

Abstract:

BACKGROUND: There are a number of practical and ethical issues raised in school-based health research, particularly those related to obtaining consent from parents and assent from children. One approach to developing, strengthening, and supporting appropriate consent and assent processes is through community engagement. To date, much of the literature on community engagement in biomedical research has concentrated on community- or hospital-based research, with little documentation, if any, of community engagement in school-based health research. In this paper we discuss our experiences of consent, assent and community engagement in implementing a large school-based cluster randomized trial in rural Kenya.

METHODS: Data collected as part of a qualitative study investigating the acceptability of the main trial, focus group discussions with field staff, observations of practice and authors' experiences are used to: 1) highlight the challenges faced in obtaining assent/consent; and 2) strategies taken to try to both protect participant rights (including to refuse and to withdraw) and ensure the success of the trial. **RESULTS:** Early meetings with national, district and local level stakeholders were important in establishing their co-operation and support for the project. Despite this support, both practical and ethical challenges were encountered during consenting and assenting procedures. Our strategy for addressing these challenges focused on improving communication and understanding of the trial, and maintaining dialogue with all the relevant stakeholders throughout the study period. **CONCLUSIONS:** A range of stakeholders within and beyond schools play a key role in school based health trials. Community entry and information dissemination strategies need careful planning from the outset, and with on-going consultation and feedback mechanisms established in order to identify and address concerns as they arise. We believe our experiences, and the ethical and practical issues and dilemmas encountered, will be of interest for others planning to conduct school-based research in Africa.