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Four other keywords to critically analyze a clinical trial: hypothesis, implementation, analysis and publication

Otras cuatro palabras clave para analizar críticamente un ensayo clínico: hipótesis, realización, análisis y publicación

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Commentary on: Ugalde A, Homedes N. Four words regarding clinical trials: Science/profit, risks/benefits. *Salud Colectiva*. 2011;7(2):135-148.

I believe that Ugalde and Homedes (1) analyze correctly the false arguments used by the pharmaceutical industry to disguise its business as science in Latin America and I believe that the examples they provide clearly put into context the pressing matter of the lack of transparency.

In my contribution, I intend to extend the analysis of Ugalde and Homedes in order to include other aspects that I consider fundamental to a critical analysis of clinical trials, regardless of the geographical location in which they are conducted. My exposition is organized according to four keywords corresponding to the phases every clinical trial must go through: statement of the study hypothesis, establishment of the protocol and implementation of the study, analysis of the data collected and, finally, publication of the results. I will now highlight the irregularities and crimes that arise in each of these phases.

1. Statement of the study hypothesis

Back in 1993 Dr. Ian Hay's virology laboratory in the US, where I conducted my first research studies, analyzed the possible relation between Chronic Fatigue Syndrome and the Herpes simplex virus type 6 and 7. When I asked Dr. Hay how the research objectives were defined in his laboratory, he invited me into his

office and explained the following: in the US, biomedical research is mainly funded by the National Institutes of Health (NIH); the NIH establish their priorities according to a list given to them by the United States Congress, whose members (most of them millionaires) are pressured by lobbies and generally yield to the most powerful groups. That is to say, that the priorities of medical research in the US are related to political and economic interests that have nothing to do with the real health interests of the American population, much less of the world population. Why is it that there are no long-term studies comparing the health indicators of vaccinated versus non-vaccinated children? (2). Why has no double-blind study been done to test the efficacy of the seasonal flu vaccine, as the head of the area of flu vaccines in the Cochrane Collaboration (Dr. Tom Jefferson) has been requesting for over ten years? (3). Why is it that study hypotheses are allowed that compare the possible effect of a new drug that the industry wants to release in the market with a placebo, instead of hypotheses that compare the new drug with the most effective drug that already exists? (4 p.221). Why do diseases affecting 90% of the population only receive 10% of research resources? (5 p.10).

2. Establishment of the protocol and implementation of the study

After stating the study hypothesis, it is time to establish the research protocol. There may be mistakes in the writing of the protocol, but I do not think they are usually intentional abuses. However, I agree with Ugalde and Homedes that the ethics committees that approve the protocols are not usually capable of checking whether the protocols are duly applied, especially with regards to obtaining informed consent. Frequently, the people that sign the consent forms do not understand the consequences and the context of what they are signing. They often believe that if they do not sign they will lose the right to be treated. Regarding the abuse implied in using someone for research purposes and then interrupting their treatment once we have obtained from this person the information we needed, I refer to the article of Ugalde and Homedes (1).

3. Analysis of the data collected

The analysis of data is again a key point in which abuses are committed that demonstrate how profits are put before science. The most frequent abuse, for which the majority of large pharmaceutical companies in the US have repeatedly been convicted, is that of concealing information (6). The case of the association between Vioxx (rofecoxib) and myocardial infarction (7 p.143) is widely known, as is that of Hormone Replacement Therapy (HRT) and breast cancer (8). More than 14,000 women sued the pharmaceutical company Wyeth (taken over by Pfizer in 2009) for concealing information related to the risks of HRT with Prempro (conjugated equine estrogens and medroxyprogesterone acetate). The majority of the lawsuits are being decided in favor of the plaintiffs and the judicial process has already made public more than 1,500 documents evidencing the existence of criminal responsibility. These documents have not only revealed the crime of concealing information but have also made known the full scope of the issue I touch upon in the last section.

4. Publication of the results

In terms of publication, 87% of the authors of scientific articles have direct financial ties to the industries that commercialize the drugs the authors investigate. And, what is even worse, most of the scientific articles currently published in the most prestigious peer-reviewed medical journals are not written by the people that stamp their names on them; rather, their authors are ghostwriters employed by specialized firms hired by the pharmaceutical companies in order to promote their products. Is it possible that the most prestigious journals lend themselves to such manipulation? This unbelievable situation is precisely what Dr. Marcia Angell, editor in chief for more than seventeen years of a medical journal with one the highest impact factors (*The New England Journal of Medicine*), denounced; and it is the same situation that Georgetown University researcher Adriane Fugh-Berman denounces after analyzing the 1,500 documents declassified during the trial against Wyeth/Pfizer (9). Companies exist that specialize in disguising propaganda as science, calling their work "publication planning"; in their offer of services they include both reviews and original articles. During the eight years it was contracted by Wyeth to promote HRT (between 1996 and 2004), a company called DesignWrite produced more than a thousand abstracts and posters and more than five hundred peer-reviewed articles, established more than two hundred scientific committees, organized more than ten thousand conferences, more than two hundred satellite symposiums, and more than sixty international training programs, and created dozens of webpages (9). To summarize the situation regarding clinical trials: the pharmaceutical company first defines the study hypothesis according to its private interests; next, it conducts the study convinced that the irregularities committed will have no consequences, because there is no adequate control of the protocol implementation; it then conceals any unfavorable information; and finally, it contacts a physician of good academic reputation to be the "main author" of an article that has already been written by an employee of the marketing company. The existence of this situation was already known, but

before the Wyeth case was studied, the magnitude of the problem was not thought to be so large.

The solution is within our reach

It is necessary to follow the suggestions made by the health committee of the English Parliament in the year 2005: that the public health system acquire the capacity to carry out its own studies of drug efficacy and safety, independently of the companies that commercialize such drugs and of their interests (10

p.116, recommendations 18-20). These recommendations have not as of yet spurred any new laws or regulations. Currently, in England as in the rest of the European countries, not only do the studies of efficacy and safety remain in the hands of the companies that commercialize the drugs and that have been accused and sentenced on numerous occasions for betraying the trust placed in them, but the office that grants licenses to commercialize drugs – the European Medicines Agency (EMA) – receives more than 50% of its funding from these same companies.

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