Transparency in recruiting patients for clinical trials

Sir,

Successful outcome of a Clinical Trial (CT) depends among many other criteria, on designing a successful patient recruitment strategy. In India, recruitment of participants in CT is not a major difficulty. However, the way these patients are recruited may result in misrepresentation of the target parent population. This will ultimately affect the credibility of these trials.

Dependence on physicians as primary sources of recruitment:

In developed countries, patients for CT are mainly recruited on the basis of advertisements in media. However in India, participants are mainly recruited by physicians and CTs are rarely advertised. This leads to many flaws, the most important one being the sample will not be representative.

If the trial is going on in a particular hospital in a city the patients are usually recruited only from that hospital. This may lead to bias resulting in uneven representation of certain segments of the population since each hospital may cater to a specific geographic area.

Physicians are not always fully aware of available CTs. As a result, some physicians may assume that none of their patients would qualify in the inclusion criteria of the trial.

Even if a physician knows about the trials conducted by other physicians, he may not mention these trials to his patients due to fear of losing them.

Competition and conflict of interest are the dangers of relying on recruitment through physicians alone.

Hence the best option would be to let the public learn about CTs from information in public domain and from advertisements.

Availability of information on CTs in the public domain:

"yalestudies.org,"[1] "Get Randomized,"[2] American Association for Cancer Research and Stand Up To Cancer (SU2C),[3] Center Watch,[4] Clinical connect[5] and Clinical research Quintiles[6] are internet sites publishing detailed information about active CTs that can be accessed freely by patients and volunteers. The site classifies data on CTs on the basis of geography and disease. Interested participants can sign up for free service. Notifications are sent to the participants as soon as a CT is posted in the medical category of interest. These sites have an extensive database of present as well as prospective trial participants. This listing reaches a wide ranging, highly captive and interested patient population via extensive and exclusive outreach efforts.

At present such websites are not available in India. Details of the trials in India are listed on CTs Registry. In India however, there is no facility for volunteers to register on this site. India should have websites similar to those referred to above with information translated into regional languages.

Advertising CT–another option

Advertisement of CT is another option to reach out potential trial participants. This may be an immediate solution and may be more effective way to recruit participants. To advertise CTs, developing a website for the institution/hospital, along with posters, brochures, newspaper ads, and arranging community health fairs in cooperation with stakeholders [sponsors, Contract Research Organizations (CROs), Principle Investigators (PIs)] within the medical school and hospital would certainly improve representative recruitment of trial participants.

Trial participant bias

Failure to advertise leads to lack of access to the trials. The perception that there are no trials nearby may frustrate many potential participants leading to unrepresentative data and loss of important information.

Connolly's study[7] has suggested that recruitment bias may exist in trials and trial integrity may be compromised by the presence of such biases.

Bias is a serious problem in applied work[8] such as clinical studies where the results are extrapolated based on the sample selected. Inferences drawn from biased samples are not as trustworthy as drawn from a truly random sample as mentioned by Friedman.[8]

It is seldom possible to eliminate all bias, but with careful and prolonged planning, one can minimize common sources and consequences of bias.

With representative sample, use of Bayesian analytic approach would be possible. Applications of the results

in such cases will be valid for a vast heterogeneous Indian population suffering from a disease being studied.

Transparent recruitment of participants through advertisement will lead to outcomes which can then be generalized to our population. These realistic outcomes would be beneficial to the society.

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