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The role of community advisory boards in health research: Divergent views in the South African experience

Priscilla Reddy, David Buchanan, Sibusiso Sifunda, Shamagonam James, Nasheen Naidoo

Abstract

In the light of the growing involvement of community advisory boards (CABs) in health research, this study presents empirical findings of the functions and operations of CABs in HIV/AIDS vaccine trials in South Africa. The individual and focus group interviews with CAB members, principal investigators, research staff, community educators, recruiters, ethics committee members, trial participants and South African AIDS Vaccine Initiative (SAAVI) staff members demonstrated differences in the respondents' perceptions of the roles and responsibilities of CABs. These findings question the roles of the CABs. Are they primarily there to serve and be accountable to the community, or to serve the accomplishment of the research objectives? Four emergent themes are discussed here: purpose; membership and representation; power and authority; sources of support and independence. The CABs' primary purpose carries significant implications for a wide range of issues regarding their functioning. The dual functions of advancing the research and protecting the community appear to be fraught with tension, and require careful reconsideration.

Keywords: South Africa, community advisory boards, HIV vaccine trials, qualitative study, South African AIDS Vaccine Initiative, SAAVI.

Résumé

À la lumière de l'implication croissante des conseils consultatifs communautaires (CAB) dans la recherche dans le domaine de la santé, cette étude présente les résultats empiriques des fonctions et des opérations des CAB dans les essais vaccinaux sur le VIH/SIDA en Afrique du Sud. Les entretiens individuels et en groupe ont été menés avec les membres des CAB, les principaux chercheurs, le reste du personnel, les éducateurs de la communauté, les recruteurs, les membres du comité d'éthique, les participants aux essais et la South African AIDS Vaccine Initiative (SAAVI). Les auteurs ont mis en évidence les différences de perception des personnes interrogées à propos des rôles et des responsabilités des CAB. Ces conclusions posent la question du rôle de ces derniers. Sont-ils d'abord là pour être au service de la communauté et être responsable devant elle, ou sont-ils là pour permettre d'atteindre les objectifs de l'étude menée ? Quatre thèmes ont été relevés et sont examinés ici : le but du CAB, sa composition et sa représentation, son pouvoir et son autorité, ses soutiens et son indépendance. S'interroger sur le principal objectif des CAB est essentiel car le choix de telle ou telle réponse entraîne des conséquences importantes sur leur mode de fonctionnement. Sa double fonction consistant à la fois à faire progresser la recherche et à protéger la communauté semble entraîner des tensions et ne plus être tenable.

Mots clés: Afrique du Sud, conseils consultatifs communautaires, essais vaccinaux contre le VIH, étude qualitative, Initiative sud-africaine sur le vaccin contre le SIDA (ISAVS).

Introduction

There is growing attention to the principle of establishing community advisory boards (CABs) to advise investigators on the conduct of health research. In 2000, the National Institute of General Medical Sciences recommended that researchers obtain community input into all phases of research, respect communities as partners, and establish appropriate community review

procedures (National Institute of General Medical Sciences, 2000). In response to controversies over the conduct of international health research (e.g. AZT to prevent perinatal HIV transmission in a placebo-controlled trial), bioethicists have issued calls to mandate community involvement in decision-making about the ethical conduct of health research in international settings (Brody, McCullough & Sharp, 2005; Weijer & Emanuel, 2000). Community

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participation is imperative to insure that communities are not exploited (Emanuel, Wendler, Killen & Grady, 2004).

Despite this surge in interest, few public policies have been enacted that define the role and responsibilities of CABs in relation to health research. This paper presents data on the functions and operations of CABs in HIV/AIDS vaccine trials in South Africa. This is part of a larger study designed to assure adequate protections for participants in HIV/AIDS clinical prevention research (Buchanan, Sifunda, Naidoo, Reddy & James, 2008).

Background and significance

Diverse influences have contributed to the formation of CABs, which has resulted in considerable ambiguity about their current role. Historically, involving CABs in health research can be traced to three major streams of influence. One stream dates to the philosophy of “participatory action research”, where social scientists thought that active community engagement was critical to achieve social change. This philosophy has been influential in shaping current “community-based participatory research (CBPR)” (Minkler & Wallerstein, 2003). In CBPR, the role of CABs focuses primarily on improving intervention effectiveness (e.g. developing culturally tailored programmes).

In another stream, CABs have served in HIV treatment research in the US since the late 1980s. Their creation grew out of conflicts between researchers and activists, who protested the random assignment of participants to a control condition, which they regarded as effectively a death sentence (Morin, Maiorana, Koester, Sheon & Richards, 2003). These efforts signified the first steps towards assuming an ethical role for CABs in monitoring research. In 1989, the Community Programme for Clinical Research on AIDS marked the first time that the NIH required the use of CABs in relation to research (Cox, Rouff, Svendsen, Markovitz & Abrams, 1998; CPCRA, 1996). In 1999, the HIV Prevention Trials Network (HPTN) recommended that sites be required to solicit community participation through CABs. Researchers were not provided instructions on forming CABs, but rather had to propose a CAB plan, which was reviewed as part of the competitive scientific review. In a 2005 statement by NIAID, CABs were envisioned to provide input on scientific matters related to achieving the research objectives (e.g., advice on conducting outreach to marginalised populations), and oversight on ethical issues related to protecting the interests of the participants (e.g. reviewing informed consent documents) (National Institute of Allergy and Infectious Disease, 2005).

A third stream has surfaced that addresses perceived shortcomings in the individual informed consent process. Strauss and colleagues (2001) proposed a set of CAB responsibilities that systematically parallel the threshold, informational and consent elements contained in the individual informed consent process. Similarly, while shifting from the individual to the community level, Emanuel and colleagues (2004) argue that community participation ensures that communities are not exploited. They state that this ethical requirement entails: developing partnerships among researchers, policy makers and the community; involving community partners in identifying health problems; assessing the value of the research; planning, conducting, and overseeing

the research; integrating the results into the health care system; respecting the community’s values, culture, and social practices; and ensuring that communities benefit from the research. Thus CABs are perceived primarily in an ethical role.

Previous empirical studies

A review of the literature revealed four empirical investigations of CAB involvement in health research. In 1998, a survey of 267 CAB members living with HIV/AIDS in the US showed that CAB members defined their role as: communicating community preferences about the research; educating community members about HIV; recruiting participants; and evaluating study-specific patient education materials (Cox *et al.*, 1998).

A study done across six HPTN international sites among CAB and research team members, found two distinct models of CAB membership: a “broad community” model that had representation from a cross section of the community; and, a “population-specific” model that consisted of the particular population at risk identified in the research protocol (Morin *et al.*, 2003). Reflecting on the dual scientific and ethical functions, they concluded that “CABs improved prevention clinical trials by assisting in protocol development, recruitment and retention” (p. 1). Furthermore, CABs “identified and helped resolve ethical issues in clinical trials” (p. 1). A follow-up study to assess the evolution of community partnerships found that the CABs had evolved new strategies for community representation (e.g. expanding the number of members to make them more representative), and had expanded their original function to become advocates for broader community interests beyond HIV prevention (Morin *et al.*, 2008).

Finally, Sharp and Foster (2002) present two case examples of work with American Indian and Alaskan Native populations to illustrate dilemmas that remain unresolved by the call for expanded community oversight. They recommend further research to 1) examine the respective merits and problems with various approaches to community consultation; 2) to conduct further analysis of the goals of community involvement; 3) to assess the degree to which the various goals of community consultation are served by different approaches; and, 4) to describe best practices with respect to resolving key issues identified in their analysis.

Thus the objectives of this study were to examine within the South African HIV vaccine clinical trial environment: the purpose of the CABs; the structure and representivity of the CABs; the scope of power and authority of the CABs; and the level of independence of the CABs.

Research methods

Study setting and sampling

The South African Aids Vaccine Initiative (SAAVI) is a programme of the South African Medical Research Council responsible for overseeing the conduct of the HIV vaccines trials in South Africa, and currently funds several HIV vaccine clinical trial sites located in the provinces of Gauteng, Western Cape, North West, KwaZulu-Natal, and the Eastern Cape. A theoretical sampling process to identify potential interview participants based on their category of participation at the various SAAVI trial sites was used. All the

research participants were actively involved in at least one clinical trial from the SAAVI trials sites. We targeted key informants such as principal investigators, counsellors, community liaison officers, recruiters and CAB members. All participants in the study voluntarily agreed to be interviewed through the signing of an informed consent form. The study received ethics approval from the South African Medical Association Research Ethics Committee (SAMAREC).

Data collection

A qualitative design using in-depth individual and focus group interviews was employed. In-depth interviews were conducted with 18 key informants, and two focus groups were held with 30 CAB members. A semi-structured open ended interview schedule based on themes identified from the literature was constructed. These themes included: 1) current involvement in HIV prevention research; 2) perceptions of community participation; 3) CAB membership recruitment and operations; 4) roles and responsibilities of CABs; 5) perceptions of research in South Africa; 6) recruitment strategies of trial participants; and 7) community education regarding HIV and vaccines in particular. The interviews were conducted by the five research team members, in English, seSotho and isiXhosa. All interviews and focus groups were recorded with digital voice recorders and then the files were immediately transferred into laptop computers at the end of the sessions, and along with the electronic transcripts, backed up as several copies and stored in a secure location at the researchers' office. A policy decision was taken by the senior research team to alter personal identifiers in the data at the end of the study so that subjects could no longer be identified.

Data analysis

Each interview was transcribed, checked for accuracy and entered into NVivo® data management software for coding. The interviews were analysed using standard methods of content analysis by reading the transcripts multiple times to gain a sense of the flow of the discussion (Miles & Huberman, 1994). Each transcript was coded independently by three members of the research team. The first step of the analysis captured the manifest

content of the interviews - the surface-level presentation of topics. Independently identified codes were then compared, and where similar, combined into single categories through consensus discussions. The second step produced 'tree nodes' or major categories that were inductively synthesised from the first step. Through a process of constant comparative analysis, relationships among the primary codes were integrated and condensed into the final four emergent themes (Fig. 1). Quotations highlighted below were selected as the most representative of the main themes identified.

Findings

The interviews and focus group discussions covered a broad range of issues on the status of HIV clinical trials in South Africa, but this paper highlights specifically the issues pertaining to the formation, roles and functioning of CABs. A range of issues about the potential value and challenges of community involvement in health research emerged throughout all the interviews. Salient differences in the respondents' perceptions of the roles and responsibilities of CABs also emerged. These differences were grouped into categories that reflect whether CABs are seen primarily to serve and be accountable to the community on the one hand; or to the trial site and the researchers on the other. As a principal investigator said: *"There's just a whole lot of contradictions within the CABs – I want you to work very hard, but I can't pay you, because if I pay you, there'll be a conflict of interest."* These divergent views emerged throughout the four themes outlined below (see Fig. 1).

1. Purpose of CABs

South Africa does not have any legal requirements for community oversight of research, as investigators are placed in a position of fulfilling international granting agencies' funding requirements. This means that there are several CABs in one trial site, essentially recruiting participants from the same geographical community. CAB members articulated their ambivalence and dilemmas regarding their purpose and role, but also demonstrated an understanding of different purposes. While these viewpoints were not necessarily mutually exclusive, how one defined the

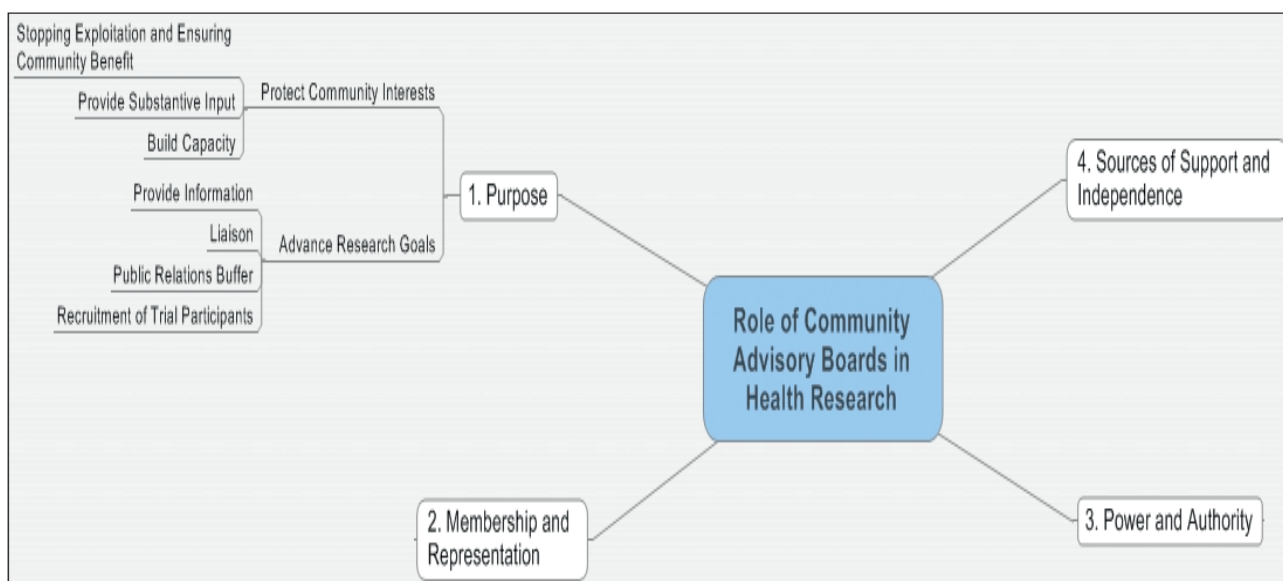


Fig. 1. Schematic representation of qualitative findings.

CABs' primary purpose had significant implications for their functioning:

If you have recruited me into the trial, I would like to know: Where are your interests? You should have interests! Does the CAB have any obligation of making sure that we recruit sufficient numbers, or does the CAB have an obligation of making sure that whatever the numbers that we recruit are well informed? I think for me that it is the difference. [CAB member]

But partnership? I am not sure about the conditions of that specific partnership, because partnership can mean quite a number of different things. We might be partnering in crime, saying we are doing research and not following some ethical issues, but because we are partners, we need to compromise. But if you actually advise, you need to be able to say, "But you are not doing it right, and that is not what those people need." So that is the difference. [CAB member]

1.1 Protect community interests

The interviews revealed three sub-themes on protecting the community's interests: a) stopping exploitation and ensuring community benefit; b) providing substantive input into the research protocol; and c) building community capacity.

1.1.1 Stopping exploitation and ensuring community benefit:

I think we must guard against the fact of over-exploitation of communities regarding research. I see that happening in South Africa quite a lot, I think it is going to be extremely important to look at the communities that you are doing the research on, and make sure that they are not over-exploited. [CAB member]

Their primary role is to have some input into some decisions that are made around the trial site for the benefit of the community. I think it is their main role within the trial sites. [PI]

In addition to safeguarding the community's interests, CABs were also seen to have a role in protecting individual research participants, as mentioned by CAB members and researchers:

Our role is to provide awareness to the community as a CAB for HIV/AIDS, vaccines and issues of science, and to look after the rights of the participants, their rights are not being violated. These are our roles as a CAB member. [CAB member]

If any of the trialists are upset, the CAB could be an ombudsman and act on their behalf. [PI]

1.1.2 Providing substantive input

CABs shared a desire to provide meaningful and substantive input into the research process from its inception to conclusion:

If you sit down with the CAB members and really ask them questions like, 'What else can you do?' they will actually say to you, 'I can make a decision about where the trial will be, we can make decisions about whole plan for the research. Can't we make decisions about the budget?' [SAAVI staffer]

When protocols are set up, there are community representatives there to participate until the end. That participation says that, if you can start from the earliest stage, it is easy to advise so that you can reach that level of saying, 'This needs to be changed.' [CAB member]

1.1.3 Building capacity

Many respondents believed that the appointment of CABs contributed to "empowering" the community, thus ensuring that "the researchers/sponsors [are] giving back to the community." Additionally, it was felt that the creation of CABs could play a role in developing a culture of human rights:

Our approach to community involvement should be both a means to an end and an end in itself. It supports the vaccine development process, but also an end in itself, it ensures that development takes place in the community, there is a human rights culture in the community, people are developed to be able to take decisions in many ways, also in terms of research I think the reality is that doing research in society involves certain risks and society's capacity to deal with it is very limited at this stage... it is critical that we build society's capacity to deal with the question of research. [SAAVI staff member]

Beyond that, they've [the researchers] got an obligation to make sure that they develop researchers amongst the community itself, because I believe that researchers are very few. So if communities are directly involved in research, they should also be groomed to become researchers at the end of the day. [CAB member]

1.2 Advance research goals

In contrast to protecting the community's interests, the various respondents indicated that other primary roles of the CABs could be to provide information and liaise with the community, as well as acting as a public relations buffer, and assisting with recruitment:

They know their communities better than we do. They are there to work with us in implementing our studies and to help us understand the community. [PI]

1.2.1 Provide information

Researchers and CAB members indicated that one of the roles they played within the trial site was to provide the community with information about the trials:

My role is to provide the community with information about the vaccines trials, to make them aware of vaccine research. You can have that information from the site and take it to the community. [CAB member]

In addition to the information dissemination role, many respondents saw the CABs as playing a two-way mutually informative liaison role between the community and the researchers. CAB members assisted the researchers to conduct the trials more effectively:

The role of the CAB is to be a link between the trial sites and the communities, and to feed back to the trial sites about the issues

of the people and the communities out there, because research is a new thing among us, so, sort of, to enlighten both sides. [CAB member]

1.2.2 Public relations buffer

More strongly, several PIs described the role of the CAB in terms of serving public relations purposes:

Advocacy is probably the biggest one that we rely on. they are supposed to be the mouthpiece of - not the mouthpiece, that would be the wrong - 'liaison' [PI]

If there are problems with stakeholders etc., then they assist with resolving it. They deal with it, rather than us as researchers having to deal with it. [PI]

1.2.3 Recruitment of trial participants

The interviews revealed a clear expectation of the researchers for the CABs to play an active role in recruitment, thus assisting in the successful completion of the trials with the required number of volunteers. CAB members expressed a dilemma regarding how they perceived their roles. They felt that they should educate and enlighten the community as well as serve as gatekeepers to the community, assisting researchers to gain access into the community and not engage in active recruitment creating a sense of conflict:

We rely on them quite a lot for recruitment. They are the advocates, recruitment in one form or the other, there is an absolute expectation that they do that. [PI]

We need 500 people. We agree on the protocol, we discuss it, they understand what's going into it. They then take it back to their group and they say 'Go and tell your mates the center needs healthy 18-35 year olds to volunteer, etc.' [PI]

Because they tend to be the gatekeepers of the community, without their permission, the doors will remain locked. [PI]

As CAB members, we are not allowed to recruit. "Does everyone agree with this?" All: "Yes." It used to be like that. We used to confuse our role and end up getting involved in recruiting. That should not be the role of the CABs. The CAB should just educate and enlighten, not actually recruit." [CAB member]

2. Membership and representation

Three models of selection processes emerged as being used to constitute CAB membership so that they were "representative" of the communities from which they originated; namely purposeful selection, election, and a mixed model.

2.1 Purposeful selection

CABs were set up by the researchers at the trial site using a 'sectoral' approach ie. inviting stakeholder organisations such as NGOs, AIDS councils, faith based organisations and so on. These organisations were deemed to have an interest in the research. Some criteria for recruiting CAB members included "hard workers" and committed individuals. However, CAB members questioned this approach as there may be issues of legitimacy and representation:

They told us that they need to formulate CABs, reps from different NGOs, there is this briefing. They explained to us what were the vaccines, what were the CABs, how the CABs interact with the research staff, what would be their role. They said, "Because you have been selected from your respective organisations, is it possible that you can be in our CAB?" We said, "No, we need to set up a fresh date", so that we could communicate back to our organisations, and then we find the relevant people to be selected. [CAB member]

2.2 Election

The interviews did not reveal the use of a pure democratic electoral model in the setting up of CABs at the trial sites, although the discussions revealed some attempt at trying to achieve such a model:

You know, sometimes the CAB gets elected by the people, when you call the meeting, you go around and tell people that we have got a meeting tomorrow. And they elect one person to represent all the 50 [houses]. [CAB member]

2.3 Mixed model

This model was a combination of purposeful selection and election processes. Researchers were uncertain about the types of organisations to invite, as there were no consistent policies on how a CAB should be constituted. Another issue was that this model frequently deteriorated into a self-selection process, thus diminishing the intention to have a democratic process. Self-selection occurred at the organisational level and among the members within the organisation, for example whether the organisation chose to respond or ignore the invitation, whether the director went or sent someone else, who at the organisation was willing to go, resulting in mainly volunteers serving on the CABs:

It depends on the different organisations that are there within a community. It really is very complex because there are maybe a hundred organisations. One issue is whether selection is based on organisation or geography: So then we filled in the slots of the sectors and the geographical areas. [CAB member]

These [volunteers] are often opinionated, but they may not be truly represented well in the community, and that is one of the problems. There is often a disconnect between people on the CAB and the general community. [CAB member]

Because they are volunteers, their attendance is quite irregular. Sometimes they come, sometimes they do not. Maybe the NGOs send different people all the time, there is no continuity. [Researcher]

3. Power and authority

Almost all the respondents explained that the CABs had limited influence on the substantive decisions of the research project. There was widespread ambivalence about the term "board", as in South Africa this implied having legal powers and authority. The CAB members realised that they had no authority and legal power. For this reason the name CAB was changed to Community Advisory Group (CAG). Researchers indicated that while CABs

were being perceived as being equal partners, in reality this was a challenge to achieve. Ethics committee members did not perceive CAGs as “ombudpersons” or “whistleblowers”. In a rare instance, where the university was not able to oversee a study directly, the CAB was used to play an oversight role:

The CAB members always complain that we impose upon them. The scientists come with everything ready and impose upon them. So they just put their signature and that is it. [PI]

We have not yet managed to achieve that role of advisor, specifically to the researchers. [CAB member]

We took the three words – community – advisory – board, and we interrogated these three words, said, ‘We are not boards; we are groups. [CAB member]

To some extent, we say they are equal partners, although we know we can never be equal in any context. It is difficult to have people who are equal, but we are saying that. [PI]

In a democracy, there are always constitutive tensions. You have tension between executive and the legislature; you have a tension between certain points of power. I think it is important that it is there. To a certain extent, CABs do play a watchdog role as well and I think that is important and they should know that. [Research Ethics Committee member]

4. Sources of support and independence

The South African health system does not legally require the formation of a CAB or CAG at research sites. The CAB members are recruited and depend upon the trial site entirely. This includes financial support, materials for working with the community and training regarding the actual trial. This compromises the CABs ability to take an independent stand on issues emanating from the study. CAB members expressed their frustration at their dependence on the researchers, and expressed a need to obtain access to an independent source of funding from, for example the Department of Health. Additionally, some CAB members had sought training about the research from external sources independent of the research team:

Do you think that CABs being resourced by the research center makes a difference in how a CAB behaves? [Interviewer]

I am sure it would do, yes. In a sense, there may be a tendency that the CAB is beholden to the researchers, because ultimately, you control them. So, I mean, no, not that we control them, but we control the money. [PI]

I think the only time we get money is when the CAB holds monthly meetings. We get some money for transportation. But if you come and say I want to go to a community, I have information for the community, then they don't have money. [CAB member]

The question is who really should be training them? Can we get the researchers to train CABs, or should we also be able to get

an external body to be training them? That's a question we ask ourselves. [CAB member]

Discussion

The formation of CABs in South Africa is researcher-initiated and driven. They are fulfilling the grant requirements as well as maintaining their scientific integrity. South African researchers have followed an international standard in setting up CABs for each of their studies, with expectations similar to those reported in the literature, namely recruitment, retention, assistance with troubleshooting (Cox *et al.*, 1998) and even participating in a “dry run”. In most instances, they strive towards achieving some form of community “representation” even though “community” and “representation” may not be clearly defined and may vary from trial site to site. While the CABs may have been formed using different processes, namely, some claiming to have representatives from stakeholders through an electoral process, while others have nominated influential gatekeepers, most CABs claim community representation.

Purpose of the CABs

The results highlight critical questions about each of the major terms: community – advisory – board. What is the “community” that they represent? Who do they “advise”? What kind of advice are they supposed to provide? Are they a “board” with executive decision-making powers? The findings indicate that there has been a change in terminology from CABs to Community Advisory Groups in South Africa. This further raises the issue of a total lack of legal standing held by the CABs, and leaves much to be discussed and debated in the context of the largely poor communities with low levels of health literacy in which the trial sites are located.

Membership and representation

Some respondents, mainly the researchers, described the primary function of the CAB as to assist the timely completion of the research. Research sites had expectations of CABs as “hard workers” who would “carry their weight” in terms of recruitment and mainly to “open doors” to large community groups. Therefore, researchers are driven to recruiting motivated volunteers from large NGOs and other community organisations which are influential. In this view, training and “capacity building” need only focus on issues of understanding the research protocol, inclusion and exclusion criteria, and the like. If their role is to assist the researchers, it “makes sense” and is acceptable for the CAB to have circumscribed decision-making authority, typically limited to making recommendations regarding the wording of project brochures and informed consent documents.

Power and authority, and sources of support and independence

In contrast, some participants, mainly CAB members, described the primary role of the CAB as protecting the participants, providing oversight, and ensuring that the community benefitted from their participation. If CABs are to represent the community's interests, then they must have a legitimate basis for their authority to speak on behalf of the community, such as through democratic election. To assure impartiality, CABs also need material, organisational

and educational independence from the research site. If it is the CAB's responsibility to protect participants and community members, then they must have real power and binding decision making authority, equal to that of a researcher or Research Ethics Committee.

According to Wertheimer (1996), for exploitation to occur, it is not necessary for one party to harm another, only that the benefit to one side be disproportionate compared to the benefit of the other. Some respondents echoed this sentiment by stating that CABs should have a role in stopping exploitation and ensuring fair benefit. To put these findings into context, it is important to recall that, because of the inherent risks involved in conducting research, there is an inescapable tension between generating new knowledge and protecting participants from harm.

Historically, it was assumed that researchers could manage this tension, monitor themselves, and carry out both functions successfully. In the aftermath of the brutal Nazi experiments on concentration camp prisoners and egregious misconduct by researchers at Tuskegee, however, there is widespread agreement these days that these functions must be separated (Weijer & Emanuel, 2000), with scientists responsible for designing the research to assure valid results, and independent ethical review boards responsible for protecting the participants (Curran, 1973). Like researchers had to do in the past, it appears that CABs are now being asked to do both, namely assist with conducting the research as well as provide the "oversight". Based on the findings presented here, the current situation appears to be fraught with ambiguity and no longer seems tenable. Depending on how one sees their principal obligations, it carries significant implications for the full range of issues regarding CAB operations.

Conclusion

In conclusion, CABs are but one form of community involvement in clinical trials. As South Africa emerges from a painful history that denied its people basic education, which resulted in diminished health literacy (South African Government, 1953), various notions of community oversight ought to be considered. Standards should be considered for the purpose, as well as parameters of community involvement. Mechanisms should be put into place for real community participation, and not just consultation and placation. All South Africans, particularly poor communities, can only benefit from national policies being

established to specify types of representation, resourcing and legitimising authority, as the clinical trial milieu develops within the fledgling South African democracy.

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