



Participant Retention in a HIV Prevention Cohort Study in Kisumu, Kenya

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Abstract

Retention of sufficient numbers of participants in longitudinal research studies is a serious methodological concern, as retention influences the validity of the research findings. An assessment of participant retention or attending all study visits was made quarterly during a 12 month follow-up of an HIV incident cohort in Kisumu, Kenya. The study objectives were to determine 1) the proportion of participants attending all study visits and 2) demographic and behavioral factors associated with missing ≥ 1 visit. The Kisumu Incidence Cohort Study (KICoS) was initiated in January 2007 (N=831). Detailed contact information was collected from each participant to enhance retention. Bivariate and multivariable analyses were used to determine factors associated with missing ≥ 1 visit. Overall retention was 90%. Of those enrolled, 46.4% were females. The adjusted odds of missing ≥ 1 study visit were greater for participants who were female (AOR=2.85; CI=1.90-4.28) and who had technical training (AOR=2.51; CI=1.20-5.25) or college/university education (AOR=1.89; CI=1.10-3.24) compared to having no or only primary education. Retention was high in this HIV prevention cohort study. However, studies could benefit by tailoring retention strategies for women.

Running Head: Participant retention in Kisumu Kenya

Key words: cohort studies, retention, HIV, females

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Introduction

The inability to retain enrolled participants poses serious threats to both the internal and the external validity of a research study. Retention may be related to different factors depending upon the population, e.g. young age and longer trial duration [1], self-identifying as homosexual and having been a male sex worker in the past 6 months [2], and male sex, age <35 years, advanced HIV/AIDS disease and increasing malnutrition [3]. As the HIV epidemic is focused in sub-Saharan Africa, antiretroviral programs as well as clinical trials necessitate a close examination of retention in African populations [3]. Understanding factors associated with retention can help in informing future screening processes and plans for retention strategies.

The Kisumu Incidence Cohort Study (KICoS) was initiated in January 2007 to prepare the Kenya Medical Research Institute (KEMRI)/Centers for Disease Control and Prevention (CDC) site in Kisumu for participation in future efficacy trials of biomedical interventions to prevent HIV infection. Participants were enrolled and followed every 3 months for a total of 12 months. The purpose of this secondary analysis from KICoS was to determine 1) the proportion of participants attending all study visits and 2) demographic and behavioral factors associated with missing ≥ 1 visit.

Methods

Study Population

The study took place in Kisumu, Nyanza Province, Kenya which has a population of approximately 500,000 residents [4], the majority of whom identify themselves as being of Luo ethnicity [5]. We recruited individuals from Kisumu and its catchment area, approximately 931 km². The study enrollment target was a convenience sample of healthy, HIV-uninfected men and women (non-pregnant) who were sexually active within the 3 months prior to study enrollment. The study was conducted sequentially in two age groups: 16-17 years of age, referred to as minors (from 28 April 2008 to 20 June 2010) and 18-34 years of age, referred to as adults (from 17 January 2007 to 21 March 2009). The study was conducted at the study clinic of the KEMRI/CDC Clinical Research Center (CRC), adjacent to the New Nyanza Provincial General Hospital in Kisumu.

The participants who came to the clinic went through pre-screening and screening. Those who were eligible and enrolled came for quarterly visits for a total of 12 months of study follow-up.

Substudy Procedure

At screening, detailed locator information was collected from participants that included their physical home address, two contact telephone numbers and details of at least one friend and/or family member. Home verification was also done by the staff once the participant was enrolled and anytime a participant migrated, for those who accepted home visits. Appointment cards were issued to all participants for follow-up visits and the next visit was scheduled on the target date. The study design, however, allowed for flexibility in visit attendance. A participant was counted as completing a study visit if they were present for a visit within six weeks before or six weeks after the scheduled visit.

Telephone, in-person or mailed reminders (in that order) were employed six weeks preceding the scheduled visits for half of the participants who were randomly selected to assess if a reminder helped ensure participants did not miss their visits. For all study participants, if the participant failed to attend a scheduled study visit, a locator visit was initiated one week later. Up to three attempts were made to reach the participant using the contact and locator information provided on the locator information form. Participants who relocated from their area of residence were followed and locator information was updated where possible.

Follow-up visits occurred at 3, 6, 9 and 12 months after enrollment. A clinical evaluation was performed (including pregnancy testing for women) and a blood sample was obtained for HSV-2 antibody testing on individuals HSV-2 negative at enrollment, for quality assurance of HIV testing, and for retrospective determination of time of HIV seroconversion using PCR. HSV-2 testing was performed on all samples obtained at 12 months, and for samples testing positive, the determination of timing of HSV-2 seroconversion were done by retrospective testing of the corresponding month 3, 6 and 9 samples. All participants received a mosquito net at the enrolment visit and a monetary reimbursement (minors: approximately U.S. \$4.00;

adults: approximately U.S. \$5.00) for their transportation costs and a bar of soap at each visit. In addition, at each visit minors received an exercise book.

HIV education and risk reduction counseling was also provided. A self-administered questionnaire using audio computer assisted self-interview (ACASI) was used to assess HIV risk behavior. Questions were asked about, for instance, demographic characteristics (e.g., age, religion, employment status), the main motivation for participating in the study, and questions about HIV risk factors (e.g., lifetime number of partners, and any drug and alcohol use in the last three months).

Ethics

Participants were provided explanations about the study, were told that the information they provided would be confidential, and were informed that their participation was voluntary. The study protocol, consent forms and data collection instruments for this study were reviewed and approved by the Kenyan KEMRI local and national Scientific Steering Committees and national Ethical Review Committee as well as the U.S. CDC Institutional Review Board.

Analysis

Data from the adults and minors were combined for analyses. Bivariate and multivariate logistic regression analyses were used to determine demographic and behavioral factors associated with missing ≥ 1 visit. All of the independent variables were entered into the multiple logistic regression model. Independent variables were gender, ethnic group, level of education, age, religion, employment status, reminder of visit, main motivation for participating, migration history, marital status, lifetime number of sex partners, any drug use in the last three months, and any alcohol use in the last three months. The proportion of participants who chose the option "refuse to answer" to our questions of interest was less than 3%, so these responses were not included in the study analysis. All analyses were carried out using SAS for Windows version 9.2 (SAS, Cary, North Carolina, USA).

Results

A total of 1,724 persons were pre-screened for the study (adults: 1,277; minors: 447). Of those, 1,106

completed screening (adults: 846; minors: 260) and 831 were enrolled (adults: 625; minors: 206); 46.4% were females. Of those enrolled, 74.3% were single, never married, separated, divorced or widowed (Table 1). Overall participant retention was 90% for the 12 months of follow-up.

Bivariate analysis - Factors Associated with Missing ≥ 1 Study Visit

Odds of missing ≥ 1 study visit were greater for participants who were female (odds ratio (OR)=2.19; 95% confidence interval (CI)=1.59-3.03), whose ethnicity was not Luo (OR=2.40; CI=1.55-3.70), who had technical training (OR=3.06; CI=1.65-5.68) or college/university education (OR=2.05; CI=1.34-3.14) compared to having no or just primary education, and who identified as being Protestant or other denomination (OR=1.41; CI=1.02-1.95) compared to Catholic (Table 2).

Multivariable Regression Analysis- Factors Associated with Missing ≥ 1 Study Visit

The adjusted odds of missing ≥ 1 study visit were greater for participants who were female (adjusted odds ratio (AOR)=2.85; CI=1.90-4.28) and who had technical training (AOR=2.51; CI=1.20-5.25) or college/university education (AOR=1.89; CI=1.10-3.24) compared to having no or just primary education (Table 2).

Discussion

Ninety percent of over 800 cohort study participants in Kisumu, Kenya completed all study visits over a 12-month period. This high rate of retention may be attributable in part to the collection of detailed contact and locator information of participants that enabled staff to contact participants, as well as the flexibility of the study design that enabled many participants to honor their visits within defined visit "windows". It may also be due to the efficient clinic process. It has been noted that dropouts occur when participants' perceived time and effort invested outweigh the perceived benefits of being in a study [6]. It is of note that the visit reminder administered to a random half of participants six weeks before the scheduled visit was not significantly associated with completion of all visits. This could be because the lead time was too long; because we did not distinguish between telephone,

Table 1: Demographic characteristics of a cohort of minors and adults enrolled in the Kisumu Incidence Cohort Study (KICoS) in Kisumu Kenya, 2007-2010.

	(N=831) n (%)
Gender	
Male	445(53.6)
Female	386(46.4)
Age range (years)	
16-19	289(34.7)
20-24	402(48.4)
25-29	103(12.4)
30-34	37(4.5)
Marital status	
Single/Never married/ Separated/Divorced/Widowed	615(74.3)
Not Married but living as married	65(7.9)
Married	148(17.9)
Ethnic group or tribe	
Luo	730(87.9)
Other	101(12.2)
Religion	
Roman Catholic	368(44.3)
Protestant/other denomination	463(55.7)
Highest level of schooling completed	
No school/Primary	303(36.6)
Secondary	294(35.5)
Technical training	53(6.4)
College/University	177(21.4)
Employment	
No work/Homemaker	569(68.8)
Self-employed	102(12.3)
Other	156(18.9)

Table 2: Risk factor analysis using bivariate and multivariate logistic regression analysis for missing ≥ 1 visit in minors and adults enrolled in the Kisumu Incidence Cohort Study (KICoS) in Kisumu Kenya, 2007-2010.

	Missed ≥ 1 visit (N=203) N%	Completed all visits (N=628) N%	OR (95%CI)	AOR (95%CI)
Gender				
Male	79(17.8)	366(82.3)	referent	referent
Female	124(32.1)	262(67.9)	2.19(1.59-3.03)	2.85(1.89-4.28)*
Age (years)				
16-19	57(19.7)	232(80.3)	1.57(0.59-4.22)	1.49(0.46-4.81)
20-24	113(28.1)	289(71.9)	2.50(0.95-6.58)	1.75(0.60-5.11)
25-29	28(27.2)	75(72.8)	2.39 (0.85-6.74)	2.16(0.71-6.62)
30-34	5(13.5)	32(86.5)	referent	referent
Marital status				
Single/Never married/ Separated/Divorced/Widowed	152(24.7)	463(75.3)	referent	referent
Not married but living as married	19(29.2)	46(70.8)	1.26(0.72-2.21)	1.61(0.87-2.98)
Married	31(21.0)	117(79.0)	0.81(0.52-1.25)	0.88(0.50-1.57)
Ethnic group or tribe				
Luo	162(22.2)	568(77.8)	referent	referent
Other	41(40.6)	60(59.4)	2.40(1.55-3.70)	1.60(0.97-2.65)
Religion				
Roman Catholic	77(20.9)	291(79.1)	referent	referent
Protestant/other denomination	126(27.2)	337(72.8)	1.41(1.02-1.95)	1.23(0.84-1.80)
Highest level of schooling completed				
No school/Primary	57(18.8)	246(81.2)	referent	referent
Secondary	66(22.5)	228(77.6)	1.25(0.84-1.86)	1.16(0.73-1.84)
Technical training	22(41.5)	31(58.5)	3.06(1.65-5.68)	2.51(1.20-5.25)*
College/University	57(32.2)	120(67.8)	2.05(1.34-3.14)	1.89(1.10-3.24)*
Employment				
No work/Homemaker	148(26.0)	421(74.0)	referent	referent
Self-employed	18(17.7)	84(82.3)	0.61(0.35-1.05)	0.60(0.32-1.11)
Other	36(23.1)	120(76.9)	0.85(0.56-1.30)	0.96(0.59-1.56)

(Table 2: Continued from page 17)

	Missed ≥ 1 visit (N=203) N%	Completed all visits (N=628) N%	OR (95%CI)	AOR (95%CI)
Migration history				
Not Moved/Less than one week	142(23.9)	453(76.1)	referent	referent
Between 1 week and a month	25(22.5)	86(77.5)	0.93(0.57-1.50)	0.73(0.42-1.27)
More than a month	35(29.4)	84(70.6)	1.33(0.86-2.06)	1.05(0.64-1.71)
Visit Reminder				
Yes	106(25.7)	307(74.3)	1.18(0.85-1.60)	1.15(0.81-1.64)
No	95(22.8)	321(77.2)	referent	referent
Main Motivation for participation				
Get Free Medical tests/Get Incentives	69(25.9)	197(74.1)	referent	referent
Learn about HIV, causes and ways to avoid infection	74(21.5)	270(78.5)	0.78(0.54-1.14)	0.71(0.47-1.09)
Help control spread of HIV/AIDS	59(27.7)	154(72.3)	1.09(0.73-1.64)	0.99(0.62-1.59)
Drug use last 3 months				
Yes	32(22.7)	109(77.3)	0.90(0.59-1.38)	1.28(0.76-2.16)
No	169(24.6)	518(75.4)	referent	referent
Alcohol use last 3 months				
Yes	81(24.2)	253(75.8)	0.98(0.71-1.36)	0.98(0.65-1.48)
No	122(24.6)	375(75.4)	referent	referent

(Table 2: Continued from page 8)

	Missed ≥ 1 visit (N=203) N%	Completed all visits (N=628) N%	OR (95%CI)	AOR (95%CI)
Lifetime number of sexual partners				
≤1	28(21.2)	104(78.8)	referent	referent
2	36(24.8)	109(75.2)	1.23(0.70-2.15)	1.36(0.74-2.49)
3-5	72(25.3)	213(74.7)	1.26(0.77-2.06)	1.46(0.84-2.54)
6-10	32(22.2)	112(77.8)	1.06(0.60-1.88)	1.69(0.86-3.30)
>10	25(26.6)	69(73.4)	1.35(0.72-2.50)	2.10(0.99-4.40)

Notes. Missing values are not included; AOR = adjusted odds ratio, CI=confidence interval.

* Overall significance, $P < 0.05$.

†Other ethnic groups included Kikuyu, Maasai, Luhya, Kisii, Arab, and Suba.

in-person or mailed reminders, some of which may have been more effective than others; or, because implementation of the visit reminders was not documented and thus, could not be examined.

Our results showed that two demographic and no behavioral factors were associated with missing ≥ 1 study visit. Females had nearly three times the odds of not completing all study visits than men. This is concerning since the prevalence of HIV infection in women in this area of western Kenya is approximately twice that of men [7] and female-focused prevention trials are planned. Little research has been conducted on factors associated with missed visits in HIV prevention research, however, in studies of medication adherence, some studies have shown women to be less adherent (e.g., medication for heart failure [8], ART in India [9]). Reasons women may have poor medication adherence are varied, representing their competing demands that include caring for children [10] and family, transportation costs and work commitments [11].

In addition, in our study, persons with more education (above secondary school) had higher odds of missing ≥ 1 study visit. Even though work was not associated with ≥ 1 missed visit, it may be that persons with more education would have a higher likelihood of being engaged in types of work which constrain schedules than those with less education and thus miss visits due to work requirements. In a study of loss to follow-up in an HIV treatment program in western Kenya, work commitment was a reason why men were lost to follow-up [10].

Our study had several potential limitations. First, our participants were volunteers and were recruited using convenience sampling, so they may not be a true representation of the Kisumu population. Second, we did not collect data on reasons for missed visits or type of employment. Third, data was not available on the type of reminder (via telephone, in-person, mailed) provided to half of the participants and the frequency of successfully reaching the participant using the methods. Finally, all of the relevant and important variables may not have been captured in our survey (e.g., peer or family social support, lack of transport or other barriers to attending visits).

In conclusion, retention was relatively high in this HIV prevention cohort study. Some amount of attrition is unavoidable as participation is voluntary and

unpredictable events may require participants to miss a visit or leave the study. It is concerning, however, that among the groups more apt to miss ≥ 1 study visit was females. Females are affected disproportionately by HIV in this area of Kenya [12] and their full participation in HIV prevention studies is needed to assure that any intervention developed will work for them [13]. For future HIV prevention studies in Kisumu, it may be beneficial to tailor retention strategies for women.

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