EDITORIAL

Which research is to be believed?

THE ETHICS OF INDUSTRIAL FUNDING OF ORTHOPAEDIC RESEARCH

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Thirty years ago, the involvement of industry in supporting orthopaedic research was minimal. Papers published in orthopaedic journals generally came from research-active individuals or institutions and issues of trust, bias and conflict of interest were few. Since then, orthopaedic surgery has undergone a dramatic transformation. Successful new treatments have produced substantial and indisputable benefits to patients suffering from a variety of traumatic, degenerative and congenital disorders of bone and joint. Alongside this expansion in available treatments has been the flourishing of an ‘orthopaedic industry’. Much of this activity has concentrated on the development of implants and, to a lesser degree, operating theatre equipment, splints and orthoses. The development and regulation of implants differs in some ways from that of the pharmaceutical industry. Many of the original ideas regarding the design and use of an implant in orthopaedic surgery came from an interested surgeon. Subsequently, modifications may have been introduced, either by the surgeon inventor or by colleagues. The industry itself has also participated in modifications of design aimed both at improving clinical outcome and at increasing market share.

During this same period of 25 to 30 years, funding of research in orthopaedics has shifted from a predominantly charitable or foundation-based system, to one in which industrial support has an increasing if not a majority role. This is true not only for research activity but also for education and sponsorship of meetings and conferences. This change has been met with enthusiasm. The universities and the Government have actively encouraged collaborative research programmes. Publicly-funded or charitably-funded research is usually undertaken without a vested interest in the result. Industrially-funded research clearly has the desire to discover positive things about the treatment or implant under investigation and for these results to be presented at scientific meetings and published in peer-reviewed journals. This, however, produces both perceived and actual bias. The orthopaedic community has responded to this new situation and most societies and journals now require detailed statements of disclosure from researchers wishing to present or publish work. While individual researchers may not believe that their results and conclusions are influenced by the source of funding, the evidence would suggest otherwise. The public perception of industrial involvement in research funding is at best one of considerable concern. This debate is clearly not restricted to orthopaedics and in almost every area of science, and medicine, industry and academia have become significantly entwined. In most fields of research the argument is just as much about how the research is funded as to what the science shows.

Acceptable forms of research involve the reimbursement of costs which are strictly necessary and are able to withstand public scrutiny. This includes the support for both designated research projects and educational meetings. Researchers should disclose all their support, its source and its level. Published research should not be subject to restrictions from the industrial partner, either in terms of timing or content. If financial rewards, such as royalties or consultancy payments, are part of any contract of research, these should be disclosed.

In February, the Director of the National Institute for Health (NIH) in the United States decided to ban all NIH researchers from acting as consultants for drug, medical or biotechnology companies.1-3 The potential to hold shares in companies was also restricted. This followed a report of considerable conflict of interest amongst NIH research workers who had received large sums of money for endorsing particular drugs. More recently in the case of an 18-year-old boy who had died during a gene therapy trial, the United States Department of Justice penalised both the researchers and the university involved. A recent paper by Mello,
Clarridge and Studdert\(^4\) reported that 70% of funding for clinical drug trials in the United States is from industry. They investigated 107 institutions and found that although only a small number were prepared to allow the industrial partner to decide whether the results should be published, approximately half allowed the funder to be involved in the analysis of the results. In a recent report by Shah et al\(^5\) in the journal *Spine*, more than 500 articles were reviewed. Industrial support was reported for 15%, foundation support for 12.7%, government support for 10.2% and institutional support for 3.2%. No funding was reported for the remaining 57.9%. The odds ratio of industry-funded research reporting positive results was 3.3 times that of studies with any other source of funding. The authors concluded that studies funded by industry were statistically more likely to report positive results.

Clearly orthopaedic surgeons involved in industrially-funded research should never put themselves in the position where they are undertaking ethically unjustifiable research, with potential risks or harm to patients. On the other hand, the draconian line taken by the NIH would strip orthopaedic surgery of an important source of funding and would inevitably result in a reduction in both the quantity and quality of research performed in orthopaedic departments around the world. What is the solution? The answer is surely that at all levels scrutiny and professional standards must be observed and maintained.\(^6\) The individual researcher, their institution, local ethics committees, journals and the industrial funder should scrutinise the ethics of the research proposed and understand and disclose all conflicts of interest. Any connection between an individual’s or an institution’s choice of implant or equipment and the award of a research grant should be avoided. Ideally, industrially-funded research should be subject to some form of external peer review where modifications to the design of the study are accepted and incorporated if necessary.

What is clear is that the public concern over the quality of published research will continue. To ignore the problem and fail to put in place appropriate measures will make it much more difficult to solve in the future.

**References**