Is the Science in Right Direction? Pitfalls of Evidence Based Medicine in Nepal

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There was a tremendous renovation in the last 20 years of teaching and practicing clinical medicine after the appearance of evidence based medicine (EBM).[1] It compelled to revolutionize the conventional theoretical reasoning by the evidence from systematic reviews, meta-analysis, high quality observational and clinical trials along with clinical proficiency and the wishes and needs of the patients. Three major components of EBM are Patient (values, concerns, preferences, expectations, life predicament), Physician (training, experience, current expertise, continued learning, demand for proof) and information (clinically relevant, proven by research, best up-to-date evidence). The standard basis of medical practice should be focussed on clinical experience, consultation with other professionals and training, case reports, non-experimental - convincing evidence from articles, product literature, patient's preferences, active search of meta-analysis, systematic reviews, randomized controlled trials (RCT) reports. Bastian et al. accounted in 2010 that there were 75 trials and 11 systematic reviews of trials and evidence showed there was an exponential growth in the current scenario of 2015.[2] So the problem is how the physicians should be up to date and cope up with this.

Hospital safety score revealed in 2015 that medical errors were the third most leading causes of death in the USA.[3] Physicians should draw attention to preventable deadly events to emphasize the extent of potential for development and better patient care. As authentic randomised control trials are known as the gold standard of evidence, it should be evaluated by the physician by a critical appraisal before applying the evidence of that. Evaluating the randomized control trials should focus on the key issues; whether the principal investigator measured all clinically appropriate outcomes, authentic ethics committee approval and clinical trial registration number, whether the statistically significant results are clinically significant, information regarding significant adverse reactions, whether the follow up procedural analysis is identical, and continuous data analysis versus end of trial data.

World Health Organization (WHO) issued a landmark new statement on the public disclosure of clinical trial results in 2015.[4] It states reporting time frames for new trials and calls for results of earlier, unpublished trials, and outlines steps to get better linkages between clinical trial registry entries and their published results. This amends 2005 - WHO's announcement that "the registration of all interventional trials is a scientific, ethical, and moral responsibility".[5]

WHO launched the International Clinical Trials Registry Platform (ICTRP) to make available a summary of clinical trial research available to all those engaged in health care decision making internationally in 2005.[5] The ICTRP is a registry platform that recurrently gets in trial records from clinicaltrials.gov, Australia New Zealand Clinical Trial Registry, EU Clinical Trials Register, Pan African Clinical Trial Registry, ISRCTN, and Clinical Trial Registries from Germany, Brazil, China, Sri Lanka, Republic of Korea, Iran, India, Cuba, Thailand, The Netherlands, and Japan.[5]

All the medical journals from Nepal should keep a mandatory rule for publishing clinical trial manuscripts as suggested by the International Committee of Medical Journal Editors (ICMJE).[6] There is a standard criteria set by ICMJE for assessing the quality of all types of research designs. They can amend this criteria to the existing author's guidelines. Reputed medical journals of Nepal can become a member of this committee to maintain the quality of scientific publishing. One of the editors should attend the ICMJE conferences and get it up-to-date. Apart from these, if the journal has the scope to publish clinical trials, then they should invite clinical trial experts [national or international] to the editorial board, who can make a wise judgement of the quality of submitted manuscript. Otherwise, it will enhance fraudulent research and also the resultant outcome (bad RCTs) can mislead the readers especially future physicians.[7]

Institutional research and ethics committee should be well aware of the clinical trial registration rules of WHO and they should not solely give the institutional permission and registration number. Currently, most of the RCTs published from Nepal has only institutional ethics committee approval.

The Nepal health research council should look into this matter seriously and get registered all the RCTs in Nepal in ICTRP, till a standard national clinical trial registry maintained by trained experts, approved by WHO and included in ICTRP clinical trial registries.

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