BMA

Transparency and doctors with competing interests – guidance from the BMA

British Medical Association
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Introduction

The need for transparency in public life, particularly in relation to financial or other competing interests is now well established. Competing interests arise in medicine where practitioners become involved in arrangements that introduce considerations that may be in tension with the best interests of patients. Although practitioners with direct financial interests attract the most attention, other competing interests, such as professional reputation, or the interests of family and friends or those otherwise close to you, can also give rise to concerns.

Competing interests arise naturally in all areas of professional life and it would be unfeasible and undesirable to try to eliminate them. Even where they do not affect decision making, they retain the potential to undermine trust, both in individual doctors, and in the health profession more widely. Where competing interests cannot readily be avoided, they should be openly and transparently declared.

Competing interests arise in almost all areas of medical practice. In this guidance note we identify specific areas where they araise most frequently and generate the greatest concern. Although in many cases separate guidance exists for different areas of practice, this note is designed to bring brief practical guidance on transparency and the management of competing interests together in one place. Links to more detailed guidance are provided throughout.

Despite the proliferation of guidance and local protocols, in some circumstances the exercise of professional judgment will be necessary. In accordance with GMC guidance, where you have doubts about whether there is a competing interest, it is sensible to act as if there is.

Competing interests – a changing landscape

It has long been recognised that the relationship between the health science industries and the medical profession can give rise to competing interests which extend to medical research and publishing. More recently, successive NHS reforms designed to introduce market mechanisms into health care delivery have led to renewed concern about the proliferation of competing interests, and their impact on trust in the health service.

Changes introduced by the Health and Social Care Act 2012 have transferred responsibility for allocating the bulk of the NHS commissioning budget to clinical commissioning groups (CCGs). Since April 2015 CCGs have been able to take an enhanced role in GP service commissioning. For those CCGs involved in these arrangements, this has led to renewed concern about competing interests.

Competing interests can also arise where central government is directly involved in setting targets, particularly when using financial or other incentives to encourage clinical decision making.

With the increase in private companies and organisations delivering care to NHS patients, doctors and other health professionals are increasingly employed by private contractors. Commercial organisations frequently have strong legal obligations to parties such as shareholders or parent companies. These can be in tension with the interests of patients. Doctors working for private providers who may have concerns about patient care or other aspects of health care delivery can also find that there are contractual restrictions on their ability to respond appropriately. Wherever doctors have concerns about competing interests in their practice, they should consider the following basic principles.

Competing interests – basic principles

- Competing interests have the potential to undermine trust, both in individual doctors and in the profession
- Doctors must not allow their decision making to be influenced by factors not relevant to the overall interests of their patients
- Where possible doctors should avoid getting involved in arrangements that are, or may be perceived to be, in conflict with their primary obligations.
- Where competing interests cannot readily be avoided, they should be disclosed in accordance with best practice and local procedures
- In some circumstances, competing interests are so material that it is not enough to declare them and doctors need to consider whether they should absent themselves from relevant decisions.

Lord Denning and the legal test for bias

> *"The court looks at the impression which would be given to other people. Even if he was as impartial as could be, nevertheless if right-minded persons would think that, in the circumstances, there was a real likelihood of bias on his part, then he should not sit. And if he does sit, his decision cannot stand . . ."* *Metropolitan Properties Co (FGC) Ltd v Lannon* [1969].

GMC guidance – Financial and commercial arrangements and conflicts of interest

Trust between you and your patients is essential to maintaining effective professional relationships, and your conduct must justify your patients' trust in you and the public's trust in the profession. Trust may be damaged if your interests affect, or are seen to affect, your professional judgement. Conflicts of interest may arise in a range of situations. They are not confined to financial interests, and may also include other personal interests.

Conflicts of interest are not always avoidable, and whether a particular conflict creates a serious concern will depend on the circumstances and what steps have been taken to mitigate the risks, for example, by following established procedures for declaring and managing a conflict.

You should:

- *use your professional judgement to identify when conflicts of interest arise*
- *avoid conflicts of interest wherever possible*
- *declare any conflict to anyone affected, formally and as early as possible, in line with the policies of your employer or the organisation contracting your services*
- *get advice about the implications of any potential conflict of interest*
- *make sure that the conflict does not affect your decisions about patient care.*

If you are in doubt about whether there is a conflict of interest, act as though there is.

NHS England guidance on managing conflicts of interest in the NHS

NHS England has issued revised and updated statutory guidance on conflicts of interest in the NHS that are in force from 1 June 2017. The guidance applies to staff working in the following NHS bodies:

- Clinical Commissioning Groups (CCGs)
- NHS Trusts and NHS Foundation Trusts
- NHS England

The guidance is available here: https://www.england.nhs.uk/ourwork/coi/. Where relevant the main features of the statutory guidance are reflected throughout this document.

The guidance from NHS England does not apply general practices or to independent and private sector organisations. Although NHS England 'invites' these organisations to consider implementing the guidance, it is not binding on GPs or those working in the independent or private sector.

GP partners (or where the practice is a company, each director) and individuals in a practice directly involved with the business or decision making of the CCG are subject to NHS statutory guidance for GPs involved in commissioning which is available here: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/revsd-coi-guidance-june16.pdf.)

Types of competing interests

Competing interests in health care are widespread and come in many guises. We list below some of the most frequently identified:

Personal financial interest – the possibility of financial gain, either personally or in relation to a family member – may include direct or indirect payments or financial interests in health providers or products

Non-personal financial interest – the possibility of payment or other benefit to an organisation in which you are employed, including research grants, grants or sponsorship to posts or members of staff

Personal non-financial interest – these include professional or reputational interests that may have a bearing on the matter in hand

Indirect interests – where you may have a close association with another individual who may stand to benefit from a decision you are making.

Guidance on specific areas

In addition to the general guidance outlined above, we set out below more detailed advice that covers those areas where competing interests are more likely to arise for doctors and set out accepted best practice. Where more detailed guidance is available we provide links.

How should competing interests be recorded?

Where competing interests cannot readily be avoided, they should be declared via appropriate channels. In some instances this will involve the use of established workplace procedures. The GMC states that where doctors plan to refer patients for investigation, care or treatment to an organisation in which they have a financial interest, or where there is an unavoidable competing interest in relation to a particular patient, they should inform the patient and make a note in the patient's record. In the absence of specific guidance or existing protocols, doctors should exercise their professional judgment as to the best way of declaring competing interests. It may mean making relevant information available on a practice website.

Commissioning services

Doctors have a valuable contribution to make to the commissioning process. Their clinical expertise and familiarity with the local health economy are key to the success of the process. Policies designed to increase patient choice and plurality of provision, such as Any Qualified Provider, may mean that doctors are more likely to have a financial interest in companies they refer patients to. Following the introduction of the Health and Social Care Act, and the transfer of commissioning responsibilities to newly created clinical commissioning groups, many doctors are directly involved in the commissioning of services. In 2015 new co-commissioning arrangements mean that CCGs can take increasing responsibility for the commissioning of local primary care services. This may mean that GPs will be in practices that are within a CCG involved in commissioning services from their own practices via commissioning committees. All doctors involved in commissioning should be aware of their obligations in relation to competing interests to ensure that the benefits of clinician-led commissioning are realised without undermining trust. Although it may present practical and administrative challenges, including a lack of expert medical knowledge when key decisions are being made, where doctors have a direct and significant financial involvement in services they may be commissioning, they should ordinarily absent themselves from the decision-making process.

Statutory guidance for CCGs on managing competing interests has been developed by NHS England and is available here: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/revsd-coi-guidance-june16.pdf.

Guidance from the British Medical Association on competing interests in commissioning for doctor as both commissioners and providers is available here: http://www.bma.org.uk/support-at-work/commissioning/ensuring-transparency-and-probity.

Key messages in relation to competing interests for doctors as commissioners

- A doctor's primary duty is to the care of their patients. This should inform and guide all commissioning decisions.
- Doctors must act in accordance with the statutory guidance on managing competing interests provided by NHS England.
- Doctors, as commissioners, must declare any financial interests in services that they are involved in bidding for and follow guidance about how to manage these interests. This will normally mean excluding themselves from the procurement process and any subsequent monitoring arrangements.
- The identification, recording and proper management of competing interests in accordance with statutory guidance is key to best practice. It is important that those who may be affected by any conflict of interest are appropriately informed of its existence so they can make decisions appropriately.

Doctors with financial interests in companies

Doctors can have private financial interests and investments in addition to their clinical interests. Where doctors have holdings in health-related commercial enterprises, there is a possibility that perceived or actual competing interests might arise. It is important that doctors are open and transparent about these interests. This protects doctors and their patients and helps maintain trust.

In *Good Medical Practice* the GMC states:

> *You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.*

Where doctors have shareholdings or financial interests in health-related products, companies or providers, they must be declared, either in accordance with local guidance or protocols or by other means. It is important that anyone who may perceive themselves to be effected by such a conflict of interest has access to relevant information about them. It may be possible, for example, to identify competing interests on a practice website.

It may be that in some cases significant financial interests in some health-related services to which doctors may refer for care or treatment – or health products which they may want to prescribe – may give rise to sufficiently serious competing interests that they will need to consider whether it is appropriate to disinvest.

In relation specifically to pharmaceuticals, the BMA believes that it is generally unwise for doctors to form business connections with companies producing, marketing or promoting such products.

Doctors employed by private providers

BMA members have raised concerns about the experiences of some doctors who have moved from NHS to private providers contracted under the NHS. Private providers may have a different culture to the NHS and if they are commercial companies will have fiduciary obligations to shareholders that may, in some circumstances, be in conflict, or be perceived to be in conflict, with doctors' obligations to patients. There may be occasions where, in order to reduce costs, private providers may restrict, limit or reduce services in ways that, in the views of doctors, may put patients at risk of harm. Decisions by private providers to withdraw from or terminate contracts early can also put pressure on the provision of local or regional health services and lead to potential harms to patients.

In these circumstances, a doctor's primary obligation is to the wellbeing of patients. Although it can be difficult for doctors to challenge the commercial decisions of employing organisations, where they have a reasonable belief that such decisions put patients at risk of harm, doctors have a duty to act. In its guidance on raising concerns about patient safety, the GMC states:

> *If patients are at risk because of inadequate premises, equipment or other resources, policies or systems, you should put the matter right if that is possible. You must raise your concern in line with our guidance and your workplace policy. You should also make a record of the steps you have taken.*

In the first instance concerns should be raised with your employing body through appropriate mechanisms. Although this can be challenging, doctors may be criticised later if they identify harms to patients and fail to act on them appropriately. Confidential advice can also be sought from the GMC, the BMA or an appropriate medical defence body. Doctors must also avoid entering into contracts of employment or arrangements that seek to constrain their ability to raise concerns. Any contract intended to prevent a doctor from raising concerns about patient safety is likely to be void under the Public Interest Disclosure Act 1988. Where doctors who are members of the BMA have concerns about their contract they should seek advice from an appropriate BMA representative.

One area of increasing concern is the impact of commercial confidentiality exemptions on the disclosure of relevant information, particularly in relation to assessing the quality of patient care. Although private providers may wish to keep some sensitive commercial data confidential, it is imperative that these clauses are not used inappropriately to prevent the gathering of information to assess the quality of clinical care provided to patients. Where doctors have a reasonable belief that commercial confidentiality is being used to conceal information that could be used to prevent harms to patients, they have a duty to raise concerns.

Guidance from the General Medical Council on raising concerns about patient safety is available here: http://www.gmc-uk.org/Raising_and_acting_on_concerns_about_patient_safety___English_0316.pdf_48902813.pdf.

Guidance from the British Medical Association on Whistleblowing including a link to a telephone helpline for members is available here: http://www.bma.org.uk/support-at-work/whistleblowing.

Incentives and inducements to manage treatment and referral

Health services across the UK are under enormous pressure to make efficiency savings in the costs of the care they provide. Over the years, the government and local health bodies have introduced a number of incentive schemes designed to encourage doctors to make good use of available resources. These have included financial incentives and similar schemes to improve the cost-effective use of medicines such as prescribing incentive schemes, and incentives focussed on specific areas of quality of care. In so far as these schemes are directly linked to patient interests they are unlikely to be problematic and there is no obligation to declare participation. It goes without saying that although doctors may wish to recommend treatments and assessments, they must not put pressure on patients to participate because of the financial benefits that they receive.

In the past, the BMA has raised serious concerns about incentive schemes that reward arbitrary reductions in clinical activity without evidence that it is in the best clinical interests of individual patients. Doctors should not participate in such schemes and should raise concerns through appropriate channels if they have good reason to think that patient safety is or may be seriously compromised by any such scheme.

In its supplementary guidance on target payments and incentives, the GMC states:

> *Health service financial incentives and similar schemes to improve the cost-effective use of medicines have a legitimate role to play in helping to make good use of available resources. Such schemes can also benefit the wider community of patients. But you must consider the safety and needs of the individual patient for who you prescribe.*

Gifts and other inducements

Best practice in relation to gifts and inducements is well established. As the GMC states, doctors must not ask for or accept gifts from healthcare industries or patients and their families, which may affect or be seen to affect the way they prescribe for, advise or treat patients under their care. Similarly, doctors must not offer these inducements to colleagues.

The Association of the British Pharmaceutical Industry (ABPI) publishes a detailed Code of Practice regulating the promotional activities of its members and their interactions with health professionals that includes sections on direct and indirect inducements. http://www.pmcpa.org.uk/thecode/InteractiveCode2016/Pages/default.aspx.

The Code of Practice prohibits the offers of inducements. It states:

> *No gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.*

Some private providers of health services may use direct or indirect inducements to encourage referrals to their services. These can include direct payments or less direct means, such as the provision of facilities or administrative support. Doctors must always refer patients to the most clinically appropriate service, whilst taking into account the wishes and choices of the individual patient.

Guidance from NHS England sets out a number of rules and principles for NHS staff in relation to gifts. These are not binding on general practices and those working for private or independent providers, but NHS England invites the boards or governing bodies of these organisations to consider implementing the guidance.

- Staff should not accept gifts that may affect, or be seen to affect, their professional judgment
- Gifts from suppliers or contractors doing business (or likely to do business) with an organisation should be declined, whatever their value

- Subject to this, low cost branded promotional aids may be accepted where they are under the value of £6.00
- Gifts of cash and vouchers from individuals should always be declined
- Staff should not ask for gifts
- Gifts valued at over £50 should be treated with caution and only be accepted on behalf of an organisation. If accepted they should be declared.
- Modest gifts under the value of £50 do not need to be declared.

NHS England guidance on hospitality

Hospitality, such as the offer of meals, refreshments and other expenses in relation to attendance at professional or educational events is an established part of professional life. It is important however that hospitality is proportionate and avoids giving rise to concerns about undue influence. Drawing on guidance from the ABPI, NHS England sets out the following principles and rules:

- Staff should not ask for or accept hospitality that may effect, or be seen to affect, their professional judgement
- Hospitality must only be accepted where there is a legitimate business reason and it is proportionate to the nature and purpose of the event
- Particular caution should be exercised when hospitality is offered by actual or potential suppliers – modest and appropriate hospitality can be accepted but senior approval should be sought and it should be declared
- In relation to meals and refreshments:
- If their value is less than £25 they can be accepted
- Between £25 and £75 they can be accepted but must be declared
- If their value is over £75 they should ordinarily be refused, unless senior approval is given.

Again, these are not binding on general practices and those working for private or independent providers, but NHS England invites the boards or governing bodies of these organisations to consider implementing the guidance.

Education and training

Medicine involves life-long learning, from medical school through to retirement. The healthcare industries can have an important role in education and training, such as when introducing new devices or interventions that require the development of new skills or techniques. Industry can help sponsor educational activities including continuing professional development. There is however considerable scope for perceived or actual competing interests to develop in relationships between industry and medical professionals. It is important that steps are taken to ensure that the involvement of industry in education and training doesn't undermine, or give the impression that it might undermine, the development of independent and objective clinical judgment. As with other actual or potential competing interests, transparency is key. Doctors should therefore make all reasonable efforts to identify whether commercial organisations are involved in their education and training and to disclose this information using appropriate systems and processes.

As mentioned above the ABPI provides guidance to the pharmaceutical industry on best practice in the relationship between the pharmaceutical industry and health professionals and some of the general principles and overall approach are relevant across the healthcare industries. Key points include:

- The involvement of industry in the provision of education is permissible where it is necessary to deliver resources that provide clear benefits to patients or adds value to the NHS
- Industry involvement in the provision of medical education or resources must not be allowed to compromise clinical independence
- Meetings or other events for health professionals sponsored by industry must have clear educational content. The involvement of sponsoring organisations must be disclosed.
- Travel and hospitality must be proportionate and secondary to the primary educational purpose of the meeting.

Medical research

The healthcare industries have an important role to play in the improvement of patient care and treatment through the development of new medicinal products and procedures. It is essential therefore that they have good collaborative relationships with health professionals. Potential or actual competing interests can give rise to concerns about the openness of research and potential problems in its design, conduct and reporting. Transparency is a necessary part of ensuring confidence in the probity of research and the integrity of research findings. Links to more detailed guidance from a variety of sources is given at the end of this section. Doctors should bear in mind the following key points in relation to transparency and competing interests:

- All doctors involved in research should follow their organisation's procedures for addressing competing interests, as well as any external requirements relating to such interests, such as those of funding bodies
- Potential or actual competing interests should be declared to a manager or other appropriate person identified by your organisation and to any ethics committee reviewing the research
- Competing interests should be disclosed as soon as researchers become aware of them
- All doctors involved in research must declare all financial and commercial involvement or interest relating to their research and its funding
- Doctors involved in research should openly and transparently declare any grant, donation or funding provided in relation to the research they are involved in. These should be declared in research documentation, available to research ethics committees, other appropriate bodies, and participants, as well as on a publicly accessible register
- Doctors must not allow their independent scientific or clinical judgement in relation to a research project to be influenced or be seen to be influenced by financial, personal, political or other external interests
- Some competing interests may be so significant they may fatally compromise the validity or integrity of the research. In these circumstances, researchers and organisations should consider whether they should discontinue the research, or consider whether it can be adequately addressed through special safeguards relating to the conduct and reporting of the research.

More detailed information about the ethics of research is available at the following locations:

Medical Research Council: http://www.mrc.ac.uk/
Health Research Authority: http://www.hra.nhs.uk/
United Kingdom Research Integrity Office: http://ukrio.org/
General Medical Council: http://www.gmc-uk.org/guidance/ethical_guidance/6005.asp.

Publication of research in journals and promotional materials

Most peer-reviewed medical journals have stringent requirements in relation to the identification and disclosure of actual or perceived competing interests. Some links to these are given at the bottom of this section.

Doctors can be involved in medical publication in a variety of roles – as contributors, editors and peer-reviewers. Actual or perceived competing interests can undermine trust in the published medical record and transparency is vital. Transparency protects authors, reviewers and editors and brings credibility to publications. Identifying whether or not a particular interest or payment amounts to a relevant competing interest can sometimes be difficult to identify. When in doubt, doctors should err on the side of caution and disclose.

Doctors involved in publication must take account of the following:

- Authors and reviewers must ensure that all relevant financial interests and any other relevant competing interests are disclosed when submitting material to a journal or reviewing material already submitted. Similarly, editors should ensure that funding sources and relevant competing interests are fully disclosed when working for journals

- Editorial independence is critical to the integrity of medical publications. Editors must not allow sponsors to control journal content and must not allow financial transactions with sponsors to affect decisions about the content of the journal
- Promotional material must go through the same editorial and quality checking process and meet the same standards as the rest of the content of the journal or publication
- Doctors should consider methods of ensuring the publication of all research findings, including negative ones.

Guidance from the BMJ for authors on declaring competing interests is available here: http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/declaration-competing-interests.

Advice from the NEJM on competing interests is available here: http://www.nejm.org/page/about-nejm/editorial-policies.

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