EVIDENCE-BASED MEDICINE CORNER

Registering clinical trials: why and how!!

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Evidence Based Medicine has now become a fact allover the world and in all specialties. The core message of EBM is to disseminate the best available evidence. In order to promote and organize research and to avoid publication bias and effort duplication, there is now a strong attitude to encourage researchers to register their trials when they setup the design. Registration facilitates the dissemination of information among clinicians, researchers, and patients, and it helps to assure trial participants that the information that accrues as a result of their altruism will become part of the public record.

This policy aimed to ensure that information about the existence and design of clinically directive trials is publicly available, an idea that leaders in evidence-based medicine have advocated for decades (1).

A clinically directive trial is defined 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" (Many research investigators and sponsors feared that registration would be burdensome and would stifle competition. Yet, the response to this policy has been overwhelming. In April 2007, the registry contained over 40 000 trials, with more than 200 new trial registrations occurring weekly. Many journals have adopted trial registration recommendations like BJOG in which I’m working as an Editor.

In May 2007, the World Health Organization (WHO) launched a new website bringing together existing key trial registers. (http://www.who.int/ictrp/search/en/) eventually providing a 1-stop search portal for those seeking information about clinical trials. The largest one is ISRCTN Register, (http://www.controlled-trials.com/isrctn/). When a trial is registered with an ISRCTN ID, it becomes automatically pooled with the rest of the registers, ensuring maximum visibility to your research. These registers allow you also to search freely for trial information.

The Registry Platform sets international norms and standards for trial registration and reporting that uphold scientific and ethical principles. The primary objective is to ensure that all clinical trials are registered and thus publicly declared and identifiable, and to ensure that for all trials, a minimum set of results will be reported and made publicly available. A public, complete and readily searchable register of clinical trials – overseen by an objective international body with the input of stakeholders – will further good research practice, assist in making treatment decisions, and help increase public trust in clinical research.

The ISRCTN Register accepts all study designs including exploratory trials, in addition to randomized controlled trials. The register items also include a Publications field, allowing trialists to provide details about published protocols, published study results and CONSORT-style structured results.
The ICTRP has taken the first steps toward developing a network of primary and partner registers that meet WHO-specified criteria (4). Primary registers are WHO-selected registers managed by not-for-profit entities that will accept registrations for any interventional trials, delete duplicate entries from their own register, and provide data directly to the WHO. Partner registers, which will be more numerous, will include registers that submit data to primary registers but limit their own register to trials in a restricted area (such as a specific disease, company, academic institution, or geographic region).

REFERENCES