the 12 months before joining the committee. This will then be handled as a non-financial professional and personal interest. If income was received for this work from the commercial sector, then this will also be a financial interest.

Members should also note the requirement to declare interests which they know are going to arise in the future.

25. Should interests related to competitor products be treated the same way as an interest in the product being appraised?

Yes. 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.

26. A committee member expects to receive future research funding from the commercial sector that might follow from guidance recommendations. Should this be declared?

Declarations should primarily focus on current interests and those in the 12 months before joining the committee (or 12 months before reappointment to a standing committee). However, consideration should also be given to any new interests that are not currently held but will arise during involvement with the committee (for example a new research project).

Personal payment to undertake sponsored research should be declared and handled as a financial interest. If the funding is paid to a third party such as a university department for which they work it will be an indirect interest.

27. A committee member is a GP who may have a financial interest in one or more specific recommendations. Is this a conflict of interest and how should it be handled?

Ownership or part ownership of a healthcare provider, including a GP who is a partner in a practice, should be declared as a financial interest, where this is relevant or potentially relevant to the committee's work.

However, GPs (partner, salaried or locum) with a general interest in the topic through the provision of primary care services are not seen as holding a conflict of interest as there is no scope to personally financially gain from the committee's recommendations.

28. Do I have to declare pension rights in a company I used to work for?

No.

29. In the 12 months before joining a NICE committee, I worked on projects that were commissioned by companies falling within the definition of commercial sector. Do I need to declare an interest?

This should be declared if the projects were relevant, or potentially relevant to the committee's work. It will be a financial interest if the projects provided income directly to you. It may be a non-financial professional and personal interest if the projects led you to publish a clear opinion about the matters under consideration.

Open declaration will usually be sufficient if the financial interest occurred in the last 12 months and is no longer held. If it is a non-financial professional and personal interest then participation will depend on whether the work could reasonably be interpreted as potentially prejudicial to an objective interpretation of the evidence, balanced against the benefit of the committee's access to your expertise.

Non-financial professional and personal interests

30. When would holding office in an organisation lead to exclusion from a committee meeting?

A non-financial personal or professional interest such as holding office or a position of authority in an organisation does not automatically disqualify a member from attending committee meetings. It is appropriate to take a risk-based approach and 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 office holder's ability to objectively consider the evidence under review.

31. A committee member is employed by an evidence contractor used by NICE. How should this be handled?

A committee member who is employed by an evidence contractor used by NICE should declare their interest if the evidence contractor's work is relevant to the committee's work.

If the committee member's work with the evidence contractor involves authoring or coauthoring a document submitted as evidence to the committee then this will be a nonfinancial professional and personal interest and the individual may need to leave the meeting for all or part of the discussion. A decision on participation should balance the risk of this interest being potentially prejudicial to an objective interpretation of the evidence (with a subsequent risk of challenge by stakeholders), with the benefit of the committee's access to the person's expertise. Where the committee member has not contributed through the evidence contractor to matters relating to the committee's discussion, this is an indirect interest. Open declaration will usually be sufficient and the committee member can participate.

32. A committee member has expressed a clear opinion about a treatment or intervention being considered. How should this be handled?

Where a member of a committee, including a lay member, has expressed a clear opinion on a particular treatment or intervention in a journal article, press, media or any other public statement in the last 12 months this is a non-financial professional or personal interest, and the response will depend on the nature of the view expressed and the risk to perceived objectivity of the individual. The chair should determine the level of future involvement in the committee's work, balancing the risk of challenge on the grounds of bias, against the benefit of the member's input to the committee. It may be decided to allow them to remain in the meeting but not to take part in the decision-making. Open declaration may be sufficient especially where views are balanced across the committee. In relation to published research, factors to consider could include the nature of the paper (eg whether it is a summary of other research) and whether it is contentious (eg whether there are opposing studies).

Interests of close associates

33. Is a committee chair or member permitted to have any close associates with interests, including financial interests?

A chair or committee member (NICE appointee) with an indirect interest usually needs to do no more than declare this interest. However, exclusion may be needed where a third party closely associated with the NICE appointee could potentially materially gain from the committee's work. Each case will have to be considered to establish the level of potential risk to the NICE appointee's objectivity.

The decision will depend on the nature of the interest. The key factors to consider are the individual's role on the committee (i.e. their ability to influence the decision making); and the scope for the third party (individual or employer) to materially benefit from the committee's work.

The interest will be "specific" if it relates directly to the matter under consideration at the committee, or "non-specific" if it relates to a general industry or sector. Open declaration will usually be sufficient when the interest is non-specific (i.e. it does not relate directly to the matters under consideration).

Question 5 above provides further information on when an indirect interest should be declared, notably what is reasonable to expect a committee member to be aware of.

34. A committee member has a close associate who is employed by a pharmaceutical manufacturer. Are they precluded from attending any committee where a product from that company is being discussed?

The action will depend on the nature of the relationship between the committee member and associate, and also the scope for the associate to benefit. Exclusion is more likely to be required when there is a very close relationship, and the associate has a senior role more likely to directly benefit from the committee's recommendations.

35. If a committee member's close family member has shares in a pharmaceutical company but they are not related to the intervention being discussed at the advisory committee, do they need to declare an interest in that appraisal?

The shares should be declared if they are held in companies relevant to the committee's work, as this is an indirect interest. This would become a specific interest if the shares are

held in the manufacturer of the product under review, or the comparators, but this would not normally preclude the individual from attending the committee.

Witnesses and other contributors who are not committee members (including stakeholder organisations)

36. Should witnesses be subject to the provisions of the policy in exactly the same way as advisory body members?

External witnesses will be asked to declare their interests at the point they are invited to give evidence.

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 and those of their close associates.

In both circumstances, the declaration would cover the preceding 12 months and will be available to the advisory committee.

Every effort will be made to select witnesses who do not have a conflict of interest of a kind which would require a member of the committee to withdraw from the discussion. However, the relevant NICE Director has discretion to invite an expert with such a conflict where he or she is the only source of advice available and the work of the committee would be seriously compromised without their testimony.

External witnesses will be required to declare their interests at the beginning of their testimony at each meeting they are invited to attend.

37. How does the policy apply to organisations who are making a written submission to the committee?

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 written submission.

38. A witness performs a procedure that is paid for by private practice and that procedure is being assessed by NICE. Is this a conflict of interest?

This should be declared as a direct financial interest and handled in the same way as it would be for a committee member. The witness will be able to give evidence to the committee if their exclusion would diminish the committee's access to clinical expertise on the matter under discussion. It will be important to consider the benefit of the committee accessing the expertise balanced against the risk of a conflict of interest.

39. How does the policy apply to contributors to products that do not use a formal committee process, such as peer reviewers who provide a published commentary?

The principles in the policy for declaring and managing interests apply to expert reviewers and commentators, which do not use a formal committee process. External experts will be asked to declare their interests at the point they are invited to provide a commentary. Every effort will be made to select experts who do not have a conflict of interest of a kind which would require a member of the committee to withdraw from the discussion. However, the

relevant NICE Director has discretion to invite an expert with such a conflict where he or she is the only source of advice available and the product would be seriously compromised without their testimony.

End