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Evaluating Community Advisory Boards' Capacity to Support Meaningful Engagement in Clinical Research: A Mixed-Methods Study

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Abstract

Active involvement of communities is fundamental in health research, and Community Advisory Boards (CABs) are among the key mechanisms used to achieve this engagement. Despite their importance, the extent to which CABs can effectively fulfill their responsibilities in clinical research is not well established in many low-resource contexts. This study explored the operational capacity of CABs to support meaningful community participation in Uganda. A cross-sectional mixed-methods design was employed. Data collection involved structured questionnaires administered to CAB members, alongside key informant interviews (KIIs) with investigators and community liaison officers. Quantitative information was summarized using descriptive statistics, while qualitative responses were analyzed through content analysis. Structured questionnaires were completed by 73 CAB members; 58.9% were male, with a median age of 49 years (range 24–70). While 71.2% reported tertiary education, a substantial proportion lacked research-related training: 42.5% had never attended research ethics courses, only 26% had training in human subject protection, 30.1% received instruction in health research, and over half (50.7%) had no training regarding CAB roles. Furthermore, 72.6% reported the absence of operational guidelines. From the 24 KIIs, CAB members were recognized as being able to review study protocols, advise on cultural and community expectations, and provide useful feedback to research teams. However, recurring barriers were highlighted, including limited funding, lack of autonomy, absence of standardized guidelines, and insufficient understanding of ethical issues. CABs in Uganda demonstrate some ability to contribute to community engagement in clinical research. Nevertheless, their effectiveness is undermined by inadequate resources, lack of independence, absence of operational frameworks, and insufficient knowledge of research ethics and participant protection.

Keywords: Knowledge, CABs, Capacity, Community engagement, Research communities, Training, Research ethics

Introduction

Community engagement is recognized as a cornerstone of health research because it establishes dialogue between researchers and the public, fostering mutual understanding. One of the most commonly adopted approaches to achieve this, particularly in HIV clinical trials, has been the use of Community Advisory Boards (CABs) [1]. A CAB represents a structured partnership between research institutions and the community, providing a formal avenue for community voices to be incorporated into research planning and implementation [2]. As part of best practice in clinical research, trials are generally expected to have a CAB that acts as a bridge between the research team and the host community [3]. This mechanism allows community perspectives to inform the research cycle, from protocol design through to dissemination of results. Uganda was among the pioneers in Africa to establish a CAB in the 1990s, initially linked to an HIV vaccine project [4].

Although CABs do not make scientific or ethical determinations, they contribute in important ways—such as reviewing informed consent materials, ensuring cultural appropriateness of study tools and incentives, and advising on community sensitivities [5, 6]. By doing so, CABs help research teams gain deeper insight into local realities at different stages of a trial [7],

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strengthening trust and collaboration between scientists and communities [8]. In Uganda, CABs have become an integral part of most research institutions, where they support activities like community sensitization and the protection of participants' rights. To be effective in these roles, however, members must possess adequate knowledge of community engagement principles, ethical frameworks, study protocols, and the socio-cultural context of the research setting.

The ability of CAB members to interpret research ethics, anticipate potential community risks, and communicate feedback effectively is central to improving engagement with lay populations [9]. CAB members themselves often view their contributions as valuable for strengthening researcher competence and enhancing the quality of studies [10]. Despite these benefits, their work faces notable obstacles. These include gaps in ethical guidance, insufficient scientific knowledge among members, weak management structures, communication challenges across languages [11], and limited independence since their activities are often supported by research teams through reimbursements and logistical facilitation [12].

In general, there is little systematic evidence from Africa, and Uganda in particular, regarding how well CABs are able to perform their expected functions. Most available frameworks only describe how CABs should be formed but do not provide clear direction on how they should operate in practice. In Uganda, this lack of clarity partly reflects limited oversight from the Uganda National Council for Science and Technology (UNCST) [13], which has not set comprehensive standards for CAB operations or the training required for members. Consequently, responsibility for establishing and supporting CABs typically falls to principal investigators or host institutions [13], who tend to prioritize protocol-specific orientation over broader training on skills needed for effective community engagement. This has resulted in gaps in knowledge and functionality of CABs.

The present study therefore set out to examine the capacity of CABs in Uganda, with a focus on identifying gaps in skills and training that could hinder their ability to carry out their roles effectively.

Methods

Study design and setting

This investigation applied a cross-sectional design with a mixed-methods strategy, where quantitative and qualitative data were collected and analyzed concurrently. The study was implemented in Uganda between March and October 2020 and involved 19 research institutions identified in the National Drug Authority (NDA) clinical trials database [14]. From a total of 74 listed clinical trials, 26 were randomly chosen, comprising both ongoing and recently completed trials (within the past year). The number of trials selected per institution depended on the volume of trials conducted: one was drawn from institutions hosting 1–4 trials, two from those with 5–9, three from institutions running 10–14, and four from institutions conducting 15 or more. This procedure yielded 26 trials across the 19 institutions. All Community Advisory Boards (CABs) linked to these trials were included. Study participants consisted of CAB members, their chairpersons, trial investigators, and community liaison officers—staff members within research institutions tasked with serving as intermediaries between investigators and the communities where studies take place.

Data collection

The quantitative component consisted of structured, face-to-face interviews with CAB members. Data were gathered electronically using KoBo Toolbox, an open-source platform, which was preloaded onto tablet devices. Research assistants synchronized data daily to the central server, allowing supervisors to review and clean the entries in real time. At the end of fieldwork, datasets were downloaded from the KoBo platform and transferred into STATA software for management and statistical analysis.

For the qualitative component, key informant interviews (KIIs) were conducted with trial investigators, CAB chairpersons, and community liaison officers. Participants were purposively selected based on their familiarity with community engagement in clinical trials. A pre-developed KII guide was followed, covering themes such as the role of investigators and CAB members, operational challenges, facilitation of CABs, regulatory oversight, investigator–CAB collaboration, and perspectives on improving trial conduct.

Data analysis

Quantitative variables were summarized using frequencies and percentages for categorical data and medians for continuous measures. Qualitative interviews were transcribed word-for-word and translated from local

languages (Luganda, Runyankole, Lusoga, and Lusamia) into English. A coding framework was developed from the English transcripts, and thematic analysis was applied to extract patterns aligned with the study objectives. Findings are presented in the form of thematic narratives supported by direct quotations. Quantitative analysis was performed in STATA version 14 [15], while qualitative data were managed and analyzed using Atlas.ti software [16].

Results

In the quantitative strand, all 73 identified CAB members agreed to participate in the structured interviews. Among them, 43 (58.9%) were male. The median age of participants was 49 years, with an interquartile range (IQR) of 24 to 70 years. **Table 1** summarizes the socio-demographic distribution of the CAB members.

Table 1. Distribution of demographic characteristics of CAB members (N = 73)

Characteristics	Number	Percentage (%)
Sex		
Female	30	41.1
Male	43	58.9
Age (years)		
< 30	6	8.2
30–39	11	15.1
40–49	23	31.5
50–59	21	28.8
60–69	11	15.1
70+	1	1.4
Highest level of school completed		
None	1	1.4
Primary	3	4.1
Secondary	17	23.3
Tertiary/university	52	71.2
Main occupation		
Formal employment	10	13.7
Farming	13	17.8
Business	45	61.6
Other	5	6.9
Marital status		
Married/co-habiting	54	74.0
Widow/divorced/separated	7	9.6
Never married	12	16.4

Among the 73 CAB members who participated, more than half—42 individuals (57.5%)—reported having no exposure to training sessions in research ethics. As illustrated in **Figure 1**, the remaining members highlighted varying levels of participation in different courses, including good clinical practice (GCP), responsible conduct of research (RCR), health research, human subject protection (HSP), and research ethics.

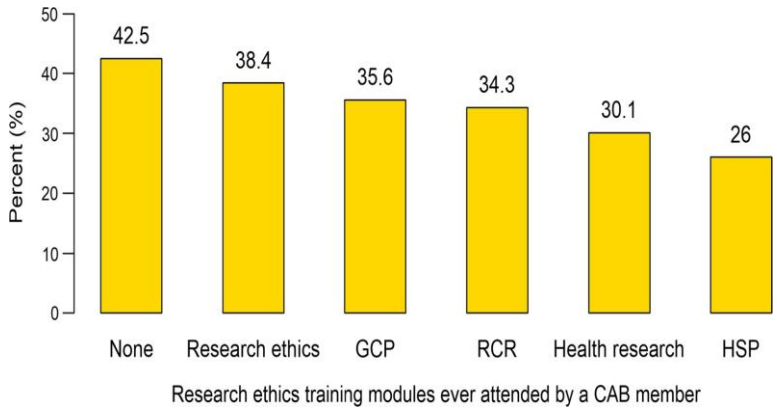

Figure 1. Percentage distribution of CAB members and the ethics training attended

Among the 73 CAB participants, just over half (50.7%) indicated that they had never received any form of training related to CAB operations. For those who had undergone at least one training session, nearly two-thirds (63.9%) noted that the ethics training they attended was organized by trial investigators, as summarized in **Table 2**.

Table 2. Training of CAB members

	Number	Percentage (%)
Number of times CAB members reported to have attended training on CABs operation during the period they served as members	N = 73	
Never	37	50.7
Once	6	8.2
Twice	12	16.4
Three or more	18	24.7
Who initiated and facilitated the training	N = 36	
Trial investigator	9	25.0
Research institution	23	63.9
Regulatory body e.g. UNCST, IRB	1	2.8
Others	3	8.3

In the qualitative component, key informant interviews were carried out with 10 CAB chairpersons (including 5 women), 10 trial investigators (3 women), and 4 community liaison officers (2 women). **Table 3** presents the breakdown of interviewees by age and sex.

Table 3. Distribution of sex and age of participants for the qualitative component (KIIs)

Characteristics	CAB chairpersons	Trial investigators	Community liaison officers
	N = 10	N = 10	N = 4
Sex, n (%)			
Male	5 (50%)	7 (70%)	2 (50%)
Female	5 (50%)	3 (30%)	2 (50%)
Age (years)			
Median (IQR)	48 (47, 58.8)	40 (34.8, 47)	44 (39.3, 47.3)
Min, max	32, 75	31, 62	28, 54

Content analysis

Analysis of the qualitative interviews revealed three major themes: (1) researchers' perspectives on the role of CABs in clinical trials, (2) the need for additional training of CAB members, and (3) challenges faced by CABs. The findings are presented according to these thematic areas.

Researchers' perspectives on CAB roles in research

Participants indicated that CAB members possess the capacity to comprehend various study documents, including consent forms, participant information sheets, and interview tools. This understanding enables them to assist in reviewing materials and provide informed guidance to the research team. Several investigators highlighted that CAB input is valuable for adapting study materials to local communities and for offering practical feedback on diverse aspects of the research.

One community liaison officer noted the importance of CABs in simplifying complex research concepts: "Most of these trials use highly technical language. For instance, explaining randomization or double-blinding to community members was challenging. When we engaged the advisory board, they suggested describing the process and rationale in detail instead of using a single technical term. This approach helped the community grasp these concepts, which illustrates the primary role CAB members play" (KII with Community Liaison Officer).

Similarly, a trial investigator emphasized the value of CAB feedback: "Whenever we present to the CAB, they provide insights that non-scientists might not anticipate. Their feedback is extremely useful for participant follow-up and overall study implementation" (KII with Trial Investigator).

Need for training

The qualitative data also revealed gaps in training for CAB members. Training provided by investigators tends to focus predominantly on study-specific protocols rather than broader research principles. Orientation usually covers the research process in lay terms and trial-specific community engagement activities, and it is typically conducted at the start of the study.

One investigator explained: "Beyond protocol orientation, we haven't provided comprehensive training. There are several areas, including general research knowledge, where CAB members could benefit, and this highlights the need for us to plan structured training sessions" (KII with Trial Investigator). Another stated: "Our trainings have mostly been brief meetings, like the initial CAB orientation covering terms of reference, roles, and expectations, with occasional refreshers during the study" (KII with Trial Investigator).

In addition, investigators reported that CABs receive guidance on the study overview, eligibility criteria, target population, and planned community engagement strategies. CABs are also trained to support participant recruitment and follow-up, illustrating their essential role in trial implementation (KII with Trial Investigator).

Some respondents highlighted that CAB members need training in areas beyond their immediate roles in clinical trials, such as research literacy and community engagement advocacy. However, such training is often tailored to the specific interests of the research team and the study being conducted. The primary goals are first to build awareness and appreciation for the role of research in daily life—essentially fostering research literacy—and second, to develop advocacy skills for engaging communities. Additionally, CAB members should be informed about their responsibilities, roles, and mandate as advisory board members (KII with Trial Investigator).

It was observed that to fully empower CAB members to perform their roles effectively, training and capacity-building efforts should not rest solely on trial investigators or research teams. Regulatory bodies and ethics committees should also actively support CABs by providing the necessary training and resources. For example, while ethical issues can be briefly introduced in training, the focus should be on understanding the project and maintaining its integrity—a responsibility that should fall under the Research Ethics Committee rather than the investigators (KII with Trial Investigator).

Challenges faced by CABs

Discussions with CAB members revealed mixed perceptions of their effectiveness. While some believed they were fulfilling their roles appropriately, others acknowledged gaps in their performance. A major challenge cited was difficulty understanding complex scientific concepts, such as blinding, placebo, treatment and intervention arms, and randomization in clinical trials.

One CAB chairperson explained

"We need support from the PIs and more accessible information on trials. As CAB members, we must understand the research language. For instance, when discussing placebo, many members don't know what it means. We need to reach a level of comprehension where we can follow discussions." (KII with CAB Chairperson)

Another CAB member recounted an experience where technical staff were challenged during a presentation by a Professor who questioned whether the information was too complex for the audience. The member noted:

"In our CAB, I am a reverend, and another member is a sex worker. The information needs to be simplified in terms we can understand, rather than using scientific jargon that confuses us and discourages participation." (KII with CAB Chairperson)

Other factors that hindered CAB effectiveness included limited independence, lack of clear operational guidelines, insufficient resources and funding, overlapping responsibilities across multiple trials, knowledge gaps in research ethics, and unfamiliarity with participants' rights. CAB members also cited insufficient basic research training and limited availability due to other livelihood responsibilities. One trial investigator noted:

"Theoretically, CABs are independent, but in practice, they are not. They should be able to act according to their conscience without fear of reprisal, work without bias, and be respected while representing both the community and research." (KII with Trial Investigator)

Concerns about the visibility and functionality of CABs were also raised. A Community Liaison Officer described the CAB as largely symbolic:

"The CAB is essentially a ghost committee. It exists on paper, but most members don't understand its purpose. If you asked trial participants today who the CAB members are, many wouldn't know, and some have never even heard of a CAB." (KII with Community Liaison Officer)

Discussion

This study aimed to evaluate the capacity of CABs for meaningful engagement of communities during the conduct of clinical trials. It provides an account of CABs' capabilities as well as the various challenges that affect their functionality in resource-limited settings. The findings indicate that CAB members possess a certain level of ability to understand and review study documents and can provide guidance on community norms and expectations, as well as relay important feedback to investigators and back to the community. However, gaps in knowledge and skills were evident, which limit their effectiveness. For instance, a substantial proportion of CAB members (42.5%) had not participated in any research ethics training, only one-quarter had received training in human subject protection, and over half had never attended any training regarding the role of CABs. Other challenges reported as limiting their capacity included inadequate resources to support their activities, lack of independence, absence of operational guidelines, and difficulty understanding and explaining scientific concepts such as placebo and randomization.

The roles of CABs encompass understanding clinical trials, reviewing study documents, and providing input on community norms and values, which were noted in the findings; however, these roles are not fully realized due to the challenges described. Insufficient resources may hinder CABs' efficiency, preventing them from holding meetings, engaging effectively with communities, or operating independently.

CABs are appointed and facilitated by investigators or research institutions, which creates an expectation of allegiance to the investigators. This perceived lack of independence may compromise their ability to fully perform their roles, as CAB members might prioritize accountability to researchers over community interests. Consequently, members may report trial violations only to the investigator or research institution, potentially limiting protection for trial participants. These findings align with previous studies, which also highlighted concerns regarding CAB independence [1, 12], often linked to the support provided by research teams, such as transport reimbursements and other assistance [12]. The independence of CABs could be strengthened if their operations were regulated by national research authorities, allowing them to report any violations directly to regulatory bodies, such as ethics committees, rather than solely to investigators.

Inadequate training among CAB members limits their ability to effectively explain research concepts such as placebo, randomization, blinding, informed consent, and the rights and welfare of research participants, thereby reducing their effectiveness. The gaps in CAB training identified in our study further reinforce the findings of Mlambo *et al.* [1], who recommended ongoing training and capacity building to enhance CAB functionality. However, prior studies have often focused on a single or limited number of CABs targeting specific study populations with a narrow scope. For instance, Mlambo

et al. [1] examined only one CAB within an HIV-affected community and collected data solely from CAB members.

A key strength of our study is the use of mixed methods for data collection and analysis, covering the entire CAB membership. Nonetheless, the study did not evaluate the procedures followed in forming the CABs, which is a limitation. It would also be valuable to explore the perspectives of trial participants regarding CAB roles in their communities, an area not addressed in this study. Additionally, the qualitative component did not capture the views of regular CAB members, which could have provided further insight. While we assessed capacity primarily through ethics training, other measures of CAB capacity could also be considered. Another limitation is that the cross-sectional design and interviews assessed CAB members' skills and abilities without observing or implementing interventions to directly evaluate their performance. Future intervention studies that examine CAB performance following training are recommended, as training alone may not guarantee effective performance due to other operational challenges.

Conclusions

The study demonstrates that CABs in Uganda possess a certain level of capacity to carry out their roles. They are capable of understanding and reviewing study documents, offering guidance on community norms and expectations, and providing valuable feedback to investigators. However, their effectiveness is constrained by multiple challenges, including insufficient knowledge and training in research ethics, limited resources to support their work, lack of independence, and absence of operational guidelines. This study highlights both the strengths and limitations of CABs, emphasizing the need to address these challenges to ensure effective community engagement in health research.

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