Editorial

Research trials: Registration, reporting and publication

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The world of medical research is increasingly concerned about the need to completely document all trials and ensure that they are accurately and completely reported. Researchers owe an ethical obligation of imparting full and correct information about their trials to both their research participants and the public at large. Thus, knowledge gained from research should be in the public domain and freely available to everybody. Making research data public also serves the purpose of conserving resources by avoiding unnecessary duplication of research work.

Evidence of selective reporting of results has sparked off a move for mandatory registration of all trials so that all results are publicly available and that ethical obligations to participants are met. The International Committee of Medical Journal Editors (ICMJE) has announced that, beginning in July 2005, all 11 ICMJE member journals will only consider those trials for publication that have been registered in a trial registry before they started. For this purpose the ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause and effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g. phase I trials) would be exempt.

There are many varieties of trial registries. At present, clinicaltrials.gov is one such registry, which offers registration for interventional and observational trials. On the other hand, the Journal of Medical Internet Research has set up the International eHealth Study Registry to meet the requirements of the eHealth and medical informatics community. Perhaps the ethics committees of various bodies should put up all the trials registered with them in the public domain. This information would include the trial protocols and proforma and it should be binding on all researchers to key in their trial data and results.

Though trial registration is an important initiation it is not a panacea since it does not provide access to unpublished data submitted to regulatory bodies such as the Food and Drug Administration.

Should the principle of only considering registered trials be applied across the board by all journals? This is undoubtedly necessary in the long run. However, it would be necessary to have a cut-off date beyond which the same would be applicable so that researchers can be educated about the need for the same in the interim period.

The general impression is that industry sponsored trials are those which do not get reported if the results are unfavourable for the sponsor. However, selective reporting of outcome frequently occurs even in publications of high quality government funded trials. Chan et al compared the protocols for randomised trials approved for funding by the Canadian Institute of Health Research (formerly the Medical Research Council of Canada) from 1990 to 1998 with subsequent reports of the trials identified in journal publications. A median of 31% of outcomes measured to assess the efficacy of an intervention per trial were incompletely reported. Major discrepancies in primary outcomes between protocols and publications were identified in 40% of the trials. Thus biases exist even in government-funded studies even though they are generally free of commercial influences and therefore thought to be more reliable. The authors state that depending on data provided in published literature would result in a tendency to overestimate the effects of intervention.

The basic premise behind doing research is to further human knowledge. Thus, after conducting any research it is obligatory on the researcher’s part to make that knowledge public. Traditionally this has occurred through the medium of publication in peer-reviewed scientific journals. That this does not happen may be due to lethargy on the part of the research worker as well as his inability to publish his work due to vari-

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Research is increasingly characterized by the complex relationship between researchers and commercial sponsors. It is important for authors to disclose conflicts of interest, financial and otherwise. This situation is further complicated by the fact that commercial sponsors may not permit publication of data that is unfavourable to them. Academic freedom includes the right of authors to have access to, analyse, review and publish all of the data obtained in their study, based on their own decisions and not those of the financial sponsor.\[6\]

Publishing in peer-reviewed journals is not without problems. Publication costs money and as a logical corollary, most scientific journals are owned by commercial concerns. When finances are involved the picture naturally changes. The would-be authors have to pay various publication charges. Peer-review too is not without its biases. Publishers publish articles that their clients – the paid subscribers would like to read. Thus, though many scientists would like their research to reach a wider audience, they are hampered by many factors. Researchers from the developing world are doubly handicapped. Fees that are easily affordable in the developed world are crippling high from the standpoint of the researcher from a developing nation. Thus, there are severe limitations on his access to good scientific literature as well as his ability to publish in such publications. Besides the issue of publication bias, other anomalies such as duplicate publication will still remain to be tackled.

The important question to ask is whether scientific knowledge is to be free? The reality is that it is not. There are many arguments on behalf of the other side. Corporates who have huge financial investments at stake would naturally argue for guarding the secrecy of their research findings. Since studies on pharmacokinetics or major toxicity (e.g. phase I trials) have been exempted by the ICMJE guidelines, this would ensure the protection of the rights of corporates and original ideas. However, it should be made mandatory for all these bodies to make public all their findings within a given framework of time as a part of their responsibility to the public at large. The executive committee of the Pharmaceutical Research and Manufacturers Association (PhRMA)\[7\] has moved in that direction by enunciating voluntary principles, for its member companies, on conduct of clinical trials and communication of clinical trial results. However, this must be ensured on a universal basis.

The other question that arises is whether complete transparency would not give rise to robbing of one’s research ideas, with the competitor developing those ideas more completely and rapidly if he has access to better resources and therefore take away one’s credit. The world is unfair and responsible human beings can only strive to strike a balance. The birth of the World Wide Web has ensured that knowledge can be widely transmitted at a fraction of the usual costs and previously required time and that both the have and the have-nots are moving towards a more equitable world. Moreover, registering one’s research trials and therefore one’s hypotheses on a universal platform would ensure that one would always be able to lay claim to the originality of ones thoughts.

References