

Establishing community advisory boards for clinical trial research in Malawi: engendering ethical conduct in research

L Manda-Taylor

College of Medicine Research and Ethics Committee (COMREC)
Administrator, University of Malawi,

Abstract

In this article I deal with extending the ethical principles of research to include communities through the establishment of Community Advisory Boards (CABs). The aim of the project on which this article is based demonstrates the need for protecting communities that participate in research in order to stimulate ethical conduct in research in Malawi. In the article, I provide an overview on the role and functions of CABs. I discuss the establishment of CABs in Malawi and present descriptions of the processes and challenges involved. I conclude by sharing experiences of some of the key lessons learnt from the establishment of CABs.

Introduction

Over the last 60 years the discourse on human subject protection has been firmly entrenched in the discipline of research ethics. The Belmont Report was the first document to provide specific guidelines for the protection of human subjects. This document is an authoritative source in the field of research ethics. The principles of respect for persons, beneficence and justice articulated in the Belmont Report provided the foundation for ethical conduct by stipulating the core ethical obligations to researchers to respect research participants; minimise risk and balance benefit; and fairly select research participants in order to equitably distribute the benefits and burdens of research¹. The increase in clinical trials over time, however, has made it imperative for researchers to go beyond the strict application of the Belmont principles.

Extending the Belmont Principles to involve communities

The emphasis placed on the individual in terms of the application of these basic ethical principles are being viewed as too narrow, and calls are made for a wider scope in the application of the principles. Gostin, Wiejer, Quinn and Williams et al. have gone so far as to suggest that the principles articulated in the Belmont Report ought to be expanded to include a fourth principle: respect for communities^{2,3,4,5}. For example, Gostin expands the application of existing ethical principles to encompass populations and communities, extending to groups the protection that was previously reserved for individuals². Group protection, asserts Weijer is necessary to address the increasing vulnerability of groups and to supplement the 'atomistic' view of the person epitomised in the Belmont Report³. Williams et al. have noted that this 'argument is made on the basis of ethical reasoning and a few reports of adverse effects of health research in communities'⁵.

College of Medicine's training in human subjects' protection

With clinical trial research on the increase in the University of Malawi's College of Medicine it necessary to comply with international standards of good clinical practice. Part of the College's Institutional Review Board's (IRB) mandate is to

provide training in the ethics of the International Conference on the Harmonisation of Good Clinical Practice (ICHGCP) to faculty members, ethics committee members, students, researchers and community members. The major topics of the training in ICHGCP include: the principles of ICHGCP, informed consent, ethics – IRB review boards, responsibilities of the investigator, responsibility of the sponsor, clinical trial protocol, investigator brochure and essential documents. A complementary course to ICHGCP is a course on human subjects' protection (HSP). A broad spectrum of topics are covered that include the history of research ethics, the role of ethics committees, informed consent, the rights and responsibilities of research participants, the role and functions of community advisory boards (CABs), the composition of CABs, leadership qualities, among others. This course places emphasis in areas that ICHGCP does not.

Including the community perspective

The introduction of HSP confirmed a gap that needed to be filled in the desire of the College to build research capacity and knowledge and enhance ethical conduct in research. Training community members in HSP, through the establishment of CABs at clinical trial sites that don't yet have one, contributes to engendering human subject protection in research. The establishment of CABs ensures that communities are respected, informed and engaged.

Community engagement or consultation, a growing field in bioethics and global health, is a formal process of working collaboratively with and through groups of people affiliated by geographical proximity, special interest, or similar situations to address issues affecting the well-being of those people⁶. As a process it is increasingly recommended as best practice in developing countries. Quinn points out that there has been little evaluation on the functioning of CABs in literature ... Research on their functions, the roles of members, barriers and challenges, and interactions with researchers and community is essential⁴.

Defining Community Advisory Boards (CABs)

The definition of CAB is derived from the term 'community'. Traditionally, the term has been understood to refer to people who share a common identity, history, symbols, language and culture. As Strauss et al. put it, CABs comprise of 'community members who share a common identity, history, symbols and language, and culture'⁷. Israel et al. echo this, but are a bit more cautious with their terminology. For them, CAB members 'may share a common interest, identity, illness experience, history, language and culture'⁸. However, there is no standard definition of a community and the same can be said of CABs because it is now accepted that those who live in the same geographical locality do not necessarily share the same perspectives, history, and language, culture or value system. In the words of Tindana et al. 'people who live in close proximity to one another do not necessarily constitute a community, since they may differ with respect to value systems and other cultural characteristics that are more relevant to the social concept of community'⁹. While there

is some disagreement about the precise definition of what a CAB is, for the purposes of this article, I define CABs as community members who reside in the same geographical area, share common community interests, a language that is understood by all, similar cultural values and illness experiences.

The role and function of CABs

What are the role and functions of CABs? To begin with, individuals who serve on CABs as representatives of the interests of the community function as a source of leadership in the partnerships between researchers and the community. Their purpose is to 'serve as a liaison between participants and researchers'⁷. In this manner, they provide 'an infrastructure for community members to voice concerns and priorities that otherwise might not enter into the researchers' agenda, and advise about suitable research processes that are respectful of, and acceptable to the community'¹⁰. They can assist in 'the development of study materials, advocate for the rights of minority research study subjects, and consult with potential study participants to provide recommendations about research study enrolment'⁴. Other functions include disseminating results to the community, ensuring the protection of research participants and clarifying the ethical obligations when participating in research. In short, the purpose in the establishment of a CAB, as Quinn states, 'is to provide a mechanism for community consultation that contributes to protecting communities and fostering meaningful research'⁴.

Challenges facing CABs

The idea of CABs as an ethical requirement for research involving human participants can also present challenges. For example, community interest in volunteerism may not be strong, especially if the benefits for doing the work are intangible. The requirement that CAB work be voluntary may not be well understood by people living in poor rural communities as members may expect some type of monetary incentive for their work of disseminating the research procedures to the community and at the same time motivating community members to play a role in addressing health-related issues that affect them¹¹. Hence, 'the process of community engagement may raise the expectation of the community to levels beyond what the proposed study may be capable of tackling'¹¹. Moreover, 'the resources allocated to the development and management of CABs tend to be limited and are often the first to be cut from study budgets when research priorities are considered'⁷. The global economic downturn has impacted on the amount of funding sponsors and funding agencies that are willing to provide and invest in research and development. In the current economic context, it is easy to see how a sponsor can perceive the establishment of a CAB as a significant cost to research.

Benefits of CABs

Although these challenges are real and exist, there are overall potential benefits of engaging with communities. Borrowing from the recommendations made by the National Institute of Allergy and Infectious Diseases (NIAID), I support the establishment of CABs because people who form a community provide the most direct opportunity for making a difference within that community while public health

research that aims to be successful cannot afford to overlook this resource when planning strategies¹². Collaboration between researchers and communities helps to ensure that communities themselves invest in the research, making data and results more significant for the community, thereby ensuring that the project is mutually beneficial¹³. Community participation also helps researchers achieve 'better penetration of communities with more acceptable and culturally relevant messages, and greater sustainability of the intervention activities and effects'¹⁴. Community participation in research can be instrumental in raising awareness about influences of HIV transmission within the community, producing attitude changes in community leaders and strengthening leadership capacity in those parts of the community most affected by illnesses such as malaria, HIV/AIDS and TB. A common perception in many communities is that researchers disregard the perspectives and needs of the community. Community participation can help build trust between the researchers and those being researched. In short, CABs present an ideal platform to address such challenges if and when they do arise.

Establishing CABs in Malawi

Malawi does not have regulatory or legal requirements or guidelines for the establishment of CABs. However, research institutions involved in clinical trial research in Malawi such as the Johns Hopkins University Research Project (JHP-Malawi), the University of North Carolina Project (UNC-Malawi), and the Malawi-Liverpool Wellcome Trust (MLW) have trained and established their own CABs to support their research activities. These research institutions affiliated to, or independent of, the College of Medicine have established CABs that 'examine a whole array of research studies'⁴. However, for independent researchers within the College of Medicine, such groups are not available. It was for this reason that a proposal was submitted by the College's IRB to the European and Developing Countries Clinical Trial Partnership (EDCTP) to call for support to strengthen its research oversight activities. The title of the grant was Enhancing Community Understanding and Protection in Human Subjects Protection in Malawi. The project lifespan was for two years, from March 2011 to March 2013. Since the commencement of this project, 228 community members have been trained in HSP and six CABs have been established.

Methods

I report on activities that involved the establishment of CABs at various clinical trial sites in Mpemba, Madziabango, Thyolo, Ndirande and Zomba. The process of establishing CABs at these sites involved conducting sensitisation meetings with traditional leaders and Health Surveillance Assistants (HSAs) in an area near or close to the health facility where the clinical trial was taking place. The aim of this meeting was to inform traditional authorities and health workers within the community about the proposed training and the establishment of the CAB. At this meeting, the concept of CAB was introduced and explained to the traditional leaders and HSAs.

Who should participate in a CAB?

It was important that local community leaders be engaged because they are the gatekeepers of the community. They are also the entry point into the community and should one wish to launch a successful project, cooperation of community leaders is vital. It was also during this meeting that the

facilitators/trainers asked HSAs to identify individuals in the community who could attend this training and to forward names of participants who were proposed to the traditional leaders for their vetting. We emphasised to HSAs the need for gender balance and to include local political leaders, local clergy members and not simply ordinary men and women. The reason was simple. These stakeholders offered a good opportunity for disseminating information to the community. Following from this meeting, workshop dates were arranged with the study team, a venue was identified and the selected participants were invited to attend.

Training

The methods employed to train and establish a CAB was a three-day training workshop conducted in the local language with community members residing near the training venue and within the catchment area of the clinical trial. The topics covered have been mentioned above.

Setting up the CAB

After participants had received the training in HSP, the facilitators/trainers assisted the community to establish a CAB for the clinical trial. Elections were held for the positions of chairman, vice-chairman, secretary and vice-secretary. The elected individuals made up the executive committee of the CAB and the remainder of the trained participants were the members. Sometime after the CAB had been established, the facilitators/trainers organised a one-day follow-up meeting which aimed to bring together the CAB members to provide a report or feedback on the CAB activities, the success and challenges and mapping the way forward. This one-day follow-up activity provided the project with a perfect opportunity to assess the impact of the CAB by listening to the input by CAB members. The information obtained from this meeting is presented below.

Findings

All the community members from the different areas demonstrated willingness to participate in the training, and they were receptive to the idea of establishing a CAB in their community. The participants revealed that they had never received such form of training, and topics such as what health research is, the role of ethics committees, informed consent and rights and responsibilities of research participants were useful. In addition, the topics that focused on CAB work generated much interest, particularly with regard to the role and functions of CABs. The participants felt that such a structure should have been put in place before health research had begun in those areas. On the whole, the training received positive feedback on the usefulness of the topics and the need for a CAB structure.

Discussion

During our follow-up meetings feedback from the functioning of CABs was presented. This feedback provided important insights into the fact that sometimes practical everyday difficulties can hinder the work of CABs. From the feedback presented, four common themes became clear at all CAB clinical trial sites.

Identity

Firstly, CAB members experienced a lack of support from their fellow community members when communicating their work, because members did not have identity documents, shirts and other paraphernalia that linked them to the research study. The perceived lack of legitimacy tended to demoralise the group's efforts to liaise with researchers and community

members. This suggests that for CABs to do their work effectively, research studies ought to embrace them as soon as possible and see them as part of the research team, while respecting their independence, thus ensuring that CABs carry out their role impartially. The caution to researchers here is not to co-opt the CAB structure, as this may jeopardise the independence of the CAB. It is important for researchers to minimise and manage conflicts of interest between the study team and CAB members so that CABs continue to work for the protection of human participants in research.

Communication and relationships

The people serving in the CAB structures in Mpemba and Madziabango reported that in the beginning the research teams did not engage with them, invite them to have a meeting or provide them with the necessary background information on the clinical trial and stationery. This oversight hampered the CAB work in the community. The hurdle these two CABs encountered in the days following their establishment demonstrated that, for CABs to be effective, both researchers and CAB members need to go to the community and disseminate information on the research, establish relationships with the community, build trust and work with the formal and informal leadership and power structures in the community⁶.

Operational challenges, mainly financial

In Thyolo and Zomba, CAB members complained that they were unable to do their work, and to meet with the study team because of a lack of transport money to enable them to travel from their homes and villages to the health centre. For this reason, CAB members expressed that they should be provided with monthly airtime vouchers and transport allowances to enable them to communicate with the research team, and to provide them with an update on the community concerns and the challenges they faced in the field. Shubis et al. noted a similar challenge in an article titled 'Challenges of establishing a Community Advisory Board (CAB) in a low-income, low-resource setting: experiences from Bagamoyo Tanzania'. The authors observed:

Working in a poor community introduced the unique challenge of monetary expectations of CAB representatives. From the beginning, BRTC has paid the travelling expenses (fare and pocket money) for the CAB members to attend all CAB related events. As small as the payment may appear, it is actually quite substantial for some of the members in our area. We are aware that this financial support could influence CAB members to alter their convictions or opinions of the research projects¹⁵.

This implied that the idea of volunteering or volunteer work during CAB training was not properly understood. This finding supports what Chileshe and Tembo report on the challenges they encountered with the establishment of CABs in Zambia.

The issue of volunteerism was often problematic for CAB members of the Zambia research studies. Most were confronted with the local reality of high unemployment and low income. Many felt that they should receive payment or an allowance for their contributions¹⁶.

Community perceptions

Other challenges reported by CABs related to the rumours and misconceptions of the research studies that, at the time, were being conducted at all the sites we visited. In Madziabango and Mpemba, a randomised control trial (RCT) testing scheduled intermittent screening

and treatment in pregnancy (ISTP) versus intermittent preventive treatment with sulphadoxine-pyrimethamine (ISTP-SP) in women protected by insecticide treated nets (ITNS) for the control of malaria in pregnancy in Malawi required that after birth, the woman's placenta is taken to test for traces of placental malaria. At the Madziabango site, enrolment of women into the trial was slow and one of the many concerns the community members had pertained to the removal of the afterbirth. In Ndirande, a similar problem existed for the RCT that looked at chloroquine as chemoprophylaxis versus intermittent preventive therapy to prevent malaria in pregnancy in Malawi. In the follow-up meetings, the Madziabango and Ndirande CABs noted that they had to address many community concerns. For example, in Madziabango, many husbands were concerned about why their wives' placentas were being taken after birth. In Ndirande, it was reported that community members suspected that researchers, after childbirth, take the placentas to sell them. This suggested that perhaps the community was not sufficiently and appropriately engaged. Before starting a research project, for instance, researchers need to have a clear community engagement plan for the communities they need and want to engage, and efforts to engage them should centre on the specific health issue or goal that the research is tackling or addressing. Another rumour that the Ndirande CAB had to deal with was that they connived with the researchers to siphon blood from participants who enrolled in the study. This rumour was similar to findings in the Zambian experience on the lessons learned from HIV-prevention trials. 'The rumours often exaggerated the amount and frequency of blood samples collected, as well as why they were collected. When study participants were reimbursed for travel expenses, some people circulated rumours that they were being paid for their blood samples'¹⁶. This suggested that the challenges that CABs face in Malawi are not unique to this context. In fact, across our geographical border, similar rumours and misconceptions are abound.

Sharing experiences: some key lessons learned, including recommendations for setting up CABs In this section, I share our experiences with establishing CABs in Malawi. As stated above, the challenges that CABs face in Malawi are not unique, but common in other settings notably, in Zambia and Tanzania.

Training and information

To begin with, I would like to assert that communities should receive adequate information education and training about the role and functions of CABs before the proposed research starts. This means that CABs ought to be established before the research activities commence so that CAB members are adequately trained for their roles as CAB members and, most importantly, on the protocol so that they can answer any study-related questions and concerns community members may raise. This also requires that researchers set up sensitisation meetings with local health authorities, traditional and political leaders and community members to explain the function of CABs thus legitimising its existence as this will ensure that communities understand the role of CABs and buy into the concept of CABs.

Involving men

Most research in Malawi tends to target female participants, because they are the ones who usually present themselves at health clinics for medical treatment and care for themselves or their children. Naturally, more women will tend to join

research studies and when they do, men in the community must be involved, engaged and informed about the research from the beginning. This is very important, especially in the African context where men are the decision-makers in the home and without their support rumours can flourish thus impacting on study recruitment rates and enrolment numbers.

The special challenge of volunteering

According to Akintola, volunteering involves committing time and energy to provide a service that benefits someone, society or the community without expecting financial or material rewards¹⁷. From our experience with CAB training and establishment, volunteerism or the notion of being a volunteer ought to be made very clear at the beginning of the CAB training workshop. Community members who are willing to serve on the CAB should understand that they are volunteering their services to the research for the benefit of the community. It should be made clear, therefore, that the only compensation they can receive for rendering their services to the research – and, by extension to the community – is through 'an honorarium to compensate for expenses incidental to the CAB meeting'¹⁸.

Conclusion

CABs address the core ethical obligations articulated in the Belmont Report which are: to minimise risk and balance benefits for research participants and their communities, respect participants and communities and promote benefit-sharing in research so that the benefits and burdens of research can be distributed equitably. In addition, CABs add to the application of the existing ethical principles to include protections to communities. In this article, I have provided a report back on the activities of the project on training and establishing CABs. Challenges and key lessons learnt from the experiences are provided, and recommendations are offered for readers who are interested in learning from our experiences.

Acknowledgements

The author wishes to thank the European and Developing Countries Clinical Trials Partnership (EDCTP) for their funding support for this capacity-building grant titled, Enhancing Community Understanding and Participation in Human Subjects Protection in Malawi[CB.2010.41302.012]. The author is grateful to Messrs Francis Masiye and John Chabuka, for the role they played as trainers for the project. The author is appreciative of the efforts Ms. Jackie Viljoen for the numerous times she proof-read and edited the content of this manuscript.

References

1. The Belmont Report: Ethical Principles and Guidelines for the protection of human subjects of Research. 1979; hss.gov/ohrp/humansubjects/guidance/Belmont.html. Accessed 14 August 2013
2. Gostin L. Ethical principles for the conduct of human subject research: population-based research and ethics. *Law Med Health Care* 1991; 19: 191-201.
3. Weijer C. Protecting Communities in research: philosophical and pragmatic challenges. *Camb Q Health Ethics* 1999; 8(4): 501-513.
4. Quinn SC. Ethics in public health research. Protecting human subjects: the role of community advisory boards. *Am J Public Health* 2004; 94(6): 918-922.
5. Williams RL, Willging CE, Quintero G, et al. Ethics of health research in communities: perspectives from the southwestern United States. *Ann Fam Med* 2010; 8(5): 433-439.
6. Centers for Disease Control and Prevention (1997) Principles of community engagement 2nd Edition. CDC/ATSDR Committee

- on Community Engagement. 1997; http://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf. Accessed 20 May 2013
7. Strauss R, Sengupta S, Quinn S, et al. The role of community advisory boards: involving communities in the informed consent process. *Am J Public Health* 2001; 91(12): 1938-1943.
8. Israel BA, Checkoway B, Schulz A, et al. (1994) Health education and community empowerment: conceptualizing and measuring perceptions of individual, organizational, and community control. *Health Educ Q* 1994; 21(2): 149-70.
9. Tindana PO, Singh JA, Shawn Tracy C, et al. (2007) Grand challenges in global health: community engagement in research in developing countries. *PLoS Med* 2007; 4(9). www.plosmedicine.org. Accessed 8 May 2013
10. Newman SD, Andrews JO, Magwood JS, et al. Community advisory boards in community-based participatory research: a synthesis of best processes. *Prev Chronic Dis* 2011; 8(3). http://www.cdc.gov/pcd/issues/2011/may/10_0045.htm. Accessed 8 May 2013
11. Nyika A, Chilenji R, Ishengoma D, et al. Engaging diverse communities participating in clinical trials: case examples from across Africa. *Malar J* 2010; 9(86). <http://www.malariajournal.com/content/9/1/86>. Accessed 5 December 2012
12. Merzel C and D'Afflitti J. Reconsidering community-based health promotion: promise, performance, and potential. *Am J Public Health* 2003; 93(4): 557-574.
13. Leung M, Yen I and Minkler M. Community-based participatory research: a promising approach for increasing epidemiology's relevance in the 21st century. *Int J Epidemiol* 2004; 33(3): 499-506.
14. Beeker C, Guenther-Grey C, and Raj A. Community empowerment paradigm drift and the primary prevention of HIV/AIDS. *Soc Sci Med* 1998; 46(7): 831-842.
15. Shubis K, Juma O, Sharifu R, et al. (2009) Challenges of establishing a community advisory board in low-income, low-resource setting: experiences from Bagomoyo, Tanzania. *Health Res Pol Syst* 2009; 7(16)
16. Chileshe M. and Tembo E. Lessons Learned from Lusaka, Zambia. In: Community involvement in international research: lessons learned from the HIV prevention trials network. Family Health International (FHI). 2006; <http://hptn.org/web%20documents/CommunityProgram/HPTNCommunityLessonsLearned/LessonsLearnedComplete.pdf>
17. Akintola, O. What motivates people to volunteer? The case of volunteer AIDS caregivers in faith-based organizations in KwaZulu-Natal, South Africa. *Health Policy and Plann* 2011; 26(1): 53-62. Doi:10.1093/heapol/czq019. Accessed 21 August 2013
18. Crawford E. The role of community advisory boards in project Eban. *J Acquir Immune Defic Syndr* 2008; 1(49). <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2853920/>. Accessed 20 May 2013