VIEWPOINT

Interventional cardiology and the medical devices industry: is there a conflict of interest?

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There is a clear potential for a conflict of interest in the interaction between the medical devices industry and interventional cardiologists. To be an interventional cardiologist and not acknowledge this is naïve and potentially damaging to the specialty. A conflict of interest may be defined as: a set of conditions where a primary interest (such as a patient's welfare or the validity of a piece of research) tends to be unduly influenced by a secondary interest (such as financial gain). The conflict is not always, however, about financial gain. Influence over an individual can also be secondary to an enhancement of reputation; either of that individual or of his/her department. The combination of enhanced reputation and financial gain can, of course, be self-perpetuating.

An example of such a potential conflict can be highlighted by the following example. An interventional company may approach an individual or department asking them to take part in an important scientific study, using a device, which will be scientifically valid and will enhance the reputation of the institution. However, the company stresses that the department will only be given access to this study if the department is prepared to put patients into a "real world registry" for which the device will be paid for by the institution. The dilemma for the individual and the institution is clear, especially if the data for the device are less than robust. Although the interventional community would all like to claim this scenario never happens, it is clear that it does, with an unfortunately high frequency.

This topic has become particularly important recently because of two high-profile "events". First, the very late stent thrombosis issue of drug-eluting stents (DES) has called into question the integrity of clinical investigators in this arena and the validity of clinical research sponsored by the devices industry.¹ During the ESC in Barcelona, Drs Camenzind and Nordmann questioned the outcome following the use of DES, suggesting an increased incidence of very late stent thrombosis and non-cardiac death with DES.^{1,2} The associated commentary by Dr Salim Youseff questioned the basis of the evidence to treat patients with angioplasty, hinting at an unhealthy association between interventional cardiologists and the industry,³ including the suggestion to establish "...a committee to find out what the real role of PCI is, of these stents, and keep industry out of it". This led to headlines in national newspapers in the UK and has subsequently been associated with a 10% fall in the use of DES worldwide. Subsequent presentations have called into question the validity of the ESC presentations, but undoubtedly there is a "case to answer".

The second event was the death of a patient during Transcatheter Cardiovascular Therapeutics (2004) while undergoing a revolutionary, live, percutaneous aortic valve replacement. *BusinessWeek*, a financial newspaper in the US, carried an article about this sad event.⁴ The article questioned whether the technology was refined enough to be ready for "prime time" and asked the question, "Did Leon's financial stake in the experimental device play a role in its being promoted at an important conference where he is the most prominent figure?". Dr Leon strongly denied this and rightly stated that the question "bordered on the offensive", which we would all agree with. Nonetheless, this is a position we have all faced ourselves; and the higher influence we develop in our community the greater the potential to be accused of a conflict of interest.

Clearly, interventional cardiologists have had a number of new devices to choose from over the years, ranging from balloons, stents, patent foramen ovale and atrial septal closure devices, to percutaneous myocardial revascularisation, thrombectomy and atherectomy catheters. Interventional cardiologists are also the "gatekeepers" of the system, receiving patient referrals, making diagnoses and potentially deciding on treatment options. Sometimes all of these processes are made without discussion with the multidisciplinary team (including surgeons!). This is an unhealthy process that should be discouraged. Potentially we are the gatekeepers to new technologies with the possibility of a financial interest in the use of that technology via a start-up company.

So, is the association all good or all bad? What are the pros and cons?

There are many positive parts of the unique association between the interventional community and the medical devices industry in the UK and beyond. The industry makes a major contribution to training, education and research to individuals and institutions at local, national and international meetings. Much of the learning experience, certainly in PCI, involves the sharing of experience during didactic lectures and live cases in these meetings. Meetings such as these (essentially an integral part of junior doctor training in interventional cardiology) are frequently sponsored by the medical devices industry. One point of view is that this is "added value" and saves money for any healthcare system; in this case the NHS. Another potential positive of the association may be physician-led advisory boards of the devices companies, which should allow physicians to steer

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Abbreviation: DES, drug-eluting stents

product development toward the improvement of devices and patient care.

The potential downside of these arrangements is at the core of the conflict of interest argument. Funds directly passing from industry to an individual or institution could, of course, potentially influence a future tender for product purchase and the possibility for inappropriate decision making on the part of the physician is high. In addition, managers within a healthcare system could see that this added value of a product actually increases costs to that healthcare system. Unbundling of the costs of the device and the "other" costs carries an attraction to administrators of any healthcare system. Within the UK this results in a body entitled the NHS Purchasing and Supply Agency (PASA).⁵ Recently, PASA attempted to introduce a system for the central purchasing of pacing and related devices in the UK. The pacing community were reluctant to follow this line and this proposal has not been progressed; for the moment!⁶ Many of us believe there may be some merit in unbundling the true cost of a device and the added value, but are concerned that the healthcare system would not agree to paying for the "extras", that the companies would be unable to continue to support such activities if their profit margins were cut; and therefore this element of the physician and education "care" would be left in limbo. The availability of very cheap products but with no expertise to implant or maintain the devices would not enhance the service to our patients.

So, how can we avoid this potential conflict of interest? First, the very acknowledgement that there is a potential problem is a positive step. Following this, there are a number of measures that can be taken by individuals, institutions and national and international bodies.

It is clearly unhealthy for an individual or institution to use just one product supported by one company, even within a tender system. All support should be declared within a central registry within a hospital. Transparency in all aspects of interaction with our industry partners should be paramount. Many research fellows are sponsored by industry. Such posts, if sponsored by a single company, are open to a major conflict of interest and "multi-company" sponsorship of research posts would appear more appropriate in the form of unrestricted educational grants. Similarly, if possible, the sponsorship of local, national or international meetings by a single company should be discouraged. Live meetings are particularly susceptible to a potential conflict of interest. Display on screens of a particular product used (essentially advertising of that product) should be discouraged.

International multi-centre interventional trials are frequently sponsored by industry. They are expensive to perform and without industry money it is unlikely that progress would be as fast as has been seen. Many of us are sceptical that "blue-chip" funding would step in to take over funding of such projects should industry withdraw, and we believe the pace of advancement of medical devices would slow. However, multi-centre interventional trials should be performed to the highest scientific standards. This should include independent monitoring of the data by safety and events committees, which are made up of highly respected members of the interventional and non-interventional community with no industry representation. Unrestricted educational grants by industry might be seen as the ideal, purest, funding of studies by the devices industry. Physicians' interpretations and "weighting" of research trials should be guided by adherence with the above models.

CONCLUSIONS

The potential for a conflict of interest and the medical devices industry is important and should be recognised. Avoiding this conflict of interest is vital to maintain the trust between our specialty, patients and the regulatory authorities. Transparency in all aspects of the working life of an interventional cardiologist should ensure that this potential conflict does not become a reality.

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