Journal Watch

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Readability of informed consent forms, sponsor participation in industry trials, and conflict of interest disclosure

Improving the readability of informed consent forms

Informed consent is a crucial feature of clinical research trials. Guidelines on developing an informed consent form urge writers to use standard plain language to provide patients with all of the relevant information they need on risks and benefits in order for them to make well-considered decisions about their treatment. Terranova *et al.*[1] conducted a study to assess, and improve, the quality and readability of informed consent forms used in cardiology. They undertook an analysis of a sample of currently used Italian and English informed consent forms used in association with seven common cardiology imaging examinations (coronary angiography, percutaneous coronary intervention, myocardial perfusion imaging, cardiac positron emission tomography, cardiac computed tomography, cardiac radiofrequency ablation, and stress echocardiography), according to the recommendations of scientific societies. As a second step they developed revised informed consent forms using reference standards (e.g. Federal Plain Language guidelines) and analysed each text for quality and readability. Quality was assessed according to three criteria: content and its organisation, text construction and layout, and development process. A readability score was estimated using various readability indexes (e.g. the Flesch–Kincaid grade level and the Italian language-tailored Gulpease level).

The results indicated that the overall quality and readability was poor in the original consent forms. They were also considered too complex and poorly organised with the most relevant information not properly highlighted. However, readability was improved with the revised forms. Although the study was small and had several limitations, it highlights the importance of writing informed consent forms that are clear and complete, which point out the risks involved in a treatment, and are developed following recommendations of plain writing.[1]

Sponsor involvement in trial conduct and reporting

There has been a lot of concern about bias and influence in industry-sponsored studies following a number of articles suggesting that industry-sponsored trials usually favour the company's product. Lundh *et al.*[2] investigated sponsor involvement in trial conduct and reporting of results in a sample of randomised clinical trials published in *The Lancet* in 2008 and 2009. Since 2002, *The Lancet* has requested that protocols are submitted with manuscripts; therefore, Lundh *et al.* obtained copies of study protocols as part of their analysis. For each protocol and publication, the authors extracted information on conduct of the trial and reporting, and two observers independently categorised the data according to pre-specified domains. They included 69 industry-sponsored trials and 12 trials that were industry-funded but independently conducted.

In the majority of cases, the sponsor or a contract research organisation was involved in the review and verification of information in case report forms, data entry, data storage, data analysis, and publication of the results, as opposed to these tasks being done independently by academic authors. Only two trials had a completely independent analysis. Even in the 12 independently conducted trials, the sponsor seemed to have a certain amount of influence in the conduct of the trial or reporting of the results. Medical writing assistance from the sponsor or someone hired by the sponsor was described in 37 (54%) of the studies. Lundh *et al.* suggest that perhaps it is the responsibility of journals to insist on more transparent reporting of the sponsors' role in the processes such as data processing, statistical analysis, and report writing. They go on to suggest that all journals should consider asking for study protocols and raw data to be submitted, and for independent data analysis.[2]

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Adequacy of conflict of interest disclosure

Off-label use is the practice of prescribing a drug for an unapproved indication or age group or using an unapproved dosage or route of administration. It is illegal for pharmaceutical companies to directly promote off-label uses, but many companies have paid physicians and researchers to endorse off-label uses of their products. Using a list of physicians and researchers involved in off-label prosecutions, Kesselheim *et al.*[3] investigated whether these individuals adequately disclose their conflicts of interest in the scientific publications they author. The authors collected complaints, filed by whistleblowers alleging off-label marketing, from the US Department of Justice, media reports, and other publicly available sources. They then identified doctors and researchers involved in these cases, examined their publications in the subsequent 3 years via Medline, and assessed the adequacy of their conflict of interest disclosures made in these publications.

Kesselheim *et al.* found 26 complaints claiming off-label marketing and identified 91 doctors and scientists involved. Thirty-nine (43%) of these 91 had authored 404 publications related to the drug(s) to which the author was linked in the complaint. In the complaints, these 39 doctors and researchers were alleged to have engaged in 42 relationships with the pharmaceutical company, such as being a paid speaker, writing articles, acting as consultants or advisory board members, receiving gifts/honoraria, and receiving support funds. However, only 62 (15%) of the 404 publications had adequate disclosures. Many of these articles (43%) had no disclosure at all; 4% had statements denying any conflicts of interest, 40% had disclosures not mentioning the pharmaceutical company, and 13% had disclosures that mentioned the company but did not express the nature of the relationship between the author and the company. Adequate disclosures varied by article type, i.e. commentaries were less likely to have adequate disclosures compared to articles of original research. Kesselheim *et al.*[3] argue that the results show the inadequacy of authors in preparing conflict of interest statements and suggest journal practices need to be improved.

References

1. Terranova G, Ferro M, Carpeggiani C, Recchia V, Braga L, Semelka RC, *et al.* Low quality and lack of clarity of current informed consent forms in cardiology: how to improve them. JACC Cardiovasc Imaging 2012;5(6): 649–55.
2. Lundh A, Krogsbøll LT, Gøtzsche PC. Sponsors' participation in conduct and reporting of industry trials: a descriptive study. Trials 2012;13:146.
3. Kesselheim AS, Wang B, Studdert DM, Avorn J. Conflict of interest reporting by authors involved in promotion of off-label drug use: an analysis of journal disclosures. PLoS Med 2012;9(8):e1001280.

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When peer reviewers and English collide

Please proofread the whole paper - there are several grammer and punctuation issues, MUCH better than before though - but still there.

This was followed in the same set of comments by:

4th paragraph - needs revision - you set up the paragraph so it sounds like youre only going to discuss post-menapause, but then start discussing pre-menapausal women.

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