CLINICAL TRIAL REGISTRATION: CAN WE ESTABLISH NATIONAL CLINICAL TRIAL REGISTRY OF PAKISTAN?

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International Committee of Medical Journal Editors (ICMJE), previously known as Vancouver Group, is a selected group of editors from leading international medical journals like *New England Journal of Medicine, The Lancet, British Medical Journal, Journal of American Medical Association etc. ICMJE* is working hard for the improvement of published medical research and has developed *Uniform Requirements for Manuscripts* (URM) submitted to biomedical journals which are regularly updated and are adopted by majority of medical journals across the globe[1]. Besides developing guidelines for authors regarding preparation and submission of manuscripts, ICMJE is deeply concerned with the issues related to publication ethics like authorship, contributorship, editorship, peer review, conflicts of interest, privacy, confidentiality and protection of human subjects and animals in research.

A major issue in publishing medical research is the publication bias[2]. The researchers and editors are more interested in publishing the studies with positive results, published more frequently and quickly than trials with negative outcomes[3]. Selective publication is unscientific and unethical as the hidden results may alter the clinical evidence and the clinical practice. To confront the publication bias, Simes RJ[4] proposed to establish an international registry of clinical trials where the objectives and endpoints of every clinical trial may be recorded in the register. In September 2004, ICMJE proposed a comprehensive trials registration policy as a possible solution to the publication bias[5]. This policy was implemented in July 2005 on 12 member journals of ICMJE and registration in a public trial registry was made a prequisite for publication of all clinical trials.

For registration purposes, ICMJE is endorsing the World Health Organization (WHO) definition of a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes"[6]. Health-related interventions include drugs, surgical and radiological procedures, devices, behavioral treatments, dietary interventions etc. All clinical trials meeting the above mentioned definition (including phase I to phase IV trials) are required to be registered at or before the enrollment of patients in the trial. However purely observational studies are exempted from registration[7]. World Medical Association Declaration of Helsinki also stressed upon registering every clinical trial in a publically accessible database before recruitment of the first subject[8]. The database where standardized information about administration and scientific contents of clinical trials are stored is called as *Clinical trial register*. The clinical trial register is maintained by *clinical trials registry* which is responsible for ensuring the validity and accuracy of the trial information and dissemination of these information to health care decision making authorities[6].

To ensure that all clinical trials are not only registered but are publically available and clearly identifiable, WHO has established *International Clinical Trials Registry Platform* (ICTRP)[9]. To facilitate the unambiguous identification of clinical trials, every trial is allotted a unique *Universal Trial Number* (UTN) which is not a registration number but it identifies the individual trial and is used in the trial protocol and all the communications about the trial. WHO Registry Network for prospective trial registries facilitates the exchange of information and working relationship among all the registries. The WHO Registry Network has laid down specific criteria based on content, quality and validity, accessibility, unique identification, technical capacity and administration for the trials registries. Depending upon the eligibility criteria, trials are categorized as *Primary Registries, Partner Registries* and *Registries working with the ICTRP towards becoming Primary Registries.* Primary Registries meet all the criteria of ICTRP and are run by nonprofit organizations[10]. ICMJE does not favour any particular registry and all Primary Registries designated by WHO ICTRP are acceptable to ICMJE[7]. Clinicaltrials.gov developed in the year 2000 is the first and the largest clinical trials registry in the world[11,12].

Unfortunately there is no trial registration authority in Pakistan and many local researchers get their trials registered with international registries before publishing their research in international journals of repute. Due to non-availability of national trial registry, Pakistani journals are experiencing problems in accepting articles without UTNs. The regulatory authorities of health care, medical education and medical research in Pakistan like Pakistan Medical & Dental Council (PMDC), Higher Education Commission (HEC), College of Physicians and surgeons Pakistan (CPSP) and Pakistan Medical Research Council (PMRC) need to take an initiative to establish a standard trial registry which should meet the WHO criteria of primary registries. When Iran[13], India[14] and Sri Lanka[15] can establish their own trial registries and get them recognized from WHO as primary registries, why not Pakistan can do it?

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