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EDITORIAL

Medical publication under fire

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The Biased reporting of research results is under scrutiny. Clinical trials have been changed from being negative to be positive by adding "Spin" to reports. The problem is aggravated in clinical research by "ghostwriting". The ghostwriters know how to lay stress upon beneficial effects and suppress negative side effects of a treatment. The Institute of Medicine in USA as well as the European Medical Writers Association has adopted guidelines how to deal with ghost management and ghostwriting.

"Believe those who are seeking the truth.
Doubt those who have found it."

André Gide

Few fields of societal activities have such a high standing as science and research. And there are good reasons for this high confidence in the universities' and research institutes' ability to generate new knowledge and to move the research frontline continuously forward. However, during the last decades this capital of confidence has become somewhat tarnished because of disclosures of many inappropriate reports of research results.

The motives to do research are many – from pure curiosity, desire to seek the truth, to make a professional career and not least to make money. Independently of motives the authors are accountable for the completeness and accuracy of their reports. Do they live up to this responsibility?

In recent years, examples appear constantly in the literature of deviation from these principles. In the May issue of the Journal of the American Medical Association (JAMA) it was reported of the practice of distorting the presentation of clinical trials that resulted in statistically non-significant results. In other words, the authors added "Spin" to their scientific report to suggest a treatment being beneficial when in fact there is no generally acceptable evidence. "Spin" has been defined as a specific way of reporting that can distort the interpretation of results and mislead readers. In this article 600 randomized controlled clinical trials published in December 2006 were examined. Only 72 met the criteria for inclusion. Spin was found in 18% of titles, 38% of the abstract result sections, and 58% in the abstract conclusion sections. In the main text the results, discussion and conclusion sections had 29%, 43% and 50% spin. This does not inspire confidence in the process of disseminating evidence of evidence-based medicine.

Treatment policy can be tremendously influenced by this misleading information – the big pharmas earn money and the patients risk their lives.

Other domains where the scientific integrity of medical science has been clouded are "ghost management" and "ghostwriting" of clinical research.

Recent decades it has more or less become a "modus operandi" for the big pharmaceutical companies to plan, carry out, analyze the results of clinical trials and then use professionals to write the article under the name of well-known academics, so called Kols (Key Opinion Leaders), who had played little role earlier in the research and writing process. In extreme cases, drug companies pay for trials by contract research organizations (CROs). According to a report from Sergio Sismondo, a professor of philosophy at Queen's University in Canada, the majority of the industry funding, 70% goes to CROs that neither make ownership claims on data nor expect to publish the data themselves. By its nature CROs research tends to be ghostly.

The medical fields that are preferably subjected to ghostwriting are the most profitable, namely those that mean a life-long treatment, for example preventive medicine. According to a study published in JAMA the rate of ghostwritten articles in 2008 varied from 2 to 11% in different medical journals.

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There are many communication companies that offer their service to pharmaceutical companies. It has been estimated that only in USA there are more than 50 such firms. One of the most famous firms is Complete Healthcare Communication (CHC). This firm claims to have written and submitted over 500 manuscripts, with an acceptance rate of 80%. CHC can achieve such a rate with resources far beyond the reach of most researchers. They have teams of more than 40 professional medical writers, statisticians and librarians. They know how to lay stress upon the beneficial effects of the studied drug and how to suppress its negative side effects. They also know that articles in distinguished medical journals have a great impact on physicians' prescription behavior. The articles are carefully calibrated to help the manufacturers sell more products.

The question is how to guard against biases created by ghost management and ghost writing? Obviously, the peer review system has not proven to be an effective tool for quality control. Further, the declarations of "conflicts of interest" most often meaning "financial conflicts of interest" in published articles are rarely complete as recently reported in The New England Journal of Medicine (N Engl J Med 2009;361). They are incomplete despite the clearly expressed view of the International Committee of Medical Journal Editors: "Published articles and letters should include a description of all financial support and any conflict of interest that, in the editor's judgment, readers should know about".

In USA it will be mandatory for all drug companies and medical device makers to organize databases with all payments to physicians. These databases will be used for stricter disclosure requirements aimed at making the firms more transparent. Those new rules, under a subset of the health care law called the Physician Payment Sunshine Act, are also expected to make it easier for the public to track a doctor's payments.

Perhaps journal editors, with awareness of the problem can recognize signs of behind the scene work and refuse to deal with publication planners. In 2009 the Institute of Medicine in USA has recommended academic medical centers to approve a common policy, which prohibits ghostwriting within their faculties. In Europe the European Medical Writers Association has adopted guidelines with advice how to deal with ghostwriting. Equally important is that investigators are aware of the mechanisms of ghost management and ghostwriting that goes under their names, and refuse to participate.

These actions from different official organizations and from prestigious medical journals are important and may lead to certain improvements. But they will not get hold of the individual researchers that misuse scientific publication for personal purposes.