Editorial

Some reflections on Clinical Trial Registries

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In the early 20th century, Sir Ronald A. Fisher from the Rothamsted Experimental Station in agriculture developed his '*Principles of experimental design*', as a precise system for the correct formulation of experiments[1]. He stressed the importance of randomization, control groups, replication, blocking and the use of factorial experiments, to assess the effects of confounding factors in interventions under scrutiny. These are fundamental principles that need to be adhered to in research, especially in interventional studies in all animals, including humans.

A clinical trial or an interventional study, is a prospective bio-medical or behavioural research venture on human subjects that is formulated to answer explicit questions about bio-medical or behavioural interventions such as vaccines, drugs, treatments, devices, or novel ways of using known drugs, treatments, or devices[2]. Such prospective biomedical or behavioural research studies on humans are designed to answer explicit questions about experimental intercessions such as new treatments as well as known interventions that need additional study and evaluation.

A Clinical Trials Registry (CTR) is an official platform for registering a clinical trial. Some countries require clinical trials being conducted in that country to be registered; others do not require it, but often strongly encourage it[3]. These registries demand all specifics of an interventional study to be submitted for registration and these particulars are available in the published public territory in the World Wide Web of the internet. The functions of these registries are to ascertain the achievability of the details of the trial, rationalisation for the study, safeguard correct conduct of the study, record subsequent evolution and most significantly, make it available for public scrutiny. Many journals, including the *Sri Lanka Journal of Child Health*, has made it a mandatory requirement for Clinical Trials to be registered in a recognised Clinical Trials Registry before even accepting the relevant manuscripts for consideration and peer-review. Yet for all that, it is not a universal practice and some journals do not require it as an obligatory condition for publishing.

Clinical Trial Registries perform a number of useful functions. At the outset these analyse and record all important and significant characteristics of the study. The feasibility, scientific rigor and other important considerations are examined meticulously. A considerable amount of information is requested, assessed and then carefully documented in the registry. Once the trial is registered, the details are inserted into the CTR site in the World Wide Web site and are available for other researchers and even the public for their perusal. Once the study is under way, regular Progress Reports are requested and obtained from the researchers. These are also posted in the web site. The final component of the trial registration protocol is to provide the data and outcome of the study in the registry web site.

There are some initiatives such as Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and Consolidated Standards of Reporting Trials (CONSORT), just to name two, which are in use to improve the quality of clinical trial protocols and for completed trials. However, provision of outcome data and outcome details in completed registered clinical trials is causing a lot of concern. Scanty and sub-standard outcome reporting in clinical trials is a well-known constraint that hampers the capability of researchers to assess, reproduce, create and even build upon the study findings. Such occurrences have implication on the ability of patients, clinicians and even policy makers to make evidence-based choices. The necessity for internationally recognised, standardised and comprehensive guidance that is applicable to all outcome types, disease areas and populations, in reporting outcomes in clinical trial protocols and reports, has now been universally recognised.

Towards augmenting the value of clinical research, an initiative to develop a coordinated, evidence and consensus based outcome recording standard would be a laudable step in attending to such a need. In that context, the recent enterprise to create a unique Instrument for Reporting Planned Endpoints in Clinical Trials (InsPECT)[4] is most definitely a very useful venture. It is a new reporting guideline, currently under development, to help improve the quality of outcome reporting in clinical trials[4]. InsPECT will be used by those accountable for the design, enactment and recording of clinical trials. Through the synthesis of such a clear and vibrant outcome recording standard, there will be a reduction in wastage of research by enabling evidence synthesis and augmenting learned

decision-making. InsPECT will eventually advance patient and health system outcomes. It may also help scientific journal editors to improve the peer review processes of clinical trial manuscripts.

It is imperative to clearly understand that it is not quite sufficient to just carry out high quality clinical trials but also to make sure that the end results would percolate finally as benefits to our patients. Research on children is very strictly and stringently controlled. In such a scenario, it is even more important for the final outcomes of paediatric research to be made universally available. Publication in reputed journals is one way of disseminating such knowledge. In that context, the fact that the initiation of any clinical trial is signalled by successful registration in a recognised Clinical Trials Registry, one would presume that it is a morally justifiable requirement for the very same registry to provide all details of the final outcome in the published public domain. In recognition of such a noteworthy postulation, InsPECT would definitely be a progressive step in the right direction.

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