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COMPETING INTERESTS

Briefing: Why do we need a mandatory register of doctors' interests?

Nine out of 10 medical professional bodies think patients have a right to know if their doctor had financial or other links with pharmaceutical or medical device companies. **Abi Rimmer** considers the next steps towards implementing a mandatory register of doctors' interests in the UK

Abi Rimmer *careers editor*

What "interests" are we talking about?

NHS England defines a conflict of interest as "a set of circumstances by which a reasonable person would consider that an individual's ability to apply judgement or act, in the context of delivering, commissioning, or assuring taxpayer funded health and care services is, or could be, impaired or influenced by another interest they hold." These include financial, non-financial, and indirect interests.¹

Lobby group Sunshine UK explains that these interests arise when doctors receive money or benefits in addition to their NHS salary. For example, doctors might be paid by a pharmaceutical company to give lectures, conduct research, or travel to attend conferences.

According to NHS England guidance, the NHS should support staff to understand that "having interests is not in itself negative, but not declaring and managing them is."

Why is a central register in the news?

The matter was brought back to light by Julia Cumberlege in her Independent Medicines and Medical Devices Safety Review report, published last year.² The independent review investigated the harmful side effects of three medical interventions—hormone pregnancy test Primodos, anti-epileptic drug sodium valproate, and pelvic mesh—across the NHS.

A key recommendation of the report was that patients should have the right to know if their doctor has links with pharmaceutical or medical device companies. "The register of the General Medical Council should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors' particular clinical interests and their recognised and accredited specialisms," the report recommended.

"In addition, there should be mandatory reporting for pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions, and individual clinicians."

Currently, there is no central register of clinicians' financial and non-financial interests in the UK. Doctors' interests are, however, often collected by their employer at a local level. Sunshine UK hosts a voluntary register of doctors' interests³ and the Association of the British Pharmaceutical Industry

(ABPI) hosts another, called Disclosure UK, for doctors receiving payments from its members. The Cumberlege report suggested expanding Disclosure UK and making it mandatory.

There is increasing support from the medical community for a central register. A survey by *The BMJ* found nearly 90% of medical professional bodies agree the UK should have a mandatory and public register of doctors' interests.⁴ Those organisations with no official position include the Royal College of Pathologists, Royal College of Psychiatrists, and Royal College of Ophthalmologists.

Why does it matter?

In her report, Cumberlege said that "the healthcare system is reliant on people motivated by the best outcomes for their patients." During the review, she heard from patients concerned that clinicians had been paid or otherwise incentivised by manufacturers in a way that might influence their practice.

Michelle Moffatt, from the patients' campaigning group Sling the Mesh, called for US-style "sunshine" legislation. "Greater controls are needed to mitigate conflicts of interest between device manufacturers and clinicians; there has been too much autonomy without sufficient monitoring," she told the review.

Carl Heneghan, director of the Centre for Evidence Based Medicine at the University of Oxford, told the review that surgeons were paid "and flown around the world to become world experts in the latest mesh device."⁵ He said, "The whole system is commercially conflicted. It's important that if I'm treating you, you should know who's paying me."

In terms of surgical procedures, Neil Mortensen, president of the Royal College of Surgeons of England, says, "If I was going to see somebody and they said, 'You should have implant X or Y,' it would be absolutely right that I knew whether they had a particular interest in that device or implant." Conversely, Mortensen adds, patients might not see a surgeon's interest or expertise in a particular area as a bad thing.

For Susan Bewley, chair of Healthwatch UK and a co-founder of Sunshine UK, a register of interests is about creating trust in the medical profession. "Nobody gives presents to doctors for no reason. The evidence is that even small gifts change behaviour. Why wouldn't your regulator be interested in something that has influenced your behaviour?"

She says that while some doctors might view gifts or payments as a perk of an otherwise difficult job, “if we have a problem with our working conditions, we need to tackle that.” She adds, “These little perks don’t look small when the outside world sees the total amounts that are being spent on influencing doctors.”

What registries currently exist?

Several voluntary initiatives exist, but requirements vary and all are currently voluntary.

Sunshine UK’s whopaysthisdoctor.org website allows doctors to submit amounts within financial brackets, such as £2000-5000 (€2320-5801; \$2834-7085) rather than forcing doctors to disclose exact amounts.

Bewley says the idea was to pilot a form “to see if it is manageable.”

“It was done on a voluntary basis because the GMC declined the suggestion that it was their responsibility,” she says, adding, “It is obvious that the only place you can hold this information centrally and make it matter—because it does matter—is through the GMC register. It doesn’t have to be on the register, but it must be connected to it. It’s also obvious now that it can be connected through annual appraisal.”

Separately, the ABPI’s Disclosure UK records payments and benefits in kind made by pharma to doctors, nurses, and other health professionals and organisations. All ABPI members, and other companies who have signed up, disclose certain payments and other benefits in kind made to healthcare professionals. There is no minimum amount required for disclosure.

Under data protection laws, however, healthcare professionals can refuse to have their name published. So, while the amount awarded to a healthcare professional would be submitted to Disclosure UK by a pharmaceutical company, the recipient can opt to remain anonymous.

In 2017, the Academy of Medical Royal Colleges recommended that all doctors should voluntarily comply with Disclosure UK. But, two years later, just 55.9% of healthcare professionals (including doctors, nurses, and others) who had received non-research and development funding had agreed to be named on Disclosure UK, according to the APBI.

That same year, pharmaceutical companies spent £160.9m on non-research and development collaborations with healthcare organisations and healthcare professionals.⁶ Of this, £3.6m was spent on registration fees, £34.1m on sponsorship agreements with organisations or third parties, £10.4m on travel and accommodation, £44.2m in donations and grants to organisations, £56.6m on fees, £7.5m on expenses agreed for services or consultancy contracts, and £4.6m on “joint working.”

But is the APBI the best place to hold such information? Bewley describes this as being “like putting the fox in charge of the chicken coop.”

“It’s a marvellous initiative but they are not a safe holder of the data,” she says, “They should hand all of the information over to the GMC, then the task would be less onerous for doctors. We can’t have the ABPI responsible for holding the trust of the medical profession.”

Richard Torbett, chief executive of the ABPI, said the organisation was proud of Disclosure UK. “We continue to work with medical communities to encourage as many healthcare professionals as possible to agree to be included by name on Disclosure UK and

support the ambition of the Cumberlege review to improve individual disclosure.”

In addition, many doctors and medical academics will be used to declaring their interests to their employer, conferences, and journals. Different organisations require different levels of disclosure, which can be confusing and time consuming for those declaring. For example, doctors and experts sitting on the Joint Committee on Vaccination and Immunisation are required to declare competing interests going back only 12 months.⁷ In contrast, *The BMJ* asks authors to declare interests in the 36 months before the declaration and those known to be occurring during the next 12 months.⁸

Bewley explains, “Academics are used to it. We’re just fed up with filling out a form every time, which is sometimes incredibly complicated. A lot of people who declare their interests regularly would welcome a simpler way of doing it.”

Margaret McCartney, a GP and health journalist, agrees with the Cumberlege review that the GMC is the only organisation suitable to hold a register of doctors’ interests as it is the only organisation that holds a list of all registered doctors in the UK.

The GMC did not comment on whether it would be willing to hold a register of doctors’ interests.

What would a central register of interests look like?

Mortensen says, from his own perspective, a central register should include any kind of financial interest a doctor may have in a device or medicine. “We want patients to know they are getting unbiased advice around what they should have done and what they should have implanted in them.

“Obviously if a company is giving any kind of financial support for travel or for educational activities that should be declared,” he says, “Around the edge of direct surgical care there would also be the question of whether you have any shares in companies which would give rise to a conflict of interest.”

The register, Mortensen says, would need to be easy to use and not cost doctors a lot of money. “We’d need to be convinced that it was light touch, effective, and that it was going to make a difference.”

For McCartney, the aim of any central register should be to decrease bureaucracy for healthcare professionals and increase transparency for patients. “Any register that we use has to be done on the understanding that that is the central register that anyone who asks for your conflicts should be using, for example NHS trusts, academic institutions, journals, conferences,” she says. “These third parties could collect the data from the central register and then doctors could be asked to confirm that it’s correct.”

McCartney and a team of researchers have been assessing the current practice of declarations of interest in the NHS. “We’ve found that some places are doing very well with template driven declarations of interest, in other places the information that’s collected and published seems to be random. A central register would be a better way.”

Finding out whether someone doesn’t have a declaration of interest can be remarkably difficult, she says, because it’s trying to prove a negative. “Unless you have a positive declaration that someone has no declaration to make you can end up chasing your tail.

“The advantage of having a central register means that if someone has a declared competing interest you know it must be there.”

What about other healthcare professionals?

In response to the Cumberlege report, the government said that any publication of declarations of interest should cover all clinical decision making staff, not just doctors.

Cumberlege told *The BMJ* that the situation for each profession should lie with their regulator. “But doctors are the principal decision makers in patient care, they determine the treatment, they perform surgery,” she says. “It is with doctors that we must start.”

Bewley agrees, “While we know that there is a lot more money being used to influence people making decisions outside of the medical profession it is ridiculous to say that a register for doctors has to wait for everyone else.” She adds, “This is where doctors and the GMC should be showing leadership. It’s clear that the most expensive, most frequent, and most harmful decisions are made by doctors.”

Colin Melville, medical director and director of education and standards for the GMC, says that the regulator had listened carefully to the findings of Cumberlege’s review. “Our guidance states that doctors must be open about conflicts of interest, including when it is uncertain whether or not a conflict exists. It is clear that changes are needed to make sure patients have access to this information to support them in making decisions about their care. It is vital that we create a culture of greater transparency and honesty.”

How does it work elsewhere?

In the US, the Physician Payments Sunshine Act 2010 places a statutory responsibility on medical product manufacturers to declare any payments or other transfers of value (including expenses) valued at over \$10 made to physicians or teaching hospitals. Anyone can search the Open Payments database for their doctor or healthcare organisation and see if they have received payments, including for research, meals, travel, gifts, or speaking fees.

Among countries in the Organisation for Economic Co-operation and Development, six others have adopted statutory “sunshine” regulations: Denmark, France, Greece, Latvia, Portugal, and Romania.⁹

In France, the Bertrand Law requires that payments to health professionals and health entities are accessible on a government website.¹⁰ Under the provisions, any direct or indirect transfers of value over €1 to health professionals, including doctors, must be reported.⁹ France has also prohibited sales representatives from providing physicians working in an outpatient setting with free samples and gifts, including gifts of food.¹¹

Commissioned, not peer reviewed.

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