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Evaluation of Recruitment Approaches for the HPTN 052 Clinical Trial of HIV Serodiscordant Couples in Rural Western Kenya

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ABSTRACT

Recruitment of couples is important for study success. The multi-centered HPTN 052 clinical trial was designed to evaluate whether immediate versus delayed use of ART by HIV-infected individuals would reduce transmission of HIV to their HIV-uninfected partners. The objective of this study was to retrospectively compare several approaches for community recruitment at our site in Kisumu, Kenya based on a) feedback from recruitment staff, b) associated cost, and c) number of eligible couples enrolled. A secondary objective was to assess the discordant couples' acceptability of the community recruitment approaches relative to the a) main recruitment venues, b) educational materials, and c) local language best suited for explaining the trial. 241 couples were screened for eligibility using nine recruitment approaches. We compared the approaches used for the 60 couples found to be eligible to those used for the 56 ineligible couples for whom that information was available. Analyses for association were carried out. In-depth interviews were conducted with 20 staff and 29 discordant couples. Records were kept of the costs associated with each approach. Overall, staff interviews revealed that acceptability of the approaches was high. Challenges were present with all approaches ranging from one member of the couple not wanting to reveal their positive HIV status to their partner (Patient Support Center or PSC approach), to not finding people at home (home based counseling and testing or HBCT approach). The PSC and the HBCT recruitment approaches were the most effective in terms of recruiting eligible participants. There was an overall significant difference between the proportion of eligible and ineligible participants among the 9 approaches (χ^2 (8) =33.5; p<0.0001). Analyses for association showed that the PSC approach resulted in attracting a greater proportion of couples who were eligible than ineligible (χ^2 (1) =6.6; p=0.016). The cost for the PSC approach was less than one-third that of the HBCT approach. All discordant couples interviewed found the two main recruitment venues (PSC and their home) acceptable. Among couples who saw the educational materials, the majority found them useful (poster 72.7%; pamphlet 90.9%; flyer 88.9%). All couples found the language they were told about the study acceptable. The evaluation of recruitment approaches indicated that working with local partners, specifically the PSC staff and HBCT staff, was the most effective way to recruit eligible discordant couples. A focus on collaborations and partnerships between research and clinical organizations will help study recruitment efforts.

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Running head: Evaluation of recruitment approaches
Key words: community recruitment, discordant couples, clinical trials

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Introduction

Enrolling qualified individuals in any clinical trial is an essential component of the success of the trial. HIV sero-discordant couples are frequently enrolled in HIV prevention intervention studies because these couples represent an important opportunity to prevent transmission. In Kenya, 5.9% of married or cohabiting couples (344,000 couples nationwide) are discordant [1]. Identification and recruitment of individuals as well as discordant couples for such studies can be particularly challenging, as there is a paucity of evidence on successful approaches. One major barrier is the low rate of both members of the couple being tested together [2] which may result from the reluctance of men in many parts of Africa to be tested [3]. Hospitals and clinics have often been cited as useful places to recruit women because the women are likely to have a history of trust with the staff, with subsequent identification of a woman's partner or spouse through further contact [4-6]. Active approaches such as using trained community members as recruiters [7] have been used as well as passive approaches (brochures, media) [8;9]. Training staff or community members to recruit women or couples in conjunction with more passive outreach such as posters, radio and pamphlets has been reported to be successful [3;10-13]. Respondent driven sampling where persons refer others they know to a study has been used to recruit discordant couples with some success likely due to the already established trusting relationship between referer and referee [7;14-16].

We evaluated recruitment approaches used for the HPTN 052 study by the Kenya Medical Research Institute (KEMRI)/Centers for Disease Control and Prevention (CDC) HIV Research Branch. This site is one of 13 trial sites participating in HPTN 052 in Africa, South America, and Asia [17]. The purpose of the HPTN 052 study was to compare the rates of incident HIV infection among seronegative heterosexual partners of HIV-infected participants who started anti retroviral therapy early (CD4 cell count=350-550) versus standard (CD4 cell count<250).

The primary objective of this site-specific analysis was to compare several approaches for recruitment of HIV sero-discordant couples based on a) experiences of recruitment staff implementing the various approaches, b) the associated cost, and c) the number of eligible couples enrolled in the HPTN 052 study through each approach. A secondary objective was to assess the acceptability of the recruitment approaches to the discordant couples in terms of a) the main recruitment venues, b) the educational materials, and c) the local language best suited for explaining the trial.

Methods

Participant Screening and Recruitment

The HPTN 052 study was conducted in Kisumu, Nyanza Province, Kenya which has a population of approximately 500,000 residents (Central Bureau of Statistics, 2000). Most residents are of Luo ethnicity [18] and speak Dholuo and often Kiswahili and English. HIV prevalence in Nyanza Province is the highest among the eight provinces of Kenya, at 14.9% [1].

Couples were screened for HPTN 052 eligibility using the following criteria: couples reported having had vaginal or anal sex with one another at least three times in the three months prior to enrollment, the index participant had a positive HIV serology within 60 days prior to enrollment, the partner was HIV-seronegative, the couple planned to maintain a sexual relationship with each other, and intended to remain in the study area for the duration of the projected study follow-up. Other eligibility criteria included: resided in the study areas (Asembo and Karemo), and that the index participant was ARV naïve and in good health with normal laboratory parameters.

During recruitment for the HPTN 052 main study, potential participants were given explanations about the study, told that the information they provided would be kept confidential, and informed that their participation was voluntary and they could refuse to

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answer any questions. Potential participants were also asked to identify the main recruitment approach that brought them to the study. All participants gave written informed consent and received a monetary reimbursement for their transport costs. CDC's Institutional Review Board (IRB) and the KEMRI Scientific Steering Committee and Ethical Review Committee provided approval for the main clinical trial and this substudy.

Purposeful community recruitment approaches were used to enroll participants for the HPTN 052 study from two local communities, Asembo and Karemo, covered by the KEMRI/CDC Health and Demographic Surveillance System (HDSS). The KEMRI/CDC HDSS routinely collects data on health and demographics from these geographically defined areas, with consent from the participants. The recruitment approaches included: (1) partnering with Patient Support Centers (PSCs; patient support center, a health facility where HIV counseling and testing occurs and persons who are HIV-positive receive care and treatment services); For the HPTN 052 recruitment, we specifically trained the PSC staff, conducted presentations about the study to the staff and interested patients during PSC sessions, and distributed IRB-approved educational and recruitment materials. PSC staff gave potential participants information about how to come for study screening; (2) targeted recruitment through home-based counseling and testing program (HBCT) among previous participants who had given consent for follow-up; (3) community health workers (members of the community) who volunteered to visit people in their homes to offer health care support; (4) general community mobilization (e.g.) at "barazas" which are meetings of the community called by a chief, educational talks at markets and women's groups, meetings at the beach and People Living with AIDS support group meetings; (5) targeted recruitment to provide study information to couples of unknown HIV status using the HDSS staff when they conduct their regular population surveys and the International Emerging Infections Program (IEIP) staff who conduct similar population-based surveillance to determine annual incidence rates for infectious diseases and characterize the epidemiology and key etiologies of major syndromes; (6) peer educators (members of the community who are People Living With HIV/AIDS who reach out to persons with known HIV positive status for psychosocial support, access to care and treatment mainly through support groups. These peer educators went to the homes of discordant couples identified by HBCT and PSC who had given consent for follow-up, and informed the couples about the study); (7) local radio announcements; (8) posters/pamphlets/flyers (IRB approved educational materials that the recruitment staff placed in areas where people congregate, e.g. posters, or material distributed to potential participants at each of the recruitment venues); and (9) participant referral of other potential participants. It is important to note that the HDSS and IEIP staff were only able to mention the study to HDSS participants and IEIP participants during their respective study visits; they did not conduct HBCT and did not know anyone's HIV status.

Chart Reviews

Data for each recruitment approach were abstracted from the chart notes this was conducted retrospectively after the recruitment period was over and was available for all 60 eligible couples and for 56/181 ineligible couples. Couples for which recruitment approach information was unavailable were potential participants who had come to the clinic site and been assigned study IDs, but did not complete the screening consent procedure or were declared ineligible due to not meeting the eligibility criteria. These couples did not proceed to the nurse counselor for the next procedure where the details of the recruitment approach were charted.

In-Depth Interviews

Recruitment staff and PSC staff. All seven study recruitment staff were interviewed. Thirteen 13 PSC staff who were not HPTN 052 staff recruitment staff were interviewed for this substudy. From each PSC, one staff member involved with referring couples to the

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study was then interviewed, but at three PSCs, two were interviewed because they were both involved with referring couples to the 052 study.

Couples. Following recruitment for the HPTN 052 study, a purposive quota sampling approach was used to recruit 29 couples waiting at the clinic to be screened. Interviews with 29 couples allowed saturation, meaning the interviewer no longer heard new information. Couples were interviewed regardless of their eligibility for the study, and their eligibility was never known to the interviewing staff from the site-specific recruitment analysis.

Analysis

Qualitative. Interviews were transcribed verbatim and translated from Dholuo or Swahili to English. A codebook was developed and *Nvivo version* 8.0, a QSR international program for qualitative data analysis, was used to organize the data according to questions from transcripts. Two researchers (KO and MN) reviewed the data independently then met to discuss their coding to reach consensus. Quotes provided in the following section were selected to best represent the acceptability of the recruitment approaches to the couples and the acceptability/ challenges perceived by the staff.

Quantitative. To assess overall differences among the recruitment approaches in terms of yield of eligible couples enrolled in the study through each approach, an Exact Pearson's chi square test was performed. Analyses for association were carried out for each recruitment approach to determine if it attracted more eligible than ineligible couples. To assess if there were demographic differences (age and place of residence) between the 56 ineligible couples for which data on recruitment approach was available and the 125 ineligible couples for which data was not available, a Mann Whitney test was used to assess whether one of the two samples had a larger median age than the other (average age of each couple was used; when the age of one partner was missing, the age of the other partner was used as a proxy for the average age), and a Pearson's chi-square test of independence was used to assess if the two samples differed in terms of the distribution of participant place of residence.

Costs associated with each recruitment approach were calculated. These costs were expenses incurred directly by the study exclusively for recruitment purposes and did not include the operating costs for programs that assisted by referring couples to the HPTN 052 study. Staff costs, including peer educators, were based on salary records from KEMRI/CDC Human Resources files during the period of recruitment. Transport costs per recruitment approach were calculated as follows: PSC- cost of a car per kilometer ($0.86) times the distance between the PSCs and the clinic site (20 kms) times the number of PSC days (average 4 per week for 6 months between December 2009 through to May 2010); General Community Mobilization - cost of car and driver ($100/day) times number of days worked between the period of September 2009 through May 2010 less public holidays and weekends; HBCT- cost of the car and driver ($100/ day) times the number of days worked between the period of January 2010 through to May 2010 less public holidays and weekends. The calculation for the PSC transport is different than the General Community Mobilization and HBCT calculations because the vehicle was not assigned to this duty for the entire day; the distance between the PSCs and the clinic site was specific and the same everyday in contrast to the other approaches where the vehicle would cover a variable distance each day. Expenses for reproduction of the educational materials and airing the recruitment announcement on a local radio station were obtained from receipts and procurement vouchers from the accounts office. No costs were incurred for the assistance from the HDSS and IEIP which are branches of the KEMRI/CDC Research and Public Health Collaboration. Similarly, no costs were incurred for the community health workers who are volunteers in the community and mainly attached to the local health facilities.

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Results

Between November 2009 and April 2010, 241 couples were screened for eligibility for the HPTN 052 clinical trial in Kisumu, Kenya using 9 recruitment approaches. During the screening process, 60 couples were found to be eligible and 181 couples ineligible. Subsequently, all 60 eligible couples were enrolled in the study. Information on the recruitment approach that brought the couples to the clinic was compared for the 60 eligible couples versus the 56 ineligible couples for which recruitment information was available. We found no significant difference between the group of ineligible couples for whom recruitment information was available (n=56 couples or 112 persons) and the group of ineligible couples for whom recruitment information was not available (125 couples or 250 persons) in terms of age (ineligible with recruitment information: median 37.0 years, interquartile range (IQR)=31.5-44.0; ineligible without recruitment information: median=35.3 years, IQR=28.5-45.0; p=0.47) or place of residence (ineligible with recruitment information: Asembo 71 (33%); Karemo 34(35%); ineligible without recruitment information: Asembo 144(67%); Karemo 62(65%); $\chi^2(1)$ =0.17; p=0.68).

Feedback from Recruitment Staff

Staff reported on the six approaches with which they were familiar (Table 1). They did not report on three of the 9 approaches carried out by other persons, specifically: community health workers who conducted follow up home health visits, peer educators who went to the homes of discordant couples identified by HBCT and PSC who had given consent for follow-up, and participant referral of other potential participants. Of the 20 staff interviewed about the couples' attitudes towards the approaches, 16 reported on the PSC, 8 on the general community mobilization, 9 on the HBCT, and 2 on the HDSS/IEIP, 1 on the radio and 19 on posters/ pamphlets/flyers. Overall, staff reported the acceptability of the approaches by couples was very high. Challenges were reported for all approaches except the HDSS/IEIP and ranged, for instance, from one member of the couple not wanting to reveal a positive HIV status to a partner (PSC approach) to not finding people at home (HBCT approach).

Number of Eligible Couples Enrolled by Recruitment Method

Among the 9 recruitment approaches used, there was an overall significant difference between the proportion of eligible and ineligible participants (χ^2 (8) =33.5; p<0.0001) the approaches yielded. The PSC approach resulted in attracting a greater proportion of couples who were eligible than ineligible (χ^2 (1) = 6.6; p=0.016). In contrast, the peer educator approach resulted in attracting a greater proportion of ineligible than eligible couples (χ^2 (1) =24.3; p=<0.0001) (Table 2).

Discordant Couples' Attitudes towards the Recruitment Approaches: Venue, Educational Materials, and Language

Of the 29 couples interviewed who had been approached for study recruitment in one of the two main recruitment venues (their homes and the PSCs), all found the venue acceptable (Table 3). Only some of the 29 couples had seen the educational materials (posters-11, pamphlets-11, and flyers-9). Most found them useful, but a lesser percentage found the posters useful (poster 72.7%; flyer 88.9%; pamphlet 90.9%). All found the language they were told about the study acceptable; for all (27/27; 100%) this was Dholuo.

Associated Cost based on Recruitment Records

The HDSS/IEIP and the community health worker approach cost no additional funds beyond what was already funding the activities of these persons; combined, the two approaches yielded only four eligible couples. The HBCT approach yielded the most eligible couples (n=27), though the total cost (exclusive of direct HBCT costs) was the second highest of the approaches used ($21,964 total or $813 per eligible couple) (Table 4). The PSC approach attracted 25 eligible couples, though at a lower cost ($8,892 total or

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Table 1: Staff interview responses regarding acceptability and challenges experienced when implementing six of the nine† HPTN 052 recruitment approaches, Kisumu, Kenya, 2010.

Recruitment Approach	Acceptability		Challenges	
	Yes N(%)	Representative quote	Yes N(%)	Representative quote
Patient Support centers (PSC) N=16	13 (81)	"I think the meetings at the PSCs went well because we are sure of the dates when different people are meeting at different dispensaries or hospitals so we are sure to get people there."	12(75)	"Others who could be willing to join are ashamed to the point of not wanting to reveal their statuses to their spouses."
General community mobilization- by study staff N=8	7(88)	"The response was positive because through that we could get clients coming to the clinic saying that they received the information from the community mobilizers."	3(38)	"Some (at beach area) were like we don't want to hear."
Home Based Counseling and Testing (HBCT) staff N=9	9(100)	"To some, it pleased them, yet to some that was not the case; it was bad but generally very few people did not like it."	9(100)	"Walking was not easy, timing of the potential clients was also not an easy task for us since we could go to homes and find that everybody else had left for the farms."
Health and Demographic Surveillance System (HDSS) and International Emerging Infections (IEI) staff N=2	2(100)	"It was okay because we could see many clients responding after being informed about the study by the HDSS staff."	0(0)	"Some people were living far away from where the study was taking place."
Local Radio announcements N=1	1(100)	"Some were like what we are doing is very ok if it is there in the radio then we are not like doing	1(100)	"If you do not get it (hear) properly, you can't rewind."
Posters/pamphlets/ flyers N=19	18(42)	"I think it was good since any client walking into the clinic could easily see and read them."	12(63)	"It is difficult for a person to read a poster when he is not interested. Few people are interested in posters because they view it as just

Approaches not included because the staff did not have a role in the approaches and thus could not provide feedback are: community health workers who conducted follow-up home health visits, peer educators who went to the homes of discordant couples identified by HBCT and PSC who had given consent for follow-up, and participant referral of other potential participants.

Patient Support Center- a health facility where HIV testing occurs and persons who are HIV positive receive care and treatment services.

General Community Mobilization- informational talks at barazas or meetings of the community called by a chief, or at markets and women's groups.

Home Based Counseling and Testing: nurses and counselors visit persons in their homes to conduct HIV counseling and testing. They use hand-held computers to enter data about the family's health, HIV test results, and the physical location of the household to allow follow-up. Persons who are found to be HIV-positive during this activity are immediately given a referral for follow-up clinical care. All persons tested are asked whether they are willing to receive a future follow-up visit.

Health and Demographic Surveillance System – KEMRI/CDC staff who carry out a population registration system that monitors health and demographic dynamics in a geographically defined population in the areas of Asembo, Gem, and Karemo.

International Emerging Infections Program staff- persons who conduct a community, population-based surveillance to determine annual incidence rates for infectious diseases and characterize the epidemiology and key etiologies of major syndromes.

Local radio announcements- infomercial-style announcements about joining the HPTN 052 study aired during the month of May 2009.

Posters/pamphlets/flyers-
IRB- approved educational materials created specifically for the HPTN 052 trial in Kisumu, Kenya.

Table 2: Success of recruitment approaches by yield of screened discordant couples who were eligible versus ineligible for the HPTN 052 study, Kisumu, Kenya, 2010.

Recruitment approach	Eligible	Ineligible	P
Patient Support Centers	25	11	**0.016**
General community mobilization	3	2	1.000
Home Based Counseling and Testing	27	16	0.084
Health and Demographic Surveillance System and International Emerging Infectious Disease Program	1	1	1.000
Local radio station	0	3	0.109
Posters/pamphlets/flyers	1	0	1.000
Community Health Workers	3	2	1.000
Peer Educators	0	19	**<0.0001**
Participants referral	0	2	0.231
Totals	60	56	

Table 3: Discordant couple interview responses (N=29) regarding acceptability of the two most frequently used recruitment venues, language used for HPTN 052 recruitment, and for those who saw educational materials, their opinions about the usefulness of the materials, Kisumu, Kenya, 2010.

Domains of Inquiry	Proportion (%)	Representative Quote
Venue- Acceptability		
Patient Support Centers	10/10 (100)	"It was good because we were together and all that happened we saw and we were told how we can help ourselves even though one of us is having it and the other does not."
Home Based Counseling and Testing	19/19 (100)	"That was good for me because he came and got us in the house, we did not pursue or look for him, he came by himself and we welcomed him."
Language heard about study- Acceptability[a]	27/27 (100)	"I understand Luo well."
Educational Materials- Usefulness[b]		
Poster[c]	8/11 (72.7)	"..let them clarify how people infected with the virus will continue living."
Pamphlet[c]	10/11 (90.9)	"I thought it was good, when one is tested then both should."
Flyer	8/9 (88.9)	"I saw it and realized that it was a program for "Sir Jaodi" so I take another look at it once more."

Note: Information was always provided in Dholuo and sometimes in Kiswahili and English. All couples listed Dholuo as acceptable to receive study information.
[a] Two persons were not asked about language acceptability so the denominator is less than 29.
[b]Not all couples saw the educational materials so the denominator is less than 29.
[c]One couple did not have an absolute opinion about the poster and pamphlet, they thought in some ways they were useful and in some ways not useful.

Table 4: Costs for recruitment approaches for the HPTN 052 study, Kisumu, Kenya, 2010.

Recruitment approach	Staff [a]	Transportation [c]	Direct costs [d]	Total estimated cost	Cost/Eligible Couple [e]
Patient Support Centers	$7,250	$1, 642	--	$8, 892	$356
General community mobilization	$11,420	$17, 800	--	$29, 220	$9,740
Home Based Counseling and Testing	$11,764	$10, 200	--	$21, 964	$813
Health and Demographic Surveillance System (HDSS) and International Emerging Infectious Disease Program[a]	---	---	---	$0	$0
Local radio station	---	---	$3,297	$3,297	[f]
Posters/pamphlets/flyers	---	---	$2,303	$2,303	$2,303
Community Health Workers [a]	---	---	--	$0	[f]
Peer Educators	$4,724	---	---	$4,724	[f]
Participants referral	---	---	---	$0	[f]
Totals	$35,158	$29, 642	$5,600	$70, 400	

Note: Conversion used Ksh. 76K per $1 (September 2009).
[a] If staff time to set up a strategy, for instance talking to the Health and Demographic Surveillance System and International Emerging Infectious Disease Program staff or training the community health workers, was less than 2 hours, it was not included in the cost calculation.
[b] Staff costs, including peer educators, were based on salary records from Human Resources during the period of recruitment.
[c] Transport costs per recruitment approach were calculated as follows:
Patient Support Centers- Cost of a car per kilometer ($0.855) times distance between the PSCs and the clinic site (20 Kms) times number of PSC days (average 4 per week for 6 months between December 2009 through to May 2010 or 96). This calculation is different than the General Community Mobilization and HBCT calculations because the vehicle was not assigned to this duty for the entire day.
General Community Mobilization - Cost of car and driver ($100/day) times number of days worked between the period of September 2009 through May 2010 less public holidays and weekends (178 days).
Home Based Counseling and Testing- Cost of car and driver ($100/day) times number of days worked between the period of January 2010 through to May 2010 less public holidays and weekends (102 days). PEPFAR funded initiative.
The Health and Demographic Surveillance System and International Emerging Infectious Disease Programs are branches of the KEMRI/CDC Research and Public Health Collaboration
Community health workers are volunteers in the community and mainly attached to the health facilities in the community and their services do not attract any pay.
[d] Costs based on copies of receipts and procurement vouchers from the accounts office.
[e] Using eligible couple number from Table 2.
[f] No eligible couple were recruited through this method

$356 per eligible couple). The most costly approaches were the general community mobilization ($29,220 total or $9,740 per eligible couple) and posters/pamphlets/ flyers ($2,303 per eligible couple), and these approaches yielded few eligible couples.

Discussion

A variety of both active and passive approaches was used to recruit discordant couples to participate in the HPTN 052 trial in Kisumu, western Kenya. Of the 9 approaches used, only one, the PSC approach, recruited significantly more eligible than ineligible couples. This was likely because the medical files could be accessed to better target couples where one member of the couple was HIV infected and had a CD4 cell count within the range required by the study. The HBCT approach also resulted in recruiting more eligible than ineligible couples, though the difference was not significant. The cost per eligible couple of HBCT was more than twice as high as the PSC approach ($813/eligible couple for HBCT versus $356/eligible couple for PSC). The community mobilization approach did not directly result in the recruitment of a substantial number of eligible couples. The total cost was more than most of the other approaches and per eligible couple identified. However, it was crucial in terms of creating community awareness and support for the HPTN 052 study. Data from couple interviews not reported here indicated that when undertaking recruitment for a research study involving HIV serodiscordant couples, approaches, e.g. HDSS/ IEIP, posters/pamphlets/flyers, local radio announcements, that may bring the fewest or even zero eligible couples should not necessarily be minimized if they help to anchor the project and generate legitimacy and support in the community. It is important to underscore that the recruitment process for HPTN 052 was not only about recruiting eligible couples, but also about improving understanding of HIV transmission between discordant couples in the local community, as well as support for clinical trials designed to test HIV prevention interventions.

Recruitment efforts through the PSC and the HBCT organizations that directly interacted with couples and had knowledge of their HIV status were the most successful. Recruitment staff reported that using the PSC approach was successful because by working with the health care staff at the PSC, they were able to know the dates that persons who met the study criteria had appointments and so could be there to provide information about the study in person if the potential participant expressed an interest to the PSC staff member to know more about the study. Using the HBCT approach was beneficial in that the recruitment staff was informed of couples who had recently been found to be discordant and had agreed to be recontacted in the future based on their HIV results. Recruitment staff could thus follow-up with a home visit to present information on the study. Other studies have also used this approach of working with health clinics or previously established cohorts [6;19-21]. Similar to our study, in these studies, most people recruited were already attendees of the clinics or counseling centers and were approached at their appointments. In another evaluation study of discordant couple recruitment approaches in Kisumu for a clinical trial of Pre-Exposure Prophylaxis for HIV, the cost of recruiting couples from the Voluntary Counseling and Testing clinic was the most expensive approach, though it was the most efficient in terms of rapidly recruiting couples [21]. It is of note, however, that study did not have specific clinical criteria (such as CD4 cell count) that needed to be targeted for the HIV-infected member of the couple recruited. Another reason why the PSC and the HBCT approaches were the most effective in recruiting eligible couples in our study may be because of the good relationships between the research and medical organizations in the area such that they partner with and help one another with studies and projects.

Couples were generally accepting of the recruitment approaches, specifically, the venues where they were approached (home and PSC), the educational materials given to them, and the language used for explaining the trial. The two main venues, the PSC and their homes, were acceptable to the couples because for instance, convenience, in that the person or couple was

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already at the PSC for another reason and the couple was together at the house at the same time and place. It is likely that the recruitment approaches based at the PSC and their homes were acceptable because the recruitment staff were associated with a recognized institution or program where a feeling of trust was already established. Other studies have found lack of trust to be a barrier and presence of trust a facilitator to study recruitment [22-24]. Overall, the educational materials were acceptable, however, staff and couples reported that the posters were viewed as less useful than the flyers and pamphlets due to the lesser amount of information presented. While educational materials can be helpful in explaining a study, using them has not always resulted in higher enrollment rates [10;25-26]. Additionally, in areas with people who speak multiple languages, presenting study information in the language most preferred is important to enrollment efforts. To ensure equal opportunity for all persons in Kisumu to enroll in the study, recruitment staff were multilingual and educational materials were presented in multiple languages (English, Kiswahili and Dholuo). Because most of the population is of Luo ethnicity, however, not surprisingly, most couples reported preferring Dholuo.

Our data had limitations. First, information on recruitment approach was available for only 56 of the 181 ineligible couples; however, there were no differences between groups in terms of age or place of residence, suggesting that the 56 couples with data available may be representative of the full group of 181 ineligible couples. Secondly, we screened and interviewed potential participants as couples, thus the couple interviews may have reflected only the male partner's opinions because of the male dominant culture of the Luo ethnic group to which most couples belonged. Thirdly, since we partnered with ongoing local programs, much of our costs were subsidized by the on-going program upon which they were layered, and are thus not reflected in our direct recruitment cost estimates. For instance, the approximate cost for the HBCT program in Asembo and Karemo (total population approximately 248 675 persons) was ~US$2.3 million over a period of one year (unpublished data). The HPTN 052 study only had to incur an additional cost of $21,964 (less than 1 % of the estimated program cost) in recruiting couples who had already received HBTC to join the study. Thus, the costs of recruitment approaches presented here may not apply to locales where fewer programs already exist. Finally, there was the possibility that participants were exposed to more than one recruitment approach as this was not an experimental study. However, we asked the participants to report the main recruitment approach that brought them to the clinic. The strength of this site specific analysis is that it provides a quantitative and qualitative evaluation of the recruitment approaches used for a clinical trial and can also be applied to programmatic work, which is increasingly focused on HIV sero-discordant couples, an important population in the multi-faceted fight against the HIV scourge.

Our successful recruitment of discordant couples to participate in the HPTN 052 trial used a combination of active and passive approaches. Our evaluation of these recruitment approaches indicated that working with local HIV programs, specifically the PSC and HBCT, was the most effective approach to recruit eligible couples with the PSC approach being the less costly of the two. Collaborations and partnerships have been highlighted as being effective in other areas of health and research [27-28]. Future research and evaluations should consider the benefits of community, health facility/provider and research organization partnerships.

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