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Balancing science and community concerns in resource-limited settings: Project Accept in rural Zimbabwe

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Background The methods and purposes of randomization are often poorly understood by participants in clinical trials. Individual misunderstandings can be compounded in community-based intervention trials, especially in research-naïve communities. Randomizing entire communities to intervention or control status risks creating the perception that control communities are being denied desirable services, ultimately undermining trust in the research process.

Purpose To develop a randomization scheme for an HIV prevention trial of a community-level intervention that would be credible to the communities involved while maintaining the scientific integrity of the intervention trial at a rural site in Zimbabwe.

Methods Project staff developed strong partnerships with community stakeholders and embedded randomization into the trial's community preparedness processes. Local idioms were used to explain the concept, purpose, and mechanics of randomization. Actual allocation of communities to intervention or control status took place at a public lottery conducted by local chiefs.

Results The Project obtained the endorsement of its randomization of eight rural communities by local political stakeholders and community members.

Limitations This case study may not generalize to other settings.

Conclusions By developing strong community partnerships, and communicating randomization through local idioms, community based intervention trials conducted in resource-poor environments can successfully mitigate risks inherent in randomizing communities to control status. Clinical Trials 2008; 5: 273–276. <http://ctj.sagepub.com>

Recent controversies regarding clinical trials conducted in developing countries highlight significant challenges to effective community collaboration [1,2]. Research studies in developing countries have been halted or suspended for a variety of reasons, including lack of consensus on ethical issues, lack of appropriate care and treatment of participants, and the perception of limited community consultation [3].

Randomization is essential to the scientific validity of clinical trials, but research has shown that despite researchers' best efforts to convey information on the mechanics of randomization,

individuals often have less than optimum understanding of its scientific purpose or its importance to the goals of a given trial [4–9]. Participants may misinterpret being randomized to treatment or control variously as being grounded in some particular individual attribute [4], or as a haphazard process taking place outside of a clinical setting and implying lack of concern for them as individuals [9]. This places a responsibility on researchers to develop means of conveying and assessing individuals' understanding of randomization that ensure that participants' consent to enroll in a trial is fully informed [5,6,10].

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Individual misinterpretations may be compounded in a community-based intervention trial, where the community itself is the unit of analysis. Particularly in resource-constrained environments, randomizing an entire community to intervention or control status has the potential to create or exacerbate local conflicts that could ultimately generate hostility towards research itself. In such settings, it is absolutely critical to develop strategies for randomization that balance a community's needs for conceptual clarity and transparency with scientific integrity of the trial. For example, the THRio Trial in Rio de Janeiro, Brazil used a randomization scheme linked to the Brazilian National Lottery to determine the order in which clinics located in low-income communities would be initiated into a clinic-based tuberculosis preventive therapy intervention. This strategy ensured maximum buy-in from community stakeholders because it could be associated with a government agency known within the communities, but independent of clinic personnel and the study team [11]. Herein we describe the process that we used to develop an active community partnership to gain acceptance for community randomization in rural Zimbabwe.

Project Accept is a behavioral HIV prevention trial in which 34 communities in sub-Saharan Africa (South Africa, Tanzania, and Zimbabwe) and 14 communities in Thailand have been randomized to receive either a community-based HIV voluntary counseling and testing (CBVCT) intervention plus standard clinic-based voluntary counseling and testing (SVCT), or SVCT alone. The CBVCT intervention has three major strategies: to make VCT more available in community settings, to encourage testing through community mobilization and outreach, and to provide post-test psychosocial support. These strategies are designed to change community norms and reduce risk for HIV infection among all community members, irrespective of whether they participate directly in the intervention by accessing VCT.

Mutoko is a rural district located about 150 km east of Harare, Zimbabwe's capital. Mutoko has had no prior experience with research trials. In accordance with the Project Accept protocol, the Mutoko site's ethnographers identified eight comparable communities with a population of approximately 10 000 each on the basis of inhabitants' shared access to schools, health service centers, markets, and transportation hubs. These communities were matched into 4 pairs that would be randomly assigned to intervention or control status.

In a resource-constrained context as obtains in most rural communities in Zimbabwe, the political and community status of leaders is often enhanced by the number of development projects they are

seen to bring into their communities. Randomizing entire communities to control status therefore carried a real risk of elected or *de-facto* leaders of communities assigned to control disavowing results and discouraging local participation in the Project. To mitigate this risk, the Project first had to devise a randomization strategy that was both scientifically valid and transparent to the community stakeholders, and then use local idioms that would make the concept of randomization easily understood by traditional leaders and community members.

Project Accept staff decided to approach randomization not as an event but as an ongoing part of the community preparedness process in partnership with the Mutoko District AIDS Action Committee (DAAC). The Mutoko DAAC members include Chief Mutoko, the Mutoko District Council Chairperson, the Council's Chief Executive Officer, the District Administrator and other stakeholders involved in HIV prevention and AIDS care activities in the district. We engaged with these stakeholders on an ongoing and regular basis in order that they appreciate, from the very outset, that Project Accept was a research endeavor wherein some communities would end up receiving the community-based VCT intervention while others would receive the standard clinic-based VCT.

To explain the concept of a randomized controlled trial (RCT) to DAAC members, we used a supplementary feeding analogy that the communities were already familiar with, likening randomizing each matched pair of communities to a set of twins from one family who end up attending two different schools, only one of which offers *Mahewu* (an indigenous energy drink) during the morning break to supplement the child's lunch box from home. To explain the random allocation of communities, we also used local Shona language idioms that would resonate with traditional leaders, such as *mhanza/raki* ('by chance'), *makasi* ('luck of the draw'), *rotari* ('lottery'), *kuda kwaMwari* ('divine intervention') and *kutonga kwevaripasi* ('the will of the ancestors').

Once the Committee's concerns about randomization had been addressed, the DAAC itself took responsibility for explaining randomization in their communities. The Committee re-labeled 'control' as 'comparison', to better convey that these communities would also benefit from the Project. In fact, in keeping with international research ethics guidance [12], the Project established a VCT Centre in Mutoko's central business district – equidistant from the rural communities under consideration – based on the highest level of prevention counseling identified in previous clinical trials [13].

The trial's protocol called for the random assignment of each site's communities to intervention or control status by computer at the Project's

Pair #	Communities	Picked up at public lottery	
		Picked up	Not picked up
1	Charehwa Nyamuganhu/Chindenga	CBVCT	SVCT
2	Kawere/Chimoyo Mbuzi A/Chimoyo A	SVCT	CBVCT
3	Nyamukapa/Mawanga Chiwore/Nyahunure	SVCT	CBVCT
4	Nyamutsahuni/Nyadire Hoyuyu	SVCT	CBVCT

Figure 1 Project Accept Zimbabwe random intervention assignments

statistical center at Charles University in Prague. However, stakeholders from the Mutoko community voiced their concern that randomization by computer in Europe would not be transparent enough for Mutoko, and could create the impression that the Project favored intervention communities over the control communities. Project staff and DAAC members agreed that a public lottery of community names would achieve maximum public acceptance of the randomization results by enhancing transparency and spreading ownership of the process. Therefore, for the Zimbabwe site, the computer designated the randomization status for each pair of study communities only as the community name that would be 'picked up' or 'not picked up' in the public lottery (see Figure 1). This randomization protocol was password-protected and sent via e-mail to the site Principal Investigator (PI) in October 2005.

In line with the old adage that seeing is believing, the climax to the randomization process was the November 2005 extraordinary sitting of the full Mutoko Rural District Council, at which guests from other community-based organizations and Government line Ministries were invited to witness the public lottery conducted by local Chiefs. At the opening of the meeting, the Project's staff reviewed the results of community ethnography and preparedness exercises that had taken place to date, presenting randomization as the next step in implementing the Project, and explaining the concept of randomization again using local idioms. The lottery was then conducted in four draws by each of four local chiefs. First, each community name was written on a separate piece of paper. For each draw, the names of each matched pair were placed in a box. A chief then drew a paper from the box and the community name was read aloud. If the randomization protocol indicated that the 'picked up' community was to receive the intervention (i.e., CBVCT), then the PI announced the drawn community as an intervention community. If the protocol called for the 'picked up' community

to be the control (i.e., SVCT), then the PI announced it as a comparison community. This process assured equal chance of being randomized to the intervention or comparison arm, and eliminated any residual fears of bias or rigging. Because it was fully transparent to the District Council members, they unanimously accepted the outcome.

Our experience in rural Zimbabwe supports the contention that simply conveying information on randomization is not sufficient to generate community understandings of the goals of a trial [4,8], and that it is possible to develop effective strategies to integrate randomization into local decision-making processes in resource-poor settings. These strategies must be carefully developed as partnerships between researchers and communities [14], expressed in local vocabularies and experiences of randomness, and grounded in locally appropriate political processes. In our case, randomization was not simply a discrete event that took place on a distant computer, but also a community-driven process endorsed by the stakeholder partners themselves.

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