

Managing conflicts of interest in the NHS: Q&A for clinical staff

What does this mean for me?

A guide for clinical staff across the health system

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Managing Conflicts of Interest in the NHS: Q&A for clinical staff

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Introduction

"Managing Conflicts of Interest in the NHS – Guidance for staff and organisations" (the guidance) came into force on 1 June 2017 and is applicable to the following organisations, which will put in place organisational policies and procedures to make sure staff can understand and meet the requirements of the guidance:

- Clinical commissioning groups ('CCGs') (through the statutory guidance for CCGs)
- NHS trusts and NHS foundation trusts (through the NHS Standard Contract)
- NHS England (though Standards of Business Conduct)

The guidance does not apply to bodies not listed above (private or third sector healthcare provider organisations, for example). However, those organisations are invited to consider implementing some of the principles of the guidance (where relevant and appropriate) as good practice, and these Q&A will be relevant in that context.

The Q&A's below are based on the principles set out in the guidance, but you should also familiarise yourself with, and apply, your own organisation's policies and any relevant professional codes.

Gifts

- 1. The family of a patient receiving NHS treatment has offered me a £30 gift voucher....what do I do?
 - a. Gifts of cash or vouchers to individuals should always be declined, and some organisations' policies will require such offers to be declared, even where they are declined. For example the statutory guidance for CCGs requires such offers to be declined and declared. You could, if appropriate, suggest that they donate the voucher to the trust's related charity or charitable funds, where it will be used to promote the work of the trust.
- 2. An NHS patient has offered me a case of wine, which I estimate to be worth £45. I have already accepted a bottle of whiskey from this family earlier this year, which retails at £25...what do I do?'
 - a. Because the original gift was valued at less than £50, it was fine to accept this as long as it wouldn't be seen to affect your professional judgement. However, because the cumulative value of multiple gifts from the same family over a 12 month period now exceeds £50, it would not be appropriate to accept the second gift personally. It should be treated with caution and may only be accepted on behalf of the organisation, and should be declared if accepted.
- 3. One of my trust's suppliers has offered me a branded pen....what do I do?
 - a. Gifts from actual or potential suppliers and contractors should always be declined, but the exception to this is low cost promotional items worth less than $\pounds 6$ so assuming it isn't a particularly expensive pen it's fine to accept it. If a gift or more than one gift together is worth more than $\pounds 6$, it should always be declined.

- 4. I contribute to the advisory board of a pharmaceutical company. How should I declare this?
 - a. The rules in the guidance on outside employment will apply. You must declare your role with the pharma company as soon as possible and, in any event, within 28 days from when it arises, to be published on your organisation's register. Depending on your contract of employment, you might need to seek prior approval from your organisation. Approval will depend on your role and duties within the NHS and whether your NHS employer is satisfied that any conflicts of interest which might arise can be either managed or avoided. You should also take personal responsibility for making any decision-making or advisory groups you are part of aware of your interest.
- 5. I am one of a small number of clinicians working in a rare disease area. We are often needed by external organisations, including the pharmaceutical industry, as well as the NHS, to provide expert advice so that correct decisions are made that are most beneficial to patients. Does the guidance mean that I won't be able to sit on procurement panels or advisory committees as a result of such external relationships?
 - a. The guidance does not stop you from fulfilling these advisory / decision-making roles, in fact it specifically states that the default response should not always be to exclude members of decision making groups with interests as this might have a detrimental effect on the quality of the decisions being made. You should make a positive declaration to be published on your organisation's register- this declaration should be made as soon as possible when any new material interest arises, and, in any event, within 28 days of the material interest arising. You should also take personal responsibility for making any decision-making or advisory groups you are part of aware of your other interests so that any actual or potential conflicts of interest can be managed.
- 6. In my NHS role I work in the diagnostics service. I also sit on an independent advisory group which makes recommendations about new scanner development. Do I need to declare this?
 - a. Yes you do. This might be seen to influence how your organisation spends taxpayers' money.

Loyalty interests

- 7. I am the chief nurse for a local provider, but in the move to new care models I am also undertaking a wider role as lead for quality and safety across our accountable care organisation (ACO). How do I make sure my role in the ACO is transparent, so I cannot be accused of favouring my provider?
 - a. The rules in the guidance on outside employment will apply, so you should declare the details of your position as chief nurse for the local provider to the ACO so this interest can be published on their register(s). As emerging ACOs (or other new care models) will differ in the degree to which their governance is formalised, the location and management of register(s) will vary. The important thing is to apply the principles of the guidance and make sure your outside interests are transparent so if in doubt, declare regardless of the formal legal status of the ACO. You must also declare the details of your quality and safety lead role within the ACO to your provider organisation so that this interest can be published on their register(s). You should also take personal responsibility for making any decision-making or advisory groups you are part of (whether within your local provider organisation or within the ACO) aware of your interests so they can be appropriately managed.

- 8. I work for more than one NHS organisation. How should I manage my declarations?
 - You will need to declare your interests openly with each organisation. There is a template form available on <u>NHS England's website</u> but this is not a mandatory form – you should check with each organisation how they require you to make your declarations.
- 9. In my NHS role I work in the neurological service. Every Saturday afternoon I volunteer in my local charity shop. The charity raises money for neurological research. Do I need to declare this as a loyalty interest?
 - a. You don't need to declare this because you are not in a position of authority within the charity. However, if you take on a position of authority in the charity, such as sitting on their board, you would need to declare this as a loyalty interest as it could be seen to influence decisions you take at work.
- 10. My department is recruiting two new members of staff, and a close friend of mine might apply. Do I need to declare this?
 - a. Yes, if you know there is a reasonable chance of them applying. You need to make this known so that the organisation can decide on the right level of involvement for you in the recruitment and / or management process.
- 11. My wife works for a company which supplies surgical equipment to the hospital that I work for. Do I need to declare this?
 - a. If your wife has decision making responsibilities in the company, then yes. If you're not sure, speak to the person in your organisation who has responsibility for conflicts of interest. If in doubt, declare.

Clinical private practice

12. I carry out some private practice in addition to my NHS role. Is this ok?

- a. NHS commitments should always take precedence over private work where there might be a conflict of interest. Otherwise, private practice is fine as long as you declare it to your organisation on appointment or whenever any new private practice arises. You will also need the prior approval of your organisation, except for in emergency situations, and you should not initiate discussions about your private professional services with patients, or ask other staff to initiate such discussions on your behalf. You should not accept direct or indirect financial incentives from private providers other than those allowed by Competition and Markets Authority guidelines.
- 13. How does the guidance apply to referrals made to private services, in which NHS clinicians may have a financial interest?
 - a. If an NHS clinician has a financial interest in a service which is doing, or may potentially do business with the NHS, then they should declare this to their organisation. The clinician must never allow their financial interests to influence, or be seen to influence, decisions they take in their NHS role.
- 14. My trust has asked me to participate in a waiting list initiative / Choose and Book initiative. If I do some of this work privately, should this be declared?
 - a. Yes, any new private practice should be declared as and when it arises
- 15. I am an NHS paramedic but I also work some shifts on private ambulances do I need to declare this?
 - a. Yes, all private work should be declared.

- 16. I do some private work but the sessions are variable from a practical perspective how should I declare this? Does it make a difference whether I am practicing privately in my own name, or being remunerated through a limited company?
 - a. Job plans should be the starting point here. If your job plan indicates variability in private/NHS sessions that is fine, but you should still use your judgement in making a pragmatic declaration such as the average number of hours per week committed to private practice, rather than specific sessions. The method of remuneration doesn't make a difference under the guidance these would both be considered as clinical private practice.

Donations

- 17. My trust has a registered charity; can I make my patients and their families aware of this in case they want to donate?
 - a. You can make them aware of the charity, but you should not actively solicit charitable donations unless this is a prescribed or expected part of your duties for the organisation.
- 18. My trust recently tested the market for potential suppliers of dialysis equipment. One of the potential suppliers has since offered a donation to the trust's charity. Can we accept?
 - a. In these circumstances the donation should be treated with caution and not routinely accepted. It can only be accepted if there are exceptional circumstances present. If accepted, the reason why it was deemed acceptable should be recorded together with the actual or estimated value.
- 19. A national cancer charity is running a campaign to raise research funds and, in my capacity as a cancer clinician, I would like to host a coffee morning to support this campaign. Can I do this?
 - a. Yes, but you need permission from your organisation if you are hosting the event in your capacity as a clinician employed by an NHS body. You will need to issue receipts for all donations made to the fund.
- 20. In my private practice, I am happy for some of my patients to make a charitable donation in lieu of paying my professional fee. Is this still permissible?
 - a. Yes, so long as you take personal responsibility for making sure that any tax liabilities related to such donations are properly discharged and accounted for.
- 21. If a member of staff receives a charitable donation in the form of a funeral directors' cheque, how does the guidance apply?
 - Donations, when received, should be passed to or paid into the charity office, who will issue a receipt indicating which charitable fund has been credited. It is unlawful to make or accept a "charitable" donation to an individual. Organisations should maintain records in line with their wider obligations under charity law.

Hospitality

- 22. I am attending an event sponsored by a pharmaceutical company and lunch is provided. I estimate the value to be £15. What do I do?
 - Provided you have used a common sense approach to estimate the value, there
 is a legitimate business reason for attending, and the hospitality will not affect, or
 be seen to affect, your professional judgment, this lunch can be attended.
 However if the company offering the lunch is an actual or potential supplier or
 contractor then senior approval would be required and the hospitality should be
 declared.

23. I am attending an event sponsored by a medical devices manufacturer and they have offered to pay for my travel and accommodation...can I accept?

- a. You can accept modest offers to pay for travel and accommodation but you must declare them if you accept. You would need senior approval before accepting any offer of first class domestic travel and accommodation or foreign travel and accommodation, or other unusually generous offer. You would also need senior approval if the company offering to pay for the travel and accommodation is an actual or potential supplier or contractor.
- 24. Following on from question 23, does it make a difference whether I attend in my own time or annual leave? What if I am offered payment to attend?
 - a. It doesn't make a difference whether you attend in work time or annual leave. If you have been invited to the event because of your status as an NHS professional you should still apply the principles of the guidance. Regarding payment, we understand that the medical technology industry is moving over time towards support through educational grants to healthcare institutions, professional societies or to conference organisers rather than direct to healthcare professionals. In the meantime, if you are offered payment to attend, you should declare this to your organisation under the "outside employment" section of the guidance.

25. Can I still receive funding from industry for clinical education?

a. Yes – but you will need to declare any funding received under the principles and rules within the guidance. The section on hospitality covers the thresholds for accepting and declaring expenses relating to attendance at education and training events such as meals, travel and accommodation.

Outside employment

26. Since I joined my organisation, I have set up my own company to do some consultancy work. This isn't directly related to my day job...do I still have to declare it?

- a. You should declare any outside employment and other similar engagements such as directorships, charity trustee roles, consultancy work, etc as it arises and in some cases you might be required to seek prior approval from your organisation. Your organisation might have legitimate reasons, within employment law, to know about these outside engagements – even if it doesn't give rise to the risk of conflict of interest.
- 27. I am an academic and have received an invitation to lecture at a conference. Do I need to declare this? And if I am paid for the lecture but I donate my fee to a registered charity, do I still need to declare it?
 - a. Yes you do regardless of who has organised the conference (e.g. a patient advocacy charitable organisation as opposed to a medical devices manufacturer).
 If you receive payment for the lecture which you then donate to charity, you should still declare this to your organisation and take personal responsibility for

making sure that any tax liabilities relating to the donation are properly discharged and accounted for.

28. I sometimes receive offers of payment up to approximately £250 to participate in surveys and focus groups. Do I need to declare this?

a. Yes you should declare this, as it could be seen to influence service or product choices. If the organisation carrying out the survey or focus group is a supplier or contractor doing business (or likely to do business) with your organisation then you should decline the offer.

Sponsored posts

- 29. I have the opportunity to establish an additional post in my team through external sponsorship. This additional capacity would really benefit the team. Can I still do this?
 - a. Yes you can, so long as you have formal prior approval from your organisation. You will need to:
 - i. Get formal written confirmation from the sponsor that the arrangements will have no effect on purchasing decisions or prescribing and dispensing habits - and you should audit this for the duration of the sponsorship.
 - ii. Make sure that the sponsor does not have any undue influence over the duties of the post or have any preferential access to services, materials or intellectual property relating to or developed in connection with the sponsored post. For example, make sure that all relevant companies are invited to open days; do not undertake any mailings on behalf of the sponsoring company.
 - iii. Have a written agreement in place detailing the circumstances under which your organisation can exit sponsorship arrangements if conflicts of interest which cannot be managed arise.
 - iv. Avoid establishing rolling sponsorship of the post unless you have put checkpoints in place to review and confirm whether the arrangements are still appropriate.
 - v. Make sure that the sponsored post holder does not promote or favour the sponsor's specific products, and that they provide information about alternative products and suppliers as well as the sponsor's.

30. An employee in my team is on a sponsored post – I expect all members of staff in my team to shape the duties (both clinical and non-clinical) of their post. Does this put me / them in breach of the guidance?

a. No, as long as this does not mean that the sponsor themselves has any undue influence over the duties of the post or preferential access to services, materials or intellectual property relating to or developed in connection with the sponsored post. As the manager, you must carefully review the activities being undertaken by the individual and be prepared to step in (as set out in local policy) if conflict arises and terminate the sponsorship if the conflict cannot be managed.

31. How does the guidance apply to staff holding honorary NHS contracts?

a. The guidance will apply in full to all those holding honorary NHS contracts. If you hold an honorary contract with an NHS organisation, you should apply the guidance in your capacity as an employee of that organisation and make any declarations to them.

32. The guidance says that rolling sponsorship of posts should be avoided unless checkpoints are in place to confirm that arrangements are still appropriate. Do

you have any recommendations for how these checkpoints should work and how often they should be scheduled?

- a. Organisations should identify these checkpoints at their own discretion, appropriate to the particular post and at the start of the sponsorship agreement. However, some suggested considerations are:
 - i. Confirming with sponsored postholders on a regular basis that they are not being put under any pressure to recommend specific products or dispensing appliance contractors (with reference to the NHS position on direction of prescriptions)
 - ii. Regularly auditing the number of patients using the sponsors' products or dispensing appliance contractor (recognising that trends suggesting bias will be hard to define and may vary) and making sure that patient choice is respected
 - iii. Being prepared to terminate the sponsorship should a conflict arise that cannot be managed.

Sponsored events

- 33. I am arranging an educational event and have been offered sponsorship by a local university and a pharmaceutical company. How do I apply the guidance in both cases?
 - a. If the event will result in clear benefit for the organisation and the NHS, sponsorship can be accepted if it is declared to your organisation, and the same rules apply for both sponsors. Local policy may require that you obtain senior approval before accepting the sponsorship. There must be no breach of patient or individual confidentiality or data protection rules, and no information should be shared which is not already in the public domain or from which the sponsor might gain a commercial advantage. You will also need to be transparent about the sponsor's support and make it clear on all event materials that sponsorship does not equate to endorsement of the company or its products.
- 34. I am arranging a specialty-specific event for clinicians in my area. A pharmaceutical company has offered support for funding the event in exchange for a presentation slot. Can I accept this?
 - a. At an organisation's discretion, sponsors or their representatives can attend or take part in the event but they should not have a dominant influence over the content or the main purpose of the event. You should also consider the requirements concerning confidentiality, commercial advantage and transparency, as set out in question 33.
- 35. My area of specialty lacks funding due to small patient population sizes. Industry can have an important role in providing investment, resources and skills to facilitate change. If I'm organising a meeting, can I still invite a sponsor to speak at an event in a manner that is appropriate to the context of the event or wider project at hand?
 - a. As per question 34 at an organisation's discretion, sponsors or their representatives can attend or take part in the event but they should not have a dominant influence over the content or the main purpose of the event. You should also consider the requirements concerning confidentiality, commercial advantage and transparency, as set out in question 33.

Sponsored research

36. I have successfully applied for funding for a piece of research relating to my clinical area. Do I need to declare this?

- a. Yes, you should declare your source of funding to your organisation. The funding must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, medical device, equipment or service. Your proposed research must go through the relevant health research authority or other approvals process. There must be a written protocol and written contract between you, your organisation, and/or institutes at which the study will take place and the sponsoring organisation, which specifies the nature of the services to be provided and any payment for those services.
- 37. I am involved in research and am about to receive some sponsorship. What is the timeframe for me to declare this?
 - a. Declarations of new material interests which have arisen should be made at the earliest opportunity (or in any event within 28 days) via a positive declaration to your organisation.
- 38. I am part of a research steering committee for a pharmaceutical company. Does the guidance stop me collaborating with pharma in this way and guiding their research programme?
 - a. This will depend on your role and duties within the NHS and whether your NHS employer is satisfied that any conflicts of interest which may arise can be either managed or avoided. The rules in the guidance on outside employment will apply, so you must declare your role with the pharma company and, depending on your contract of employment, you may need to seek prior approval from your organisation. You should also take personal responsibility for making any decision-making or advisory groups you are part of aware of your interest.
- 39. Do the principles in the guidance apply only to NHS research? Or are commercial and university-based research also covered? These are already subject to full ethics committee requirements.
 - a. The guidance applies to all NHS bodies and staff and any research they are involved in by virtue of their NHS employment.
- 40. I have completed some sponsored research, and have some surplus funds left over. Is this issue within the scope of conflicts of interest?
 - a. No this is an issue for the ethics of the research and the agreed purpose of the funds provided.

Shareholdings and other ownership interests

- 41. I hold a small shareholding in a large medical devices company. I don't have any controlling interest...do I still need to declare this?
 - a. If the medical devices company might reasonably be expected to do business with your organisation then yes, you should make a declaration whatever the size of your shareholding. It doesn't matter whether you have a controlling interest or not.
- 42. I have purchased an annuity. I don't manage the fund but I know that it is predominantly invested in the biomedical sciences industry. Do I need to declare this?
 - a. No you don't need to declare shares or securities held in collective investment or pension funds or units of authorised unit trusts.

Patents

- 43. In my spare time I have developed a prototype car radio, which I am in the process of patenting. Do I need to declare this?
 - a. If the patent relates to a product which might be expected to be procured by your organisation then yes, you should declare it. In this case, a car radio wouldn't reasonably be expected to be procured or otherwise used by an NHS organisation so there's no need to declare the patent.
- 44. I am in the process of developing a patentable quality improvement methodology for my clinical specialty. I want to use some of my non-contact time for this; the finished product will really benefit my team. Do I need to declare this?
 - a. Yes, and you will need to seek prior permission from your organisation before entering into any development agreements which impact on the organisation's own time, or use its equipment, resources or intellectual property.

Advisory and decision making groups

- 45. I sit on my organisation's medicines committee, which makes decisions about the medicines and devices we use. What are my responsibilities relating to conflicts of interest?
 - a. Any group making key strategic decisions like this is subject to the guidance. Other examples would be groups making decisions around contracts, procurement or grants. You should make sure that all interests, or potential conflicts, are declared in accordance with local arrangements within 28 days of any changes. In meetings, you have a personal responsibility for declaring any material interests at the beginning of each meeting and as they arise, which will be added to the organisation's register if not already included. If the chair considers that your interest might create the risk of conflict with an item of the group's business, they might take a range of management actions relating to your participation in the group to make sure that this risk is properly managed.

46. Do advisory committees include managed clinical networks and local professional networks?

a. Your involvement in these networks would be unlikely to create a conflict with your role at your employing organisation. If you're not sure, speak to the person in your organisation who has responsibility for conflicts of interest.

Procurement

47. I am arranging a procurement panel for my organisation. How should I apply the guidance?

- a. Nothing in the guidance waives or modifies your other existing legal obligations around procurement. That is (in summary) procurement should be managed in an open and transparent manner, compliant with procurement and other relevant law, to ensure there is no discrimination against or in favour of any provider. You and your organisation should:
 - i. Keep a clear audit trail of how conflicts of interest have been identified and managed as part of the procurement process.
 - ii. Refer to existing guidance published by NHS Improvement and NHS England on procurement processes.
 - iii. Conduct procurement processes in a manner that does not constitute anticompetitive behaviour - which is against the interest of patients.
- b. In putting together the procurement panel, you should make sure steps are taken to identify and manage conflicts of interest. For example, it would be advisable to:
 - i. Review the register entries for each person under consideration for the panel, to make sure that any conflicts are identified. Individuals with

actual or potential conflicts should only be appointed to the panel where you are satisfied that the potential conflict can be properly managed

- ii. Make sure each individual on the panel is aware that they will be 'decision making staff' as a result of this appointment, and that they make updated declarations of interests upon appointment to the panel;
- iii. Where a conflict arises, make sure that it is managed appropriately to minimise any risk to the organisation, and that a comprehensive written record is kept to show how the conflict was managed. This might include removing people from the panel if required.

Identification of interests and publication of registers

- 48. I don't have any interests which create a risk of conflict. Do I still need to make a declaration?
 - a. If you meet your organisation's definitions of "decision making staff" then yes. You will need to update your declarations or make a nil return on appointment, when you change roles and in the annual declaration round arranged by the organisation. Check your organisation's policy to see if this applies to you.

49. How do I know if a conflict of interest is so significant that it cannot be managed without removing an individual from their role altogether?

There will undoubtedly be some circumstances where a conflict of interest is so profound and acute that the organisation is likely to conclude that it is not possible to manage the conflict and the appropriate course of action might be to require an individual to step down from – or not be appointed to - a particular role. The guidance sets out principles to help guide decision making in these circumstances. Each case will be different and will depend on the specific circumstances, and it is impossible for any guidance document to provide a comprehensive and definitive set of rules to cover every potential eventuality. The guidance is intended to complement rather than replace the exercise of good judgement on a case by case basis.

50. Does the organisation need to make publicly available the number of nil returns? I.e. should the register account for 100% of decision making staff?

a. The published register should, as a minimum, account for all interests declared by decision making staff. Best practice would be for the number of nil returns to be specified, so that there is transparency around the number of staff who have no interests to declare. Your organisation should have processes in place to enable staff to make representations that information on their interests should not be published in certain circumstances, for example where this could give rise to a real risk of harm or is prohibited by law.

51. I am a decision making member of staff, and have declared my interests. However I would prefer that these were not made public. Is this ok?

a. In general, no. This guidance is about transparency and public confidence so the default will be to publish the interests of decision making staff. However, your organisation should have processes in place to enable staff to make representations that information on their interests should not be published in certain circumstances, for example where this could give rise to a real risk of harm or is prohibited by law. If you have particular concerns then you should contact the person named in your organisational policy to discuss this.

Breaches

52. I have become aware of a situation at work where I am concerned that the rules around conflicts of interest might have been breached. What should I do?

- a. Your organisation should have a clear policy setting out how to raise concerns, and who to notify or speak to if you are unsure of whether there has been / is potential for a breach. If you are unsure or unwilling to speak to those individuals, you could contact
 - i. Your organisation's Freedom to Speak Up Guardian
 - ii. The local counter-fraud specialist

Disclosure UK

53. In my directorate, only 57% of my clinicians have given their consent to Disclosure UK. How can I improve this?

a. You could suggest that the scheme is included as a discussion point for clinical appraisal, or local clinical excellence awards. If you want to raise awareness by discussing the scheme with your clinicians you can find further details on the scheme: <u>http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx</u>. Whether or not individuals have consented to the scheme, they **must** declare all of their relevant interests on the organisation's register in accordance with the policy. The organisation may also have made compliance with Disclosure UK compulsory under local policy.