Conflict of Interest & Transparency

The ROYAL COLLEGE of OPHTHALMOLOGISTS

Background Document

Introduction

Increasingly, the relationship between the industry that generates healthcare products and the healthcare professionals who use these products is being closely scrutinised. Both industry and healthcare professionals have a common goal, to treat and cure disease and alleviate suffering. For each, however, the motivation and/or the perception of it, is different. Industry develops and markets products to help patients and make financial gains in the process. Healthcare professionals use these products to do the best for their patients. Inevitably there is a grey line (area) where activities overlap. Industry may use the services of healthcare professionals to promote their products and healthcare professionals may develop products or work with industry for financial reward. When the grey line is crossed in either direction or when individuals work in the grey area, there exists a 'Conflict of interest' (COI). Often an individual may not be aware that he/she has a COI.

Having a conflict of interest is perfectly legitimate and is not to be construed or depicted as a stigma. It has to be managed such that in all its aspects: the nature, the extent, the reward, is there for all* to see (*patients, colleagues, managers, paymasters, funders and the public). The word 'Transparency' in this context reflects the disclosure of the COI.

The purpose of this discussion is: (a) for Council to examine the intricacies of COI and review College policy and documents on COI; (b) for Council to consider revision of policy and documents to make them more robust, comprehensive and transparent; (c) following from these deliberations, if needed, to give a lead to the Scientific committee to review College statements and guidelines related to management of age related macular degeneration† (†I have received several letters expressing concern on the College's position on this issue).

The objective is to ensure that our processes are in keeping with international standards on COI and Transparency and thus protect the College and its members from any aspersions or outright accusations. The outcome of this discussion will form the basis of the College's approach to all relevant matters until the next review.

1. BACKGROUND

1.1 ***One side of the coin***

Facts about Industry

i. We work in partnership with industry (Device, Instrument and Pharmaceutical - DIP). We are able to provide modern treatment to our patients because of the invention, innovation and development of products by industry. Much of what we take for granted in our daily clinical practice is a derivative of DIP industry.

ii Industry and scientists/clinicians have to work closely together to evaluate safety and efficacy, and one may add cost effectiveness of DIP, both before and after release for widespread clinical use for post release monitoring. Many adverse or unexpected beneficial effects of DIP come to light following widespread use over varied populations and for a longer duration than the clinical trial.

iii Industry has to deploy considerable resources (including financial) to bring DIP to clinical use. This includes development from laboratory to clinical trials and complying with regulations in different countries.
iv For all products that we see clinically there are an unknown number that do not see the light of the day, adding to the overall cost and expenditure incurred by industry.
v Industry is a business. Some are publicly owned and accountable to shareholders. They are in it to make a profit and 'sell' their product. They do try and deliver quality DIP products but at a price.

Conclusion: We need industry.

1.2 The edge of the coin – the interface

Industry employs scientists and clinicians but also takes ideas from scientists and clinicians working in the NHS or equivalent (in different countries) – and develops them and scales them for mass production.

Some clinicians and scientists patent their ideas and seek industry help to develop them, for example by assembling prototypes or through animal and clinical trials. Some clinicians and scientists start their own companies which exist as independent entities or are later taken over or sold to other more established industries.

Industry seeks approval of their DIP products by opinion leaders (OL), who are indeed established and well respected and highly regarded (by their peers) members of the clinical and academic ophthalmic community nationally and/or internationally. This approval can take several forms:

i. Encouraging them to use the product.

ii. Some clinicians may be using the product anyway, without industry pressure or inducement. Industry may encourage these individuals (often by offer of incentives such as lecture fees, honoraria or contribution to research funds and cover of travel expenses) to talk about their use of the products at scientific meetings or specific industry organised promotional or educational meetings.

iii. Industry may call upon the expertise and skill of opinion leaders for monitoring and continuing evaluation of DIP post release.

iv. Industry supports, often generously, *bona fide* educational events such as symposia, conferences, courses etc. in exchange for the opportunity to advertise and display their products to a relatively captive audience that congregates for such events. Advertisements in clinical and scientific journal are another example of such symbiosis.

Conclusion:
(a) Industry needs us;
(b) Industry and healthcare professionals can work together for mutual benefit without compromising patient care or the cost of that care.

1.3 ***The other side of the coin***

v. The opinion leaders may have contributed to the initial development of the product or have been an investigator for the industry in the clinical trial of the DIP for which a fee was paid to self or department.

vi. The individual may serve as an advisory board member or a consultant to industry by virtue of his/her specific expertise or experience in the subject area of the DIP.

vii. The DIP may be the original brain child of the OL and was sold or co-owned with the industry. The OL may hold the patent for the DIP and may have carried out some of the original research that informed the process leading to clinical use of the DIP. The OL may have promoted the DIP without any initial contact or inducement by industry but later approached the industry for support, financial or otherwise, for his/her research or other endeavour.

viii. Industry may use the services of OL to endorse their products, for a fee, regardless of the experience of the OL with the specific DIP. Industry may provide the 'slides' for the lecture or modify the content of the lecturer's slides (this is usually but not always for technical accuracy and to comply with expectations of regulatory bodies).

ix. The OL may be encouraged to speak on the positives of the specific DIP and highlight the negatives of the competitor DIP. The OL or a family member may hold shares in the industry which own or sells the DIP, or be in a position to gain financially by the commercial success of the DIP.

x. An individual, OL or otherwise, in a responsible position, may be incentivised or induced to cast favourably a specific DIP by influencing legislation, regulation, guideline, protocol, publication, public pronouncements, procurement or clinical practice.

Conclusion: Conflict of interest can knowingly or unknowingly influence clinical decisions.

CONFLICT OF INTEREST

All the above scenarios from i. to ix. are legal. Aspects of item x., too, may be legal. However, in all ten scenarios intentional or inadvertent bias may occur and hence could constitute a conflict of interest.

Conflict of interest is usually, but not always, related to financial gain. The individual may have invented or created the treatment option, surgical procedure or intervention under consideration. He or she may promote that for kudos, impact, esteem or academic gain. This also constitutes a conflict of interest.

Any conflict of interest must therefore be declared. This is to allow people who hear, read or use the individual's work or contribution, to be aware of the individual's other interests so that they may receive and understand the work in the context of any benefit the individual may accrue from it. For example one may rightly and legitimately promote a particular medicine but if one also tells the audience that one is a paid consultant to the industry that manufactures that medicine the audience may wish to get a second opinion from someone else who is not so connected before making up their mind.

In this example the misconception is that individuals who are paid by the industry would make a conscious and deliberate attempt to portray the medicine in a positive and favourable manner or mislead the audience. Whilst in some instances this is true, more often than not the individual may honestly believe in the positive aspects of the medicine he/she is promoting, just as he/she would do if he/she were not paid by the industry. However, a subconscious bias, unknown to the

individual can influence the thought process or psyche of the individual. Hence declaration of COI is important.

The consumer is entitled to competent, fair, honest and impartial information and opinion on any DIP. Not only must this be so but it should also be seen to be so. The latter aspect introduces certain complexities. Individuals and OL who have the expertise, experience and skills to provide competent advice on a DIP are also sought by industry to develop, test or use their products. Whenever these individuals opine about a DIP or that of its competitors, a COI situation arises. If they declare their COI then the opinion, spoken or written is diluted and may need corroboration.

In the Context of The Royal College of Ophthalmologists

A COI may manifest in several activities undertaken by the College such as:

1. Symposia, conferences, study days and training sessions.

2. College guidelines.

3. College public statements released to the Press or published on the College's website.

4. College Examinations and Assessments where the schedule may require the member to examine or assess a family member or close friend or a trainee.

5. Evaluating grant applications, reviewing manuscripts for journals and judging posters and papers for award of prizes related to individuals mentioned in 4 above.

Individuals connected with any of the above should declare any reward or incentive provided by any industry in general or if specifically related to any DIP mentioned or discussed in the activity under consideration. Such a declaration should be made in respect of the individual personally, his/her family members and the department or institution where the individual works.

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