THE ROLE OF SOCIAL SCIENCE RESEARCH IN CLINICAL TRIALS: PROSPECTS AND CHALLENGES

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Abstract

In clinical trials, interventions involve rationally designed experiments that assign human subjects to control or treatment groups to test the efficacy of medical devices or procedures for the prevention of human diseases. In such studies, social science research plays a vital role in understanding human responses to the set devices. Devices' behaviour could be properly observed through human behaviour. Likewise, under the leadership of the AEGIS (Advancing Evidence for the Global Implementation of Spatial Repellents) research project, a clinical trial was initiated in 2023 to test the efficacy of a Spatial Repellent (SR) designed against Dengue Mosquitoes in three selected Medical Officer of Health (MOH) divisions (Negombo, Wattala and Kelaniya) in Gampaha District. Two foreign universities from the United States of America led the study, in collaboration with a local state university, the Ministry of Health, and a private clinical institute. Spatial Repellents are products in which a defined amount of the registered chemical transfluthrin is included and can be pasted on a wall to limit human exposure to mosquitoes within a given space. The trial's planned timeline was two years. In addition to testing the efficacy of the installed SRs by collecting mosquitoes and by frequent checking of infected patients during the study periods by a science team, a concurrent social science (SS) study was also designed and implemented to observe human responses to installed household SRs. Unlike in the science cohort of the study, the sample sizes of the social science research methods were not extensive. However, various methods were utilized, including Ranking, Free-listing, Retail audits, and Trials of improved practices with participants of different sample sizes. The main aim of this study was to explain the prospects and challenges, including institutional and contextual factors, in designing and implementing social science research in Clinical studies. Data collection involved a participatory approach, as the researcher herself was able to analyze the advantages and challenges encountered in the design and implementation of the social science study while working full-time in the initial phase of the trial. The findings revealed that the SS team could build trust among recruited participants in the epidemiological and entomological study by making frequent visits to collect data and using multiple research approaches, which enabled them to listen to participants' grievances, such as direct claims against the SRs. As the SS team was trained in and known for the art of talking to clarify participants' doubts, participants' suspicious behaviour towards the SRs was eradicated. Allowing access to a house is a significant sacrifice given by a participant, and keeping them in the study for 2 years was also a major challenge for the science team. Houses that were not eligible for SR installation were creating myths, gossip, and unwarranted fear about the overall study. With the SS team's engagement, SR installations continued, and participants' withdrawals from the science study were reduced. Challenges included recruiting and training the SS team to use multiple languages in participant-friendly materials, negative household attitudes towards the frequent visits, social issues such as drug-addicted household members, and issues related to compromising social science research requirements for the study's epidemiological and entomological teams. In conclusion, the engagement of rationally adopted multiple research approaches into a large-scale clinical study in Sri Lanka was a new effort. Integrating social science perspectives into a science-based study has brought many advantages.

Keywords: Social Science Research, Clinical Trials, Role, Prospects, Challenges