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**Balancing rigour and acceptability: the use of HIV incidence to evaluate
a community-based randomised trial in rural Uganda**

Authors-

Ms. Kirstin Mitchell
Ms. Sarah Nakamanya
Dr. Anatoli Kamali,
Professor James A.G. Whitworth

Affiliation of all authors

MRC Programme on AIDS in Uganda/UVRI
PO Box 49
Entebbe
Uganda

Tel: +256 (0)41 320272 / 320042
Fax: +26 (0)41 321137 / 321461
Email: mrc@starcom.co.ug

Contact address for first author (Mitchell, K.)

C/o Jeremy Armon,
FCO Uganda,
King Charles Street,
London,
SW1A 2AH

Tel: +256 (0)77 423776
Tel: +256 (0)41 266995

Email: jakm@infocom.co.ug

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Balancing rigour and acceptability: the use of HIV incidence to evaluate a community-based randomised trial in rural Uganda

Abstract

Recent debate about the evaluation of community based, HIV/AIDS behavioural interventions has focused on the appropriateness of the randomised controlled trial (RCT) design, and the difficulty of obtaining reliable outcome measures. A community based HIV/AIDS behavioural change RCT, recently conducted in rural Uganda, used HIV incidence as the principal outcome measure. This paper examines the acceptability of the trial from the community perspective. It asks whether, in a rural African setting, it is possible to implement a scientifically rigorous evaluation without compromising acceptability of the trial to the community. Opinions of the trial held by community members working as trial field workers were collected by semi-structured interview (n=37), and focus group discussions (4). Community opinions of the trial were ascertained through 10 focus groups. For both field workers and the community, the sero-survey was more salient than the intervention, and the source of many rumours and disputes. Despite intensive mobilisation and close monitoring of field workers, it was impossible to ensure the veracity of explanations about the survey at ground level, and to protect each individual from coercion. The community expected a reward in return their blood. Although the introduction of incentives at the final survey round increased the acceptability of the trial, they not only created jealousies and tensions, but also led to expectations of greater rewards in future. We conclude that RCTs in poor, rural communities are feasible, but the challenges involved should not be underestimated. Obtaining community support for the trial, respecting established hierarchies, and close

supervision of field workers are all essential, but even then, controversies should be anticipated. There is an urgent need for relevant guidelines to help researchers navigate the complex ethical issues involved.

Keywords

community based intervention, ethics, HIV/AIDS prevention, Uganda, process evaluation, randomised controlled trial

Balancing rigour and acceptability: the use of HIV incidence to evaluate a community-based randomised trial in rural Uganda

Introduction

This paper explores the community response to a randomised controlled trial (RCT) which used HIV incidence as the principal outcome measure. It asks whether, in a rural African setting, it is possible to implement a scientifically rigorous evaluation without compromising acceptability of the trial to the community. The consequent ethical issues are explored, with the aim of informing the discussion on ‘good practice’ in the implementation of ethical community-based interventions in developing country settings.

Ideally, community based interventions would be implemented independently of any evaluation. In this ideal world, surveillance data would be comprehensive and reliable enough to allow comparison of study and non-study communities. Because this is rarely the case (particularly in developing countries) researchers are left with the challenge of balancing rigour and acceptability in the design of evaluations.

Proponents of randomised controlled trials (Oakley, 1990; Oakley, *et al.*, 1995; Stephenson & Imrie, 1998; Stephenson, 1999) argue that this methodological ‘gold standard’ can and ought to be applied to behavioural and community based interventions. Their critics (Kippax & Van den Ven, 1998) argue against this ‘epidemic of orthodoxy’, claiming that the use of RCTs to evaluate HIV health promotion interventions is ‘not only

unnecessary, but in most, if not all cases, inappropriate'. Drawbacks include the expense involved in random allocation, the difficulty of preventing 'leakage' from intervention to control groups, and the possibility that other programmes or broader social changes will contaminate the study area (Friedman & O'Reilly, 1997, Susser, 1995). RCT evaluations have also been found to create suspicion among HIV affected communities (Dockrell *et al.*, 1998).

There has also been much debate about the most appropriate outcome indicators for measuring behavioural interventions (Aral & Peterman, 1996). If the purpose of the intervention is to reduce HIV, then the use of HIV incidence is clearly the most appropriate indicator. Despite the weaknesses inherent in proxy indicators such as knowledge and attitudes (Johnson *et al.*, 1990, Aral & Peterman, 1996), sexual behaviour (Catania *et al.*, 1990; Stephenson, 1999), and biomedical outcomes (Aral & Peterman, 1996), HIV incidence is rarely used as an outcome measure (ibid 1996). We are aware of only one other randomised trial evaluating the impact of a behavioural intervention on HIV incidence (Mzezewa *et al.*, 1998). In the West, this partly reflects the low incidence of HIV in general populations and even in high risk groups (Stephenson, 1999).

However, even where HIV incidence is sufficiently high (as in Uganda) and large scale trials are feasible, the measurement of HIV in the community may raise other practical and ethical issues.

The ethics of research on AIDS in developing countries has recently been the focus of academic debate and media scrutiny. Criticism has focused on vaccine and drug trials on

poor, uneducated populations, who do not subsequently benefit (Guardian Weekly, May 11th, 2000). Because such research populations are vulnerable, there is an onus on the researchers to maintain the highest ethical standards. A number of important guidelines (e.g. the Belmont report of 1978) have been developed for the conduct of trials and the issues have been well reviewed (e.g. Ashcroft *et al*, 1997). Yet, the debate has focused predominantly on clinical trials with individuals (Glanz *et al.*,1996). The ethical issues relevant to community-based research have been largely unexplored and there has been little empirical work examining the acceptability of such trials from the community perspective. Issues arise from the fact that the research population does not comprise a set of independent and isolated individuals, but a society consisting of members who interact and affect each other in established hierarchies. Guidelines which recognise such dynamics are not readily available. Furthermore, while the important contribution of social science to research on AIDS in developing countries is widely recognised, there has traditionally been a predominance of epidemiological studies and lack of collaboration between disciplines (Ankrah, 1989). This paper demonstrates a complementary role for social science and epidemiological research by exploring process issues which may contribute to an understanding of trial results.

Study setting

The intervention was a randomised controlled community intervention trial, conducted by the Medical Research Council (MRC) Programme on AIDS in Uganda. The aim was to assess the impact on transmission of HIV infection of a community-based behavioural change intervention and improved management of STDs. Situated in Masaka and

Ssembabule districts (approximately 150km south west of the capital, Kampala), the study area comprised a rural, patriarchal and hierarchical society, engaged primarily in subsistence farming. While the Buganda tribe and the Catholics predominate, both districts are ethnically and religiously heterogeneous. In rural Uganda, 69% of the population are under 25, and 13% of men and 34% of women have no formal education (Government of Uganda, 1995).

The trial had 3 arms with 6 parishes in each arm (a parish is an administrative unit of about 10 villages with a population of about 5000 adults). Arm A received the IEC (Information, Education, Communication) intervention, comprising drama and video shows, community meetings, leaflet distribution, and peer education. Arm B also received IEC, combined with improved STD management (training of health workers, support to health units). In arm C, the comparison arm, routine government health services prevailed in addition to community development (supporting existing income generating clubs) and home based care initiated by the programme. HIV testing and counselling were available to all individuals within the study area and a condom social marketing programme, promoting male condoms to both men and women, was implemented in all three arms.

The outcome of the trial was evaluated through three house-to-house KABP (knowledge, attitudes, behaviour, practice) and serological surveys carried out at 18-24 month intervals in 3-4 villages per parish. Following mapping and census of all eligible adults (13+ years), households were revisited by a survey team who sought individual written

consent to participate, administered a KAP questionnaire and requested a blood sample (testing for HIV and other STDs). Similar procedures were repeated at first and second follow-up and at each round participants were given the option to return for their HIV result. In addition to HIV incidence, secondary biological indicators (such as incidence of *T.pallidum* and Herpes simplex virus –type 2 infections) and behavioural indicators (such as reported condom use) were also measured.

Community mobilisation was an important aspect of the sero-survey. From the outset, existing hierarchies were carefully respected. These hierarchies were based on traditional systems (clan leaders, Buganda kingdom leaders, landlords), political and religious groups (old and current chiefs including local politicians, priests, catechism leaders, sheikhs, and imams), and those with informally accredited status (the most educated, richest or those rendering valued services, such as traditional healers). Mobilisation (including site tours of the MRC office) was initially targeted at these influential individuals in order to ascertain their views and seek their support in encouraging community participation. They were often called upon to lead the survey teams and explain the purpose of the research to the rest of the community. AIDS Prevention Committees (APCs), consisting of respected community members, were established in each parish to oversee trial activities and give the community a sense of ownership of the trial. During the first round, a drama was used to assist in explaining the purpose of the sero-survey at community mobilisation meetings. At each subsequent round, an MRC team returned to the village to repeat explanations and answer questions. However, field

workers with the supervision of a MRC mobilisation officer undertook much of the mobilisation at ground level.

The data presented here come from a process evaluation of the IEC component of the trial. The objectives were: to explore the community response to the outcome evaluation; and to determine whether the outcome evaluation affected the acceptability of the trial to the community. The process evaluation also explored the effectiveness of the IEC channels, and the acceptability of the intervention to the community (Mitchell, forthcoming).

Methods

Opinions and experiences of the trial were gathered from two perspectives: the views of community members recruited as volunteers to implement the trial in their communities (field workers); and the views of community members who were recipients of the intervention (henceforth referred to as the community). Triangulation between data sources enhanced the validity of the findings (Mays & Pope, 1995) and enabled divergent opinions and unusual or isolated incidents to be explored more thoroughly.

Field worker views were explored through 37 semi-structured interviews. Interviewees were asked not only about their own experiences as field workers, but their perceptions of the community response to the trial. Four separate interview schedules (adapted for each category of field worker) were piloted among a sub-sample of field workers (n=7).

Purposive, non-probabilistic sampling, following a rough quota according to field worker

role, age, parish and gender was used to achieve a representative sample. The final sample comprised 6 Parish co-ordinators (PC), 13 community educators (CE), 9 AIDS prevention committee members, and 9 drama group members¹. Field workers fitting the sampling criteria were identified during parish visits and interviewed. Of the 37 interviews, 23 were conducted in the local language (Luganda) by the second author and the rest (including all the PC interviews) were conducted in English by the first author. The interviews lasted between one and two hours.

The interview data was augmented by four field workers focus groups. Six randomly selected PCs from arms A and B² (alternate names taken from the list of PCs), and all the PCs in arm C attended discussions, facilitated by the first author and conducted in English³. CE focus groups were held in two of the parishes (one arm A and one arm B) with 15 (8 men) randomly chosen CEs (by selecting every third name on the list of CEs in that parish). These were facilitated by the second author and conducted in Luganda. All the groups were held before or after scheduled monthly meetings. The discussions lasted between one and two hours.

Community opinions of the trial were explored through 10 focus groups. Eight groups were held with 53 drama or video audience members in arms A and B (27 men, 26 women and 30 aged under 25, 23 aged over 25). The topic guide was pre-tested during a

¹ Parish co-ordinators (PCs) are responsible for supervision and monitoring of community educators (CEs) and overseeing IEC activities in their parish. They are assisted by AIDS Prevention Committees (APC), 1 in each parish, which meet on a quarterly basis. Each parish has around 24 CEs and a volunteer drama group. All field workers are local Ugandans.

² All those not attending the focus group were interviewed individually.

pilot session and revised accordingly. Groups, quota sampled for age, sex and parish, met prior to the start of a show and explored community experiences and opinions of the trial. After the show, they reconvened to discuss issues raised in the plays. Two, mixed sex, adult focus groups were held with arm C community members, one in a non-survey village and one in a survey village (n=16). For all groups, the composition was decided beforehand, based on quota sampling. Participants fitting the selection criteria were recruited by the second author who walked around the village just prior to the discussion, inviting individuals to attend a discussion, followed by the drama or video show. The discussions lasted between one and two hours and were conducted in the vernacular (Luganda) by the second author.

Developed through discussion between authors, the topic guides probed awareness and understanding of the intervention and evaluation, opinions of intervention activities, and field worker role and relationships. Although adapted for each category of respondent, questions about the outcome evaluation generally included the following:

What do you think is the purpose of MRC activities?

Why do you think the MRC chose to work in this parish?

Why do you think the MRC take blood?

What do you think happens to the blood?

What do the people in your parish say are the reasons that the MRC collect blood?

Why do you think some people refuse to give blood?

Do those who refuse to give blood also refuse to attend MRC activities such as community meetings?

The interviews and focus groups were audio-taped, translated and transcribed by the second author. Themes were identified and codes established by reading through several

³ The PCs were more educated and able to speak both Luganda and English.

transcripts. Subsequent transcripts were coded according to these themes and categorised using the qualitative software package NUD*IST.

Results

Since the views of field workers were often similar to those of the community, they have been reported together. Similarly, since there were few notable differences between the views of parish co-ordinators, peer educators, drama members and AIDS prevention committee members, they are usually referred to collectively as ‘field workers’.

Informed consent: impossible to ensure?

(Mis)understanding the sero-survey

F: *Most people say that [the MRC] take that blood sample for sale.
[.....]*

Interviewer: *Are there any other reasons that people think the MRC take blood, apart from selling it, or testing for diseases?*

F: *To take [infected blood] and inject another person who is not HIV positive. That is how people think sometimes.*

Younger women, community focus group

Despite intensive efforts to explain the purpose of the sero-survey at both individual and community level, evidence from both field worker interviews and community focus groups suggests that the introduction of the sero-survey was characterised by scare-mongering and rumours. The most frequently cited rumour was that the MRC was intending to profit by selling the blood abroad. It was reasoned that MRC staff would not put so much effort into persuading people to provide a blood sample unless they were

somehow profiting. That many of the staff were ‘fat’ (traditionally regarded as an indication of wealth) was cited as further evidence. Field workers and MRC staff refuted this rumour fairly easily, by explaining that the blood taken was so little (2ml) and, given its monetary value, much more blood would need to be taken from each individual in order to make a profit. This explanation was counteracted by a few who said that though the blood was little, the MRC extracted mercury from it.

Less common, but perhaps more harmful, were rumours that the ‘Bazungu’ (whites) were trying to kill off the Africans by injecting them with the virus or making them impotent. These beliefs appeared to stem from a deeply rooted fear, also encountered by family planning advocates, of Western plans to curb African population growth. As one field worker explained, it was for this reason some of the community was particularly wary of the vacutainer system (Becton Dickinson, Meylan). The yellow gel at the bottom of the tube was said to contain the virus, which would enter the vein before the blood was extracted. According to field workers, this particular rumour lost some credibility when it became clear that all those who had participated at round one had not subsequently died.

It is difficult to assess how widespread these rumours were. They were reported by almost everyone interviewed, but nearly always expressed as views held by *others*. In fact, within the community focus groups, participants often said that they themselves believed blood was taken in order to know how many people were infected. Knowledge among field workers was high; most of the community educators knew that blood was taken in order to assess whether the MRC activities had had any impact on levels of HIV,

though only the parish co-ordinators were aware that different activities were being compared.

It seems reasonable to assume that rumours were spread by a few and at least half-believed by a significant minority of the population. Some of the field workers believed that they were propagated by individuals seeking to sabotage the survey, either because they were dissatisfied by the lack of material assistance from the programme, or because they were jealous of local councillors (LC) who received small incentives for assisting the sero-survey team. It was not uncommon for LC members to fuel such jealousies by exaggerating and boasting about the amount they had received. This view was re-iterated by a community member:

F*What prevented most people from giving blood was that they thought that these people who moved with the sero team (the LC members) got a lot of money. That was the major reason.*
(older woman, Community focus group)

At other times, the survey was used to fuel existing disputes within the community. For instance, in one parish, a man who had contested, unsuccessfully, with the parish co-ordinator, for Local Council chairmanship, tried to persuade people not to provide blood, as a way of exacting revenge on the parish co-ordinator.

Not all refusals were based on rumour. Again, despite efforts to explain clearly, at both individual and community level, many of these purported reasons were based on misconceptions. Field workers reported that some of those who refused, did so because

they feared the needle or believed, incorrectly, that the amount withdrawn would leave them weak. Others said they did not want to know their HIV status (even though this was optional) or were concerned that other people would find out. Some people already knew their status and therefore saw little point in being tested.

The dilemmas of individual level consent

In this trial, informed consent was given at an individual level. The obligation to respect individual autonomy at times conflicted with traditional practices, whereby the man, as the head of the household, is accustomed to taking decisions on behalf of his family.

Difficulties sometimes arose where the man refused to comply but other family members provided blood samples in his absence:

M:[there are] some few men who did not allow their wives to give blood without their consent. When the MRC staff came to get blood and the wife gave blood, the man would quarrel with the wife when he came back and found out that his wife had given blood without his permission.

Male field worker, arm A

Protecting individuals from coercion

There was evidence that enthusiastic supporters of the survey within the community sometimes used the promise of an impending cure to cajole neighbours and peers into providing blood.

M:the ones who had agreed to give blood challenged the others saying, 'You are not going to be cured. We have participated but you have refused so you are not going to get the cure.' I hear some people say that.

Male field worker, arm B

Field workers were also occasionally guilty of coercive tactics. The impossibility of ensuring that individuals are protected from coercion is illustrated by this quote from a field worker, who, despite careful briefings, was passing false messages to the community.

F: [.....] *we also tell them that if a cure for AIDS is found, it will be given only to those people who gave blood.*
Female field worker, arm B

In arm C, the lack of an obvious link between the control arm activities and the evaluation meant that the rationale for the survey had to be explained more vaguely, using terms such as ‘researching the virus’. As in intervention arms, the community equated ‘research’ with finding a cure. The arm C parish co-ordinators all envisaged the search for a cure as one of the main purposes of taking blood and this belief filtered down to the community; *they have a hope that from this research the MRC is doing, we might get a cure. (arm C, field worker focus group)*. Given this widespread belief, some individuals in arm C may well have provided a blood sample under the illusion that they would personally benefit from a cure.

Expectations of reward: impossible to ignore?

Long term expectations - a cure for AIDS

Perhaps the most difficult dilemma of the sero-survey was that study participants, having provided a blood sample, expected something in return. A common question to the sero-

survey team was ‘*nfunirawa?*’ (‘How do I gain?’). The expectations here were both short and long term; in the short term participants expected at least a small material reward for their blood. In the long term they expected a cure for AIDS. As rumours subsided, most came to accept that the MRC was researching the virus and research, for many individuals, could be equated with finding a cure. It was clear that this expectation motivated at least some individuals to provide blood. It also gave rise to frustration with the MRC.

M: *What people say most often is, ‘Why don’t [the MRC] get a cure for AIDS?’. That is what upsets people. Because the MRC takes blood to research the virus, so why don’t they find a cure?*

Male field worker, arm A

Short term expectations – a bottle of soda

In the short term, it was clear that the community expected ‘*at least a bottle of soda*’ in return for their blood. They were particularly expectant because the intervention was being run by ‘Bazungu’: *...people are very fond of free things and when they see an organisation of the whites, they just know that those people are very rich and so they expect to be given something (Older man, community focus group).*

Even seemingly harmless general household questions can inadvertently create expectation of material reward. For instance, the initial census survey asked respondents whether they possessed certain household items (such as radios, hurricane lamps). One field worker reported that in his parish, these questions generated an expectation that

those who provided blood would eventually receive such items. Such expectations tended to persist, despite mobilisation messages to the contrary.

Precedents set by neighbouring research organisations also fuelled expectations.

M: *...because there are some other organisations which take blood but they give an incentive [.....] so when the people who get something for their blood happen to talk to the ones who give their blood freely, they tell them what they get for their blood and in that way our people are disorganised.*

Male field worker, arm A

The dilemmas of incentives

Within one of the study parishes, participants in a separate, smaller MRC social science study had their transport costs met. This created jealousies and tensions among those not involved and was used to further argue that the community deserved something in return for their blood. Having resisted such requests in rounds one and two, survey participants were offered a health promotional gift (washing up bowl, soap and t-shirt) at the end of the trial. According to field workers, this increased the acceptability of the survey, and the MRC in general, within the community. However, this strategy may have simply generated further expectations: *Because we were given those incentives when we gave blood, people are now looking forward to more valuable items.* (**Older man, community focus group**)

Rigour and acceptability: achieving a balance

The impact of the evaluation on the acceptability of the intervention

There can be little doubt that the reputation of the MRC in the community was inextricably linked to the taking of blood. During community focus group discussions, ‘taking blood’ was always one of the first activities to be mentioned when participants were asked what the MRC does in their parish. Field workers reported that, during survey rounds, the sero-survey team often earned nicknames such as ‘*blood suckers*’. According to field workers, it seems that at the beginning of the trial, when rumours about selling blood were rife, the survey hindered at least some community members from attending MRC activities. This was often because they believed that the purpose of the plays was to persuade them into giving a blood sample. As rumours died down and understanding of the survey increased, it seems that individuals attended activities regardless of whether they were willing to provide blood. The majority of field workers appeared to agree that the sero-survey had no adverse effects on the intervention itself.

Interviewer: *The people who refuse to give blood, do they also refuse to come to the MRC activities?*

M: *They don't refuse [...]. I have an example of a certain family and whatever activity we take there, they attend and they thank us for bringing the activity. But when you go there to take blood, they refuse. They say they have never given blood and never will.*

Male field worker, arm B

In arm C, the message given to the community by some of the parish co-ordinators was that the MRC came ‘*to bleed and to research about AIDS but development activities are added as a supplement*’ (Arm C field worker focus group). Thus the evaluation had greater saliency than the intervention itself. In focus group discussions, participants did not

distinguish between intervention and evaluation activities and ‘researching the virus’ was viewed as the principal activity of the MRC. All the villages received the arm C activities except home based care (provision of basic medical care to house bound patients), which was administered only in survey villages, so that taking blood became linked with receiving medical treatment. The arm C parish co-ordinators reported that many people in non-survey villages had asked to provide blood samples and *‘those people of other villages which do not receive [home based care] are complaining why we do not give them these services’* (arm C field worker focus group). Participants in the non-survey focus group expressed an interest in providing blood because they saw it as a route to receiving medical treatment. They were acutely aware that the MRC was providing treatment to other villages. While participants in the survey village were unaware of MRC activities in the rest of the parish, the non-survey participants were able to state exactly which villages in the parish provided blood samples and received treatment. Acceptability of the trial may therefore vary between survey and non-survey villages.

Despite the lack of cohesion between the evaluation and intervention, compliance was as high in arm C as it was in the intervention arms. This may well have been linked to satisfaction with the home based care, but it also seems possible that because this was the only major AIDS related activity in the parish, people were keen to be involved in a project which might contribute towards the alleviation of the epidemic.

M: *Myself, I gave blood because I wanted them to find my HIV status and to carry out research and get something that would be beneficial to the whole nation.*

Survey village community focus group

The impact of ethical obligations on scientific rigour

When asking for blood, the MRC felt ethically obliged to meet individual questions and concerns about AIDS. In arm C, in the absence of IEC activities, questions about AIDS fell to the survey team. As a consequence, the survey village participants tended to regard the sero-survey team as ‘teachers’. The mobilisation meetings and individual discussions with survey team members appeared to be their principal source of information about AIDS:

F: *Some do not have radios so it is this organisation of the virus (MRC) which has given us most of the information about AIDS and the radios have only added to what we had already got from the virus (MRC).⁴*

Survey village focus group

Although the survey village participants did not feel they knew enough about AIDS and requested more teaching, their outlook differed perceptibly from those in the non-survey village, particularly in attitudes towards people with AIDS as the quotes below illustrate:

M: *Since the MRC came and taught us how AIDS is spread, we are now firm and no longer live in fear like we used to because we have been taught. Before we used not to come near AIDS patients thinking that flies and mosquitos could spread the virus to us.*

Survey village community focus group

M: *...we hear that people who are infected also get annoyed when you try to discriminate against them and we hear that some of them urinate in wells where other people get water. We hear that at times HIV victims do such things and so we end up eating such*

⁴ Note that the MRC is commonly referred to as the Virus by community members.

things but I do not know if we can get infected in that way [.....] Yet you cannot help isolating HIV people because it is human, you cannot help touching your nose when someone passes out bad gases.

Non-survey village community focus group

Participants in the non-survey group recognised their lack of knowledge. In fact, the participants saw the focus group discussion as an opportunity to raise their queries about AIDS. Persistent questions about AIDS and about the work of the MRC presented difficulties for the facilitator who was forced to spend time answering queries rather than generating discussion.

Interviewer: *Do you feel you have enough knowledge about AIDS?*

F: *We do not know much about it yet.*

M: *Do you think we have ever got anyone to teach us?*

M: *Aha (no), we have not seen them yet.*

F: *And this is what we want.*

Non-survey village community focus group

It seems that, in the control arm, the evaluation may have heightened awareness about AIDS in survey compared with non-survey villages.

Balancing efforts towards the intervention and evaluation

There is a risk that the demands of scientific rigour in evaluation may have drawn attention and efforts away from the intervention itself. For instance, during interviews with field workers, it was evident that some individuals tended to confuse the intervention with the evaluation, such that their criteria for ‘success’ was not so much whether people had learnt the IEC messages but whether they had complied with the

sero-survey. There was some evidence that field workers perceived a pressure to achieve high compliance and therefore concentrated their efforts in study villages:

Parish co-ordinator: *The central (MRC) staff give equal attention to all villages, but for us in the parish, we always work harder in study villages.*

Interviewer: *Is the same true in other parishes?*

Parish co-ordinator: *I think it probably is, because we have to convince people so that they give their blood.*

Female Parish co-ordinator, arm A

This perceived pressure had the potential to impact on staffing decisions. For instance, in the parish co-ordinator focus group, the PCs admitted that, prior to a survey round, they would try to avoid dismissing a community educator who was not doing their job properly, in case that community educator later stirred up trouble during the sero-survey.

Positive aspects of the evaluation

There were also positive aspects to the sero-survey. Firstly, at least some of the community appreciated the opportunity to find out their HIV status. Results from a neighbouring MRC study suggest that around 10% of sero-survey participants return to find out their status (Ruberantwari 1995). For the same reason, individuals in neighbouring parishes occasionally made requests to participate in the survey. When requesting a blood sample, the sero-survey team provided simple symptomatic-based treatment for participants with common ailments and referred more serious cases to health units. This also met with appreciation from community members. Secondly, the sero-survey effectively introduced and enhanced the acceptability of HIV testing to the community. Thirdly, because the survey team often resided in villages for the duration of

the survey, rapport often developed between them and village residents. This was viewed as a positive aspect of the trial:

M: Another thing that I have to say is to thank the MRC because [.....] the staff who came here to take blood were polite and they were very peaceful people who managed to make many friends with the residents which means that the MRC trained its staff very well.

(Older man, community focus group)

Discussion

Before exploring the challenges encountered by the sero-survey, it is worth considering some of the probable biases of this process evaluation. The evaluators (the first and second authors) were MRC employees, and therefore unavoidably associated with the organisation. This may have given rise to a desirability bias. In a poor, hierarchical society, the problem may be compounded by the presence of a white researcher (the first author) where such people are regarded as potential benefactors or as having status (in terms of wealth, education and power). For instance, field worker interviewees would often only admit to experiencing problems after the interviewers had described incidents in other parishes. In community focus groups, the facilitator (the second author) had to work hard to win the trust of the participants in order to move beyond initial polite responses. The data analysis was conducted with this potential bias in mind and extremely positive responses were viewed with discernment. The congruence between community and field worker views suggests that field workers were in touch with community opinions.

It appears that the use of HIV incidence to evaluate the outcome of the trial had clear ramifications for the way the trial was perceived by the community. 'Taking blood' was viewed as one of the main MRC activities by the community, many of whom did not distinguish between the evaluation and the intervention. This association of the MRC with taking blood was possibly unavoidable, given the degree of suspicion about the procedure. One might argue that alternative methods of measuring HIV (such as urine or saliva) may have engendered less controversy. The drawback of these alternative methods is that they do not allow for so many tests for other STD's. Furthermore, earlier pilot studies conducted in the study population found neither urine nor saliva to be any more acceptable than blood.

The prominence of the evaluation relative to the intervention is a concern to the extent that it impacts on the acceptability and effectiveness of the intervention. As the trial progressed, and understanding increased, the sero-survey gradually gained acceptance and the opportunity to be tested came to be viewed by some as a positive aspect of the trial. Furthermore, refusal to participate in the sero-survey did not necessarily imply refusal to attend intervention activities. In the control arm, acceptability of the study appeared to be higher in survey compared with non-survey villages, though this was possibly because study villages also received home based care. However, one concern identified by our research, is that in the effort to achieve high compliance rates, field workers may have given higher priority to the evaluation over the intervention. This is evident in the extra effort exerted by field workers in survey villages. The balance is

difficult to achieve, but it is important that the effectiveness of the intervention is not compromised by the need for methodological rigour in the evaluation. The approach taken by the implementers of the trial is instrumental in ensuring that field workers are guided towards the right balance.

Deciding the appropriate level of detail to disclose when obtaining informed consent, is an acknowledged ethical dilemma (Levine, 1986; Faden & Beauchamp, 1986), particularly where local perceptions of disease differ from those of the western researchers (Christakis, 1988). Ethicists have argued that participants should understand the nature of the research, in order to give valid informed consent (Beauchamp & Childress, 1983). Since educational backgrounds vary across individuals, and since individuals tend to require different levels of information (Kent, 1996, Leach *et al.*, 1999), mobilisation strategies, such as community meetings, which operate at community level, face difficulties in determining the appropriate level at which to pitch explanations. For this reason, participants were also given the opportunity to talk to the sero-survey team individually, prior to signing the consent form. However, with such large-scale evaluations, it is difficult to ensure the veracity of explanations given to individuals, no matter how intensively field workers are trained and monitored. Our results suggest that not only field workers, but also ordinary members of the community may distort messages to their neighbours. The impossibility of protecting every individual from false or misleading information suggests that in large-scale community trials, signed consent forms cannot be taken as a guarantee of ‘true’ informed consent.

The widespread rumours suggest that, at least at the beginning, there was much confusion about the reasons for taking blood. Although these rumours subsided, misconceptions tended to persist. For instance, some participants believed they were participating in the search for a cure for AIDS, particularly in the control arm. Whether it is necessary or desirable to refute this misconception, particularly when individuals are keen to envisage a personal contribution to a higher cause, is a dilemma. Deception of research subjects is morally questionable, but this must be weighed against pragmatic factors. For instance, more detailed explanations risk biasing the reported behaviour of survey participants if they become 'unblinded' to the aim of the trial, and furthermore, such misconceptions may do no harm (unless, of course, individuals believe that they personally will receive a cure as a result of their participation). Respect for individual participants and the wider community must be the starting point, but beyond that, there are few easy answers. Most guidelines on informed consent are designed for clinical trials, notably vaccine trials, and their helpfulness may be limited, since requesting a blood sample from members of a community is clearly a different matter to requesting participation in a clinical trial involving significant health risks.

In the control arm another ethical issue emerged: how should the sero-survey team respond to survey participants who asked questions about HIV/AIDS? Failure to provide widely known factual information is clearly unacceptable, but improving levels of knowledge in the control arm may impact on the outcome results. By instructing the sero-survey team to answer such questions, the MRC gave priority to ethical obligations over

methodological rigour. This of course, makes the questionable assumption, that by increasing knowledge, one may impact on sexual behaviour in the control arm.

Debate exists between those who advocate an internationally agreed standard of informed consent and those who propose culturally specific ethical guidelines (Ijsselmuiden & Faden, 1992; Christakis, 1988; Barry & Molyneux, 1992; Levine, 1991). Those who support the idea of an international standard argue that community consent leaves individuals vulnerable to unethical researchers or community leaders. Their opponents argue that the blanket application of a western model of individual consent is neither culturally sensitive nor morally acceptable (Christakis, 1988). In this trial, consent was sought at the individual level. Disagreements between couples posed a real dilemma, since respecting the autonomy of the wife, automatically implied disrespecting the rights of the male head of household. Although instances of family disputes appeared to be fairly isolated, they need to be acknowledged as a drawback to the individual level approach. That is not to say that individual consent should be abandoned in such communities. It is highly probable, that consent given at community or family level would have given rise to far more practical and ethical difficulties. Moreover, the most vulnerable members of the community (women and young people) would have the least say in the decision.

Within under-served communities the issue of incentives is particularly problematic. It is understandable that individuals should be given at least some token of gratitude for their time, particularly after an invasive procedure and particularly when they have not presented themselves voluntarily but have been approached. Importantly, incentives can

mitigate against high attrition rates which may otherwise threaten scientific rigour (Glanz *et al.*, 1996). But in a community-based trial where poverty is endemic, small tokens of gratitude can take on great significance and may incite gossip, jealousies and tension. They may also generate greater expectations of future incentives, and once introduced, there is no going back. Furthermore, where whole communities are concerned, giving incentives sets a precedent that future research organisations come under pressure to follow. Vital surveys such as government censuses may experience difficulties where communities have come to expect something in return for information. The rumours and misconceptions about incentives in this study were tenacious and tended to persist despite attempts to explain otherwise. Again, this is a particular challenge of community-based interventions.

It is argued by some ethics committees that any form of compensation has the potential to be manipulative, while others allow incentives that do not constitute ‘unreasonable enticement’ (Glanz *et al.*, 1996). Faden & Beauchamp (1986) distinguish clearly between coercive strategies, and persuasive or manipulative strategies. They argue that persuasive influences do not preclude substantial autonomy, while all forms of coercion, and some forms of manipulation may represent ‘undue influence’ and may therefore be incompatible with informed consent. Certainly, the community here was subjected to persuasive influences, both through mobilisation meetings, small incentives, and home based care in the control arm. It is important also to recognise the possibility of more subtle factors such as the intrinsic power imbalance between western researchers and rural African subjects, which may give rise to a sense of obligation in the latter. It is

unlikely that the incentive used in this study were so irresistible so as to prevent an autonomous decision about whether to accept. Furthermore, they were given only after the third round, to individuals who had already participated in rounds one and two. In extremely poor communities, particular care must be taken in determining the point at which a material incentive constitutes ‘unreasonable enticement’. Both for ethical and pragmatic reasons, the decision to introduce incentives should not be embarked upon lightly.

Conclusions and recommendations

Given the drawbacks of both the experimental method (Kippax & Van de Ven, 1998) and the use of HIV as an outcome measure (Aral & Peterman, 1996), are such trials worth pursuing? We conclude that RCTs using HIV incidence in poor rural communities are feasible but the challenges involved should not be underestimated. This paper highlights several issues for those involved in the design of future community based trials in similar settings. Firstly, researchers should not under-estimate the potential for controversy that this type of evaluation may have within the community. Such controversies, if handled badly, may compromise both the rigour and acceptability of a trial. Sensitivity is required in establishing relationships with community leaders and in understanding the social and political dynamic of their community. It is, of course, essential to work through the recognised channels, but equally important is the need to ensure that messages filter down to grassroots. Secondly if the sero-survey is to be both rigorous and acceptable then time and resources need to be devoted to ensuring that the community understand and support the overall aims of the research project. In order to protect individual

participants from misinformation or coercion, field workers must be carefully trained and closely monitored and the researchers need to stay alert to events at ground level. This can be done informally, through regular meetings with community representatives, and formally through the systematic collection of process data. Finally, requests for incentives should be anticipated, and the response carefully thought out.

Community-based RCTs face a daunting challenge in achieving both scientific rigour and acceptability to the study community. This is particularly true where the target community is poor and unaccustomed to research. Currently, there is a lack of guidelines to guide researchers through the ethical issues involved, those borrowed from clinical trials or research in the west are not always relevant or helpful. If this problem is to be addressed then further empirical work is required in order to more fully comprehend the experience of trials from the community perspective. This needs to be accompanied by greater discussion of the issues among researchers working in poorer countries.

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