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Clinical Trial Participation in India

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Introduction

India is the clinical trials hub for some pharm companies of developed nations [1-10]. We are a nation with a vast pool of heterogeneous patients, substantial number of restorative ability with English tongue, expanding rates of clinics with great foundation and therapeutic supplies. The expense of clinical trial is reduced up to 60% when compared to that of developed nations. Notwithstanding that we have got some great administrative power set up in our nation [11-20]. Focal Central Drug Standard Control Organization (CDSCO) regulates the clinical trial process in India through, ICMR and Indian GCP. These trials directed in India are guaranteed and sanction by universal rules and regulations, as, ICH and FDA under strict review of IRB/IEC. Clinical Trials in India had a look from CDISC because of its fast growth in the trials. Although these facilities seem to be enough for the establishment of more trials the limitations cease from the development. In this article we will discuss such limitations [21-30].

Clinical trials are broadly recognized as the back bone of evidence based medicine addressing important and previously unanswered questions.¹ Research is traditionally led by committed clinicians, who improves patient care and enhances the professional reputation of their institution and the clinicians who work there [31-41]. Advances in health care are impossible without clinical trials whether the treatment is a cancer drug, a vitamin, a surgical procedure, a new way to detect disease or a medical device [42-51]. Clinical trials prove extremely beneficial to cancer patients, who may have exhausted all other forms of standard treatment, yet still have active disease. Patients may find hope in new treatments offered only through clinical trials apart from the altruistic satisfaction that their participation may lead to safer, more effective treatments for future patients [52-62].

Even though, it is largely believed that subjects participating in clinical trials are exposed to experimentation and are at increased risk, this perspective reinforces the perception of sacrifice and altruism from public point of view [63-73]. From a scientific perspective, generation of clinical trial evidence can clearly improve public health in long term. Still, individual patients instinctively hope to derive some personal benefit from whichever treatment they are given as part of their health care and, as such, are unlikely to opt for a process that they see as sacrificial rather than beneficial. Conversely, there is a professional perception that clinical trials represent superior care. Clinical trials may induce discomfort or risks, particularly when the treatment principle is new and not yet investigated. In contrast to the public perception, many health professionals recognize that clinical trials are good for us as a society and support the concept of a beneficial trial effect for participants.² Indeed, research subjects have repeatedly voiced their preference to enter a trial rather than receive inadequately evaluated routine care [74-84].

Perhaps unfairly, health professionals have the upper hand in trials that they have access and exposure to current evidence, the bulk of which seems to support a favorable trial effect.^{3,4} These include the Hawthorne effect wherein merely the awareness of being observed may impact the outcome,⁵ the treatment effect resulting from the treatment under study being superior to the standard alternative, the care effect where the trial protocol requires more comprehensive care, and the protocol effect,⁶ which is basically same as that of Hawthorne effect [85-95]. Clinical guidelines improve the quality of clinical practice, so it is clearly plausible that a similar effect can be achieved by the systemized protocols used in clinical trials that guide clinicians through clear and explicit processes of care, resulting in improved outcomes in trial participants whether in the intervention or the control group. In order to measure a protocol effect, it would be feasible to conduct a controlled trial in which participants were randomly allocated entry to the clinical trial or care following a standardized guideline or protocol [96-106].

Another important aspect in clinical trials is seeking informed consent with adequate comprehension, which sometimes is the biggest challenge in most of the developing countries. Even though International and national regulatory guidelines for human subject research governing clinical trials worldwide dictate to ensure that clinical trials participants should be informed of clinical trial goals, benefits, potential risks, methods, and are provided the right to choose or refuse participation; they fail to define guidelines for adequate understanding of informed consent. The content of informed consent forms typically is explained to the potential participant by a member of the research team who is well versed in the methods, risks, benefits, and alternatives to participation in the trial. The potential subject's education level, physical health, and prognosis are but a few factors which might impede comprehension [107-117].

Thus, clinical trial subject's satisfaction and understanding regarding aspects of clinical trials need to be addressed. Quality assurance and quality improvement methods are cornerstones of healthcare management, which are also the mainstays of clinical trials. This retrospective study was designed to test the effectiveness of one of the Quality System in terms of research subject feedback at a research centre in Pune, India aimed at increasing clinical trial subject understanding of research and informed consent, satisfaction with facility, patient care provided and role of the research team [117-127].

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