

THE ORTHOPAEDIC SURGEON AND INDUSTRY

Like other medical specialists, orthopaedic and trauma surgeons have a very close relationship with the medical device and pharmaceutical industry (1). Apart from newly developed drugs, are new instruments and implants for trauma and orthopaedic operations. Thus, there often exists a complex relationship between the surgeon and the medical devices industry. In many countries, industry has played an important role in improvement of healthcare provision. It has contributed a lot in the way of providing support for education, surgical training, continuing professional development activities and support for conferences. Where new implants or instrumentation systems are being introduced, industry provides opportunities for the surgeons to familiarize themselves with the products, and hopefully form their own informed opinions on the need to adapt the same (2). In some cases, the representatives from the companies are present in the operating theater, ensuring that all the instruments and components needed are on hand and ready for use (3). Ultimately, this relationship should, ideally, translate to benefit to the patient.

However, potential pitfalls abound in this relationship. These pitfalls may sometimes cross professional boundaries, and ultimately affect the benefits that accrue to the patient. The benefits due to the patient should never be sacrificed at the altar of benefits to industry or the surgeon. The pitfalls range from conflict of interest to frank bias. The patient-surgeon relationship is based on the principle of beneficence, the surgeon acting in the best interest of the patient when deciding on a treatment method. The surgeon, on deciding a course of treatment considers the patient's condition, goals and the available treatment options (4). This, clearly, does not include benefits to the surgeon or industry. The main interest of the orthopaedic industry, however, is to sell their products, useful in treatment of musculo-skeletal conditions, and ultimately make a profit (5). Where there is no robust evidence guiding treatments, the surgeon sometimes relies on colleagues, local or regional influence leaders, continuing medical education presentations, or information from industry (4). Clinical evidence from industry sources has however, been shown to be potentially biased (6,7), whilst key opinion leaders may have undeclared conflicts of interest. Direct financial or non-financial gain by the surgeon may also lead to intrinsic bias. This gain may be in the form of paid honoraria, being a consultant or key opinion

leader of a certain product, sponsorship to educational activities or stock options. This intrinsic bias may influence decision-making, research output and potentially lead to worse outcomes for the patient (8,9). The introduction of some metal-on-metal hip arthroplasty implants into routine clinical practice without proper evaluation, and their subsequent failure comes to mind (10,11). The rate of rise of spinal fusions worldwide, disproportionate to the increase in the numbers of patients requiring it has also been attributed to an increase in marketing and use of spinal arthrodesis implants (12-14). A survey of physicians involved in generation of clinical practice guideline and appropriate use criteria, for the American Academy of Orthopaedic Surgeons showed that many of them received substantial payments from industry (15). It is possible that patient care could be compromised due to the conflict of interest amongst the contributors to these clinical practice guidelines.

Similar to the cold war nuclear arms race is the frequency with which newer implants and technologies are introduced and marketed. Scarcely does a year go by, without a new hip replacement being introduced, presented as an improvement, and offering often unproven, advantages over the older implants (16). These newer implants tend to be more expensive, and sometimes the unwary surgeon may fall into the trap of believing that these newer and more expensive treatments are better or superior than others. The Charnley low friction hip arthroplasty has had good long-term outcomes, with survival analysis showing a 10.7% probability of revision at 20 years (17). There has however been a rise in the use of cementless implants, which, though useful for a specific patient population, may not be cost-effective and do not improve health outcomes sufficiently to justify their higher costs (18-20). For fixation of displaced distal radius fractures, the anatomic locking plates have also edged out the humble Kirschner wire, though the DRAFFT trial showed no difference in functional outcome in patients with dorsally displaced fractures of the distal radius treated with Kirschner wires or volar locking plates (21).

Certainly, these concerns of conflict need to be addressed, whilst maintaining a robust relationship between industry and the surgeon. At the individual level, surgeons must take on the responsibility to independently and critically appraise new technology and devices, and their role in shaping surgical care.

In choosing treatment, the surgeon must also ensure that all reasonable alternatives are explored. Regulatory bodies and professional associations need to also have explicit statements as far as conflict of interest is concerned. The American Medical Association and the American Academy of Orthopaedic Surgeons require that any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value, should have “no strings attached” and should not include cash payments (22,23). It would be worthwhile, as the Kenya Orthopaedic Association, to come up with similar statements to guide the relationship between members and industry. The surgeon must also bear in mind that a disclosure of conflict of interest does not absolve him/her from making decisions that are in the best interests of the patient, and must ensure that his/her own interests, or those of industry, do not trump those of the patient.

The role of industry in advancement of medical care cannot be gainsaid, with many advances in medicine having come from partnerships between industry, medicine and academia. Objectivity and independence in these partnerships need to be scrupulously protected and preserved, even if that means publication of findings which may not be favorable to the sponsoring entity. Clinical decision-making by the individual surgeon must always focus on what is in the best interest of the patient. Financial incentives may impede such decision making and have no role in the practice of orthopaedic surgery (4).

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