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ORIGINAL ARTICLE

Community-based recruitment for clinical trials poses the need for social and ethical considerations

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Abstract

Objective: This article's objective was to describe the processes, strategies, and challenges of community-based recruitment to complement hospital-based recruitment for a global clinical outcomes trial on chronic obstructive pulmonary disease (COPD).

Study Design and Setting: To increase the subject recruitment for the clinical research, field staff were trained on community-based recruitment strategies and activities. Courtesy calls and coordination with community organizations were done before recruitment activities. House-to-house interviews using patient referral checklist, lay fora on COPD, and spirometry camps identified eligible participants in five sites in the Philippines.

Results: Of 3,202 individuals interviewed, 27% potentially eligible were referred to hospital sites. Of 55% who were successfully screened, 9% were randomized. Courtesy calls and endorsements identified potential recruits. Issues related to communication, work, health condition, and family members' encouragement affected participation. Complexity of the eligibility criteria contributed to the high screen failure rates. Enabling full subject protection entitlements before informed consent taking was one of the ethical issues identified.

Conclusions: Community-based recruitment may increase subjects for clinical trials depending on the complexity of the requirements. Adopting a community-based recruitment strategy must be decided at the planning stage for efficient coordination of activities. Social preparation should consider socioeconomic and cultural factors. Current ethical guidelines and regulations indirectly address issues on community-based recruitment.

Keywords: Community-based recruitment; Clinical trial; COPD; Philippines; Ethical guidelines; Low- and middle-income country

1. Introduction

Successful recruitment of eligible study participants is one of the most common challenges of randomized controlled trials [1]. Given the value of study participants and the importance of timely completion, having a pool of potential subjects is essential while ensuring ethical and good clinical practices.

Guidelines and regulations underscored by Good Clinical Practice govern recruitment of participants for clinical trials. These guidelines were prescribed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use [2]. Recruitment should be conducted under specific inclusion/exclusion/withdrawal criteria aimed at "promoting and safeguarding the rights, safety, and well-being of all trial participants." Subject selection and recruitment considered various ethical concerns: (1) conflicts of interest of sponsors, investigators, and the recruitment team; (2) protection of privacy and confidentiality of subject information; (3) informed consent and recruitment modalities; (4) vulnerability of subjects; (5) incentives and compensation for subjects; and (6) community considerations.

Ethical guidelines are generally embedded in existing research governance or oversight systems such as those used by institutional review boards. In the Philippines, the National Ethical Guideline mandates these regulations for health research [3]. These requirements for protection of subjects are premised on controlled environment and availability of facilities and infrastructure in a hospital-based study. Such studies have a system for receiving patients seeking a specific health care service. In hospital-based

Conflicts of interest: None.

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What is New?

Key findings

- In LMIC, community-based recruitment may complement clinic/hospital recruitment of patients to fill the enrollment demands of large studies.
- Social preparation which marks entry to the community may be facilitated through the help of gatekeepers and collaboration with local leaders who provide legitimacy of the activity and encourage community participation.

What this adds to what was known?

- Existing local and international ethical guidelines and regulations do not directly address some of the ethical issues particularly informed consent process and full subject protection entitlements on community-based recruitment. In this study, the community recruitment team obtained the local officials' approval for the conduct of the interviews and verbal consent of the participants for the administration of the questionnaires. The investigators were not yet directly involved in the clinical trial and the clinical trial informed consent process had not officially begun.

What is the implication and what should change now?

- The community recruitment team coordinated with the local health organizations including physicians at the health centers to secure possible listing of patients with underlying disease of interest.
- Owing to lack of access to health care in LMIC, the clinical trial should cover costs for screening tests and transportation. The community recruitment team provided transport service to participants going to the referral hospitals that performed screening tests in addition to spirometry in order to establish and document clinical history of the participants.
- Collateral benefits to the LMIC community include opportunities for information dissemination, patient education, screening and medical consults. The community recruitment team conducted lay fora and spirometry camps to increase awareness of and participation to the clinical trial.

studies, therefore, patient identification and recruitment is facilitated by the patients themselves [4].

Given the processes, strategies and challenges of recruitment in the community, this article attempted to argue that community-based recruitment, in addition to hospital-based recruitment, may be beneficial to clinical trials. However, it also presents social and ethical problems.

2. Review of literature

One of the most challenging tasks in a clinical trial was patient recruitment as it can delay study completion [5]. Patient recruitment involved locating patients who satisfy the eligibility criteria and encouraging them to enroll in a clinical trial. To be considered successful, recruiting enough number of patients on a specified timeline is very essential. Around 80% of all clinical trials failed to meet subject recruitment goals, and about 15% to 40% dropout rates were common [6]. Those involving a clinical trial unit did better, with 65% recruiting to target [7]. Furthermore, clinical trials in developing nations took up to twice as long as originally anticipated [8].

Before a drug is released in the market, regulatory agencies require efficacy and safety studies. Thereby, the demand for subjects for clinical trial is increasing. The traditional approach of recruiting patients into a clinical trial is the ''physician-based recruitment,'' defined as those methods where the physician or site staff was the main facilitator targeting patients [5]. The physician or site staff may use their own patient database and initiate contact with the patient to provide information about the study and its benefits.

Given the increasing demand for subjects, physician-based recruitment alone was unlikely to meet the need; hence, additional strategies of patient recruitment were warranted. Community-based recruitment strategy was cited by some clinical studies as another approach to patient recruitment [5,7–12]. It was centered on a specific community and its members and included recruiting patients via events or locations and using various members such as municipal health workers [5]. Community outreach activities included setting booths in health fairs, attending community meetings or patient support group meetings, and gaining support of a well-known leader in the community. A systematic review reports that community-based strategies are essential in the recruitment process; using printed materials and electronic media are top strategies. Collaborating with community health workers is one of the best ways to achieving sufficient numbers of study subjects [5].

Community health workers or barangay health workers, the frontline primary health care providers working voluntarily in specific villages were well integrated and trusted leaders in their own community. In collaborating with community health workers, a study was able to attain 53% of the patients. The community health workers' enduring relationships as well as familiarity with existing social networks and various community organizations was an