Retention of adults from fishing communities in an HIV vaccine preparedness study in Masaka, Uganda

Authors: Ubaldo Bahemuka[1], Andrew Abaasa[1], Eugene Ruzagira[1], Christina Lindan[3], Matt A Price[2,3], Anatoli Kamali[2], Pat Fast[2]

Authors affiliations: [1]Medical Research Council (MRC)/Uganda Virus Research Institute (UVRI) and London School of Hygiene and Tropical Medicine Uganda Research Unit, Entebbe, Uganda; [2] International AIDS Vaccine Initiative, New York, USA; [3] University of California, San Francisco

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Corresponding author: Ubaldo Bahemuka, MRC/UVRI & LSHTM Uganda Research Unit . P.O Box 49 Entebbe, Uganda. Phone: +256 (0)417 704000, Mobile +256 702 523665

Author's emails

Ubaldo Bahemuka: Ubaldo.Bahemuka@mrcuganda.org, Ubaldo.Bahemuka@lshtm.ac.uk

Andrew Abaasa: Andrew.Abaasa@mrcuganda.org

Eugene Ruzagira: Eugene.Ruzagira@mrcuganda.org

Christina Lindan:Krysia.Lindan@ucsf.edu

Matt A Price:MPrice@iavi.org

Anatoli Kamali: AKamali@iavi.org

Pat Fast: PFast@iavi.org

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23 # Abstract

24 **Introduction:** People living in fishing communities around Lake Victoria may be

25 suitable for enrolment in HIV prevention trials because of high HIV incidence. We assessed

26 the ability to recruit and retain individuals from fishing communities into an HIV vaccine

27 preparedness cohort study in Masaka, Uganda.

28 **Methods:** HIV high risk, sero-negative adults (18-49 years) were identified from four

29 fishing villages bordering Lake Victoria through door-to-door HIV counselling and testing

30 (HCT). Interested persons were referred for: screening, enrolment, and quarterly follow-up

31 visits at a study clinic located approximately 40 kilometres away. Repeat HCT, HIV risk

32 assessment, and evaluation and treatment for sexually transmitted infections were provided.

33 Rates of and factors associated with study dropout were assessed using Poisson regression

34 models.

35 **Results:** A total of 940 participants were screened between January 2012 and February

36 2015, of whom 654 were considered for the analysis. Over a two-year follow-up period, 197

37 (30.1%) participants dropped out of the study over 778.9 person-years, a dropout rate of 25.3

38 / 100 person-years. Dropout was associated with being female (aRR =1.56, 95% confidence

39 interval [CI] 1.12-2.18), age, being 18-24 years (aRR=1.64; 95% CI 1.03-2.60), 25-34 years

40 (aRR=1.63; 95% CI 1.04-2.55); having no education (aRR=2.02; 95% CI: 1.23-3.31); living

41 in the community for less than one year (aRR=2.22; 95% CI: 1.46-3.38) or 1-5 years

42 (aRR=1.68; 95% CI: 1.16-2.45) and occupation.

43   **Conclusions:** It is possible to recruit and retain individuals from fishing communities,

44   however, intensified participant tracing may be necessary in a vaccine trial to keep in follow

45   up female, young, less educated, those in mobile occupations and new residents.

4

Introduction

47

48 New HIV infections continue to occur in sub-Saharan Africa, despite behavioural and

49 biomedical prevention efforts(1). Therefore, development of an effective HIV vaccine will be

50 essential to reducing incidence in this region(2). Efficacy testing of HIV vaccine candidates is

51 more efficient among populations with favourable retention and high HIV incidence rates(3).

52 Fishing communities in Uganda have a high burden of HIV with HIV prevalence and

53 incidence ranging from 20-40 percent (4-6) and 3-9 cases per 100 person-years of

54 observation (PYO) respectively (7-9).   This high level of risk suggests that persons living in

55 these communities may be an ideal population for HIV vaccine efficacy trials. However,

56 fishing communities are typically located in remote areas and often have little if any health

57 care infrastructure, factors that may present challenges to the rigorous implementation

58 requirements of HIV vaccine preparedness and efficacy studies(10).

59 A number of studies have evaluated the suitability of fishing communities around Lake

60 Victoria for participation in future HIV vaccine efficacy trials in terms of participant

61 retention. In three recent studies, (9, 11, 12) the 12-month retention was reported to be 83%

62 ,77% and 85% respectively. In these studies, recruitment and follow up assessments were

63 conducted at clinics established in each of the participating fishing community. During the

64 conduct of a Simulated HIV vaccine trial(SiVET) in the cohort of our study, Abaasa et al

65 (13)reported a 73%% retention in the observational arm of the study.

66 In some cases, it may be advantageous to conduct an efficacy trial in a central location,

67 recruiting volunteers from surrounding areas. The clinical research centre in Masaka town

68 situated is inland from the neighbouring fishing communities. Little is known about how

69 retention might be affected if participants from fishing communities had to travel to a clinic

70 outside of their communities to attend study visits. In order to answer this question, we

5

71 investigated retention and dropout rates among fisher folk enrolled in a HIV vaccine

72 preparedness cohort at a research clinic located approximately 40 km away from their

73 communities.

Methods

Setting and participant identification

76 The International AIDS Vaccine Initiative (IAVI) in collaboration with the Medical Research

77 Council/Uganda Virus Research Institute Research (MRC/UVRI) has supported a clinical

78 research centre in rural South Western Uganda with the aim of conducting future HIV

79 vaccine efficacy trials. The research Centre is located in Masaka town, approximately 30 to

80 40 kilometers (km) away from the shores of Lake Victoria. The clinic is equipped to conduct

81 HIV vaccine trials, Good Clinical Laboratory Practice (GCLP) accredited laboratory, a

82 vaccine pharmacy, and Good Clinical Practice (GCP) trained staff (14). The HIV vaccine

83 preparedness study described here was conducted among individuals identified from four

84 mainland fishing communities on the shore of Lake Victoria located in Masaka and Kalungu

85 districts, in southwest Uganda. These communities were selected because they had the largest

86 populations (≥1000 adults) among fishing communities in these two districts.

87 Between January 2012 and January 2015 a field study team consisting of both male and female

88 counselors visited houses, docked boats, fishing stalls and other venues at the four landing-

89 sites, to offer free rapid HIV testing and counseling on-site to adults. Persons aged 18-49 years

90 old who were identified as HIV uninfected were asked if they would be willing to enroll into a

91 longitudinal study that would require repeated travel to the research clinic. Those who had a

92 positive rapid test result underwent confirmatory testing by having venous blood samples re-

93 tested at the MRC/UVRI laboratory in Entebbe. The participants with confirmed HIV positive

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94 results were invited by the field team on phone or physically to receive their results at the clinic

95 approximately one to two weeks after the blood draw. HIV positive participants were linked to

96 care at a treatment center of their choice in accordance with the clinics HIV referral plan.

Screening and enrolment

98 Interested individuals who travelled to the study clinic were given detailed information about

99 study procedures in a group setting. Individuals also had one-on-one sessions with a study

100 nurse-counselor who provided additional study information, answered questions, and

101 obtained written informed consent. After obtaining consent participants were assessed for

102 eligibility based on the following criteria: being 18-49 years, HIV uninfected, and sexually

103 active defined as having had sex at least once in the last the three months. Participants also

104 needed to be considered at high risk of HIV acquisition by reporting at least one of the

105 following: self-reported history of a sexually transmitted infection (STI) in the last three

106 months, or the presence of an STI based on medical history/physical exam; condomless

107 vaginal or anal intercourse with a new or with more than one sexual partner in the past 3

108 months; staying away from home for at least two nights in the past three months; drinking

109 alcohol at least once a week or using illicit drugs (marijuana, Khat, or any other stimulants) in

110 the past month. Participants who fulfilled the above criteria were enrolled into the study.

111 They then completed interviewer-administered questionnaires in either the local language

112 (Luganda) or English, depending on their preference. All enrolled participants had a baseline

113 demographic interview and HIV risk assessment by the study nurse counsellor. The study

114 physician, performed a medical history and physical exam to assess for STI and circumcision

115 status for males. Participants provided physical addresses and phone numbers in order to

116 facilitate future contacts and follow-up.

117

Follow-up visits

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119   Participants returned to the clinic every three months for repeat HIV counselling and testing,

120   provision of updated locator information and interim medical history. Everyone underwent a

121   symptom-directed physical exam and a clinical evaluation for STIs. Every six months'

122   participants provided information on HIV risk behaviour, and were evaluated annually if they

123   continued to fulfil the requirements for participation in the study. At month 12, volunteers

124   were re-assessed for eligibility based on the above risk of HIV acquisition criteria.

125   Participants who were determined to no longer be eligible were withdrawn from the study. If

126   a participant missed a scheduled appointment, study staff would attempt to contact them via

127   phone or physical tracing by visiting their home. A group of 10 study participants who were

128   considered peer leaders assisted with participant tracing. Participants who missed two

129   consecutive visits were considered to have dropped-out at the time of their last study visit. To

130   bolster study retention, continuous interaction was kept with community advisory board and

131   study staff conducted a series of community activities (research awareness meetings and

132   football matches among others) as a way of improving research awareness. Participants

133   received reimbursement for transportation and time (5000 Uganda shillings, approximately

134   1.4 USD) at the end of each visit.

Laboratory testing

135

136   Rapid HIV antibody testing was performed on venous blood samples using a single rapid test,

137   Alere Determine (Alere Medical Company Ltd. Chiba, Japan). Specimens that were positive

138   by rapid test were tested with two enzyme linked immunosorbent assay (ELISA) tests in

139   parallel (Murex Biotech Limited, Dartford, United Kingdom, and Vironostika, BioMérieux

140   boxtel, The Netherlands). Discrepant ELISA test results were resolved by testing with either

141   Statpak (Chembio Diagnostic Systems Inc., USA) or Western Blot (Cambridge Biotech,

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142   USA). The results of HIV negative rapid tests were given to participants immediately; while

143   participants with confirmed HIV positive results were invited by the field team to receive

144   their results approximately one to two weeks after the blood draw and referred as described

145   earlier. Syphilis testing was performed using the rapid plasma reagin (RPR) test (Microvue,

146   Becton Dickson, Maryland, USA). Samples with an RPR titre of >=1:8 were also tested using

147   the Treponema Pallidum Hemaglutination Assay (TPHA) (Biotech Laboratories, UK). Active

148   syphilis infection was defined as having both a positive RPR titre of >=1:8 and a positive

149   TPHA result.

Statistical analysis

151   Data were analysed in Stata 14.0 (Stata Corp, College Station, TX, USA). Participant baseline

152   characteristics were summarised using proportions and means, and stratified by gender.

153   Proportions and means were used to compare baseline characteristics of participants who

154   dropped out of the study to those that completed their scheduled follow up visits. Dropout was

155   defined as all-cause (including withdrawal by self or investigator, death, unknown loss-to-

156   follow-up and refusal to continue) over a maximum of 24 months of follow-up. Participants

157   that were ineligible at the annual reassessment of eligibility to continue were not considered as

158   dropouts and contributed follow up time up to 12 months. HIV sero-positive participants were

159   not considered to have dropped out, but their follow up was censored at the estimated date of

160   HIV infection. Time of HIV infection was estimated as the midpoint between the date of the

161   last negative and the first positive HIV test result. Seventy-two of the enrolled participants that

162   were enrolled but did not return for any follow up visit had their person years of observation

163   (PYO) corrected to one month and the same added to all participants' PYO. The dropout rate

164   was estimated as the number of participants who dropped out divided by the total person years

165   of observation (PYO). The PYO were calculated as the sum of the time from enrolment

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166   (baseline) to the date of the last clinic visit or date of censoring. Dropout rates were compared

167   by demographic and clinical characteristics. Rate ratios (RR) and 95% confidence intervals

168   (CI) were calculated for the association of factors with dropping out using a Poisson regression

169   model. All factors for which univariate associations attained a significance of p < 0.1 on the

170   log-likelihood test were included in an initial multivariable model. Factors were retained in the

171   multivariable model if the p-value for inclusion using the log-likelihood test was ≤0.05. We

172   calculated a Kaplan- Meier estimate of dropout rate over time for the participants in the cohort.

173   We further performed a sensitivity analysis excluding seventy-two that never returned at all for

174   follow up. Similar approaches as for the primary analysis were followed for the sensitivity

175   analysis.

Ethical considerations

177   The study was approved by the Research and Ethics Committee of the Uganda Virus

178   Research Institute, and by the Uganda National Council of Science and Technology. Written

179   informed consent was obtained from each participant before enrolment. Those who were

180   confirmed to be HIV sero-positive were referred for HIV care and treatment at the

181   appropriate facility.

RESULTS

Screening and enrolment

184   A total of 940 individuals were screened between January 2012 and February 2015; 279 were

185   not enrolled (245 were at low risk for HIV, 8 were HIV-infected, and 26 were excluded for

186   other reasons). We present data on 654 (69.6%) participants who were due for at least one

187   follow-up visit.

Baseline characteristics

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189 The majority (61.4%) of the participants were male, Table 1. The mean age was 27.7 years

190 (SD 6.9). Nearly half were married, most (71.3%) had attained primary education and

191 engaged in fishing or related occupations (51.1%). The majority of the sample (76.9%) was

192 of Christian faith and of Baganda ethnicity (44.0%). Only a third had lived in the fishing

193 community for more than five years and about 50% had stayed away from home for at least

194 two days in the last three months. Most (60.0%) reported having two to three sexual partners

195 in the last three months and three quarters reported having a new sexual partner in the same

196 period with 63.5% reporting condom use with this new partner. Majority of the participants

197 462(70.6) were recruited from Lambu fishing community.

198 **Table 1: Baseline socio-demographic and behavioural characteristics of men and women enrolled**

199 **in a longitudinal HIV vaccine preparedness study, Masaka, Uganda**

Variable	All N=654		Male N=402		Female N=252		P-value of gender difference
	n	(%)	n	(%)	n	(%)	
Age (years)							0.003
35+	248	38.0	132	32.8	116	46.0	
25-34	282	43.0	186	46.3	96	38.1	
18-24	124	19.0	84	20.9	40	15.9	
Current marital status							<0.001
Single	186	28.4	132	32.8	54	21.4	
Married	319	48.8	217	54.0	102	40.5	
Separated/Widowed/divorced	149	22.8	53	13.2	96	38.1	
Education level							0.033
More than primary	125	19.1	66	16.4	59	23.4	
Primary	466	71.3	301	74.9	165	65.5	
None	63	9.6	35	8.7	28	11.1	
Occupation							<0.001
Small scale business	49	7.5	32	8.0	17	6.7	
Fishing/fishing related[1]	334	51.1	280	69.6	54	21.4	
Services(Bar/lodge/restaurant/saloon)	67	10.2	21	5.2	46	18.3	

Other(Peasant farmer/House wife)	204	31.2	69	17.2	135	53.6	
Religion							0.729
Muslim	151	23.1	91	22.6	60	23.8	
Christian	503	76.9	311	77.4	192	76.2	
Tribe/Ethnic group							<0.001
Baganda	288	44.0	178	44.3	110	43.7	
Banyankole	93	14.2	58	14.4	35	13.9	
Banyarwanda	136	20.8	64	17.9	72	28.6	
Other	137	21.0	102	25.4	35	13.9	
Duration of stay in community (years)							<0.001
0-< 1	164	25.1	57	14.2	107	42.5	
>1- 5	289	44.2	201	50.0	88	34.9	
> 5	201	30.7	144	35.8	57	22.6	
Fishing Community							
Lambu	462	70.6	279	69.4	183	72.6	0.776
Kachanga	68	10.4	45	11.9	23	9.13	
Kaziru	32	4.9	21	5.2	11	4.3	
Other	92	14.1	57	14.2	35	13.9	
Away from home ≥ 2 nights, last 3 mos	299	45.8	221	55.1	78	31.0	<0.001
Number of sexual partners, last 3 mos							<0.001
1	215	32.8	80	19.9	135	53.6	
2 to 3	333	60.0	230	57.2	103	40.9	
4 or more	106	16.2	92	22.9	14	5.6	
New sexual partner, last 3 mos	480	74.1	324	81.2	156	62.7	<0.001
Condom use with new partner, last 3 mos	305	63.5	205	63.3	100	64.1	0.859
Drank alcohol , in last month							
Never	239	36.6	128	31.9	112	44.1	
Sometimes	354	54.1	229	57.0	126	49.6	
Daily	61	9.3	45	11.1	16	6.3	
Drank alcohol before sex, in last month							0.005
Never	352	53.8	197	49.0	155	61.5	
Sometimes	204	31.2	135	33.6	69	27.4	
Always	98	15	70	17.4	28	11.1	
Drug use, in last month							<0.001
None	570	87.2	334	83.1	236	93.7	
Marijuana	35	5.3	25	6.2	10	4.0	
Khat	41	6.3	39	9.7	2	0.8	
Other	8	1.2	4	1.0	4	1.6	
Genital sores, last 3 mos, self-report	272	41.6	145	36.1	127	50.4	<0.001
Laboratory confirmed syphilis	23	3.5	16	4.0	7	2.8	0.417
Circumcised	--	--	164	42.0	--	--	

200   Mos-Month

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201   More women (46.0%) than men (32.8%) were more than 35 years of age, p=0.003. More men

202   than women reported being single (32.8% vs. 21.4%) and being divorced or widowed (38.1%

203   vs. 13.2%), p<0.001. More women had attained more than primary education (23.4% vs.

204   16.4%, p=0.033). While most (69.6%) of the men were involved in fishing or fishing related

205   occupations, most women (53.6%) were engaged in other activities, p<0.001. At enrolment, a

206   higher proportion of men reported having been living in the community for more than 5 years

207   (35.8%) compared to women (22.6%), p<0.001. More than half of men (55.1%) reported

208   spending more than two nights away from home compared to women (31.0%), p<0.001. In

209   the previous three months, more women (53.6%) than men (19.9%) reported having had only

210   one sexual partner, p<0.001. More males (82.1%) reported having new partners in the last

211   three months compared to females (62.7%), p<0.001. More males (17.4%) than females

212   (11.1%) reported always drinking before sex, p=0.005.

Study drop out

214   One hundred ninety-seven (30.1%) of participants dropped out of the study, (Figure 1),

215   including 72 who did not return for the first follow up visit at month three. The dropout rate

216   averaged over the entire 24-month study period was 25.3 / 100 PYO (95% CI: 22.0-29.1),

217   Table 2. Excluding the 72 volunteers who never returned, the dropout rate was 17.1/100

218   PYO (95% CI 14.4-20.4). The most common reasons for dropping out included: moving

219   away from study area (112), being untraceable (26), withdrawal from the study (31), and

220   death (3). Fifteen participants were determined to be ineligible due to lower risk at the 12-

221   month visit, and did not participate further (i.e. they were not counted among drop outs).

222   During the two years, 45 participants became HIV-infected and were also not counted among

223   drop outs. The HIV incidence amongst study participants in this cohort of 6.04 per 100

224   person years at risk (95% confidence interval: 4.36 – 8.37) has been reported previously (15).

Table 2: Demographic and behavioural factors associated with study drop out (DO)

Variable	N	DO	PYO	DO/100PO	RR(95% CI)	LRT P-value	aRR(95% CI)	LRT p-value
Overall 2 year drop out	654	197	778.9	25.3				
Gender								
Male	402	103	507.9	20.3	Ref	<0.001	Ref	0.002
Female	252	94	270.9	34.7	1.7(1.29-2.26)		1.56(1.12-2.18)	
Age (years)								
35+	124	25	166.3	15	Ref	0.004	Ref	0.007
25-34	282	88	340.3	25.9	1.72(1.10-2.68)		1.63(1.04-2.55)	
18-24	248	84	272.2	30.9	2.05(1.31-3.21)		1.64(1.03-2.60)	
Current marital status								
Single	186	64	217.4	29.4	Ref	0.107		
Married	319	85	394.5	21.5	0.73(0.58-1.01)			
Separated/Widowed	149	48	166.9	28.8	0.98(0.67-1.42)			
Educational level								
More than primary	125	39	156.0	25	Ref	0.013	Ref	0.01
Primary	466	131	563.3	23.3	0.93(0.65-1.33)		1.06(0.74-1.52)	
None	63	27	59.5	45.4	1.82(1.11-2.97)		2.02(1.23-3.31)	
Occupation								
Small scale business	49	8	68.3	11.7	Ref	0.006	Ref	0.035
Fishing/fishing related[1]	334	99	413.2	24	2(0.99-4.21)		1.98(0.95-4.11)	
Services (Bar/lodge/restaurant/saloon)	67	17	80.0	21.2	1.8(0.78-4.21)		1.18(0.50-2.78)	
Other	204	73	217.3	33.6	2.9(1.38-5.95)		2.05(0.98-4.31)	
Religion								
Muslim	151	41	187.8	21.8	Ref	0.272		
Christian	503	156	591.1	26.4	1.21(0.86-1.70)			
Tribe/Ethnic group								
Baganda	288	83	339.2	24.5	Ref	0.762		

Banyankole	93	29	103.1	28.1	1.15(0.75-1.75)				
Banyarwanda	136	39	170.3	23	0.94(0.64-1.37)				
Other	137	46	166.3	27.7	1.13(0.79-1.62)				
Duration of stay in community (years)									
>5	201	41	277.8	14.8	Ref	<0.001	Ref	0.004	
1 to 5	289	92	341.3	27	1.83(1.26-2.64)		1.68(1.16-2.45)		
0-<1	164	64	160.0	40	2.71(1.83-4.02)		2.22(1.46-3.38)		
Fishing community									
Lambu	462	144	555.5	25.9	Ref	0.474			
Kachanga	68	10	39.6	25.2	0.97(0.51-1.85)				
Kaziru	32	14	79.9	17.5	0.68(0.39-1.67)				
Other	92	29	103.8	27.9	1.07(0.72-1.61)				
Away from home ≥ 2 nights, last 3 mos									
No	354	107	425.1	25.2	Ref	0.912			
Yes	299	90	351.9	25.6	1.02(0.77-1.34)				
Number of sexual partners, last mos									
0-1	215	64	261.7	24.5	Ref	0.565			
2 to 3	333	97	396.8	24.4	0.99(0.73-1.37)				
4 +	106	36	120.4	29.9	1.22(0.81-1.84)				
New sexual partner, last 3 mos									
No	168	48	205.9	23.3	Ref	0469			
Yes	480	148	563.7	26.3	1.12(0.81-1.56)				
Condom with new partner, last 3 mos									
No	175	60	198.7	30.2	Ref	0.322			
Yes	305	88	365.0	24.1	0.79(0.57-1.11)				
Drank alcohol, last month									
Never	293	80	280.5	22.9	Ref	041			
Sometimes	354	98	418.9	19.2	0.82(0.61-1.10)				
Daily	61	19	79.4	15.3	0.84(0.51-1.38)				

Drank alcohol before sex, last mos								
Never	239	113	407.8	27.7	Ref	0.368		
Sometimes	354	58	254.3	22.8	0.82(0.59-1.13)			
Always	61	26	116.8	22.3	0.8(0.52-1.23)			
Illicit drugs use,in last month								
None	570	169	680.5	24.8	Ref	0.754		
Khat	35	11	46.8	23.5	0.94(0.51-1.74)			
Marijuana	41	14	42.8	32.7	1.32(0.76-2.27)			
Other	8	3	8.9	33.7	1.35(0.43-4.24)			
Genital sores, in last 3 months								
No	382	114	454.7	25.1	Ref	0.884		
Yes	272	83	324.1	25.6	1.02(0.77-1.36)			
Laboratory Confirmed Syphilis								
No	591	180	695.1	25.9	Ref			
Yes	63	17	83.7	20.3	0.78(0.48-1.36)			
Male circumcision								
Yes	164	64	296.3	21.6	Ref			
No	231	37	202.6	18.3	0.84(0.56-1.27)			

226 [1]Drying fish, salting or smoking fish, Mos-Month

227   Factors that remained independently associated with dropping out in the adjusted analysis

228   included: gender, with females at increased risk of dropping out (adjusted rate ratio (aRR)

229   =1.56; 95% CI 1.12-2.18) compared to males, education level, with participants having no

230   education at all being twice more likely to drop out (aRR= 2.02; 95% CI: 1.23-3.31) than

231   those with more than primary education (Table 2). Younger participants were at greater risk

232   of dropping out, those aged 18-24 years old (aRR=1.64; 95% CI: 1.03-2.06) and 25-34 years

233   old (aRR = 1.63; 95% CI: 1.04-2.55) compared to those aged 35+ years. Short duration of

234   stay in community, participants who reported to have lived in the fishing community for one

235   year or less were two times more likely to drop out (aRR=2.22; 95% CI: 1.46-3.38) compared

236   to those who had spent over 5 years. Occupation was also independently associated with drop

237   out with participants engaged in fishing (aRR=1.98; 95% CI: 0.95-4.11), services (aRR=1.18;

238   95% CI: 0.50-2.78) and other (aRR=2.05; 95% CI: 0.98-4.31) being more likely to drop out

239   than those involved in small scale business.

240   Compared to those who completed at least one follow up visit, those who never returned for

241   follow up were younger (mean age of 25.5 vs. 28.0; p=0.004) and more likely to have had no

242   education (19.4% vs 8.4%, p=0.010) and to have lived for less than a year in the community

243   (45.8% vs 22.5%, p<0.001).

DISCUSSION

244

245   In this HIV vaccine preparedness open cohort study among fisher folk, we observed a

246   dropout rate of 25.3/100 person years of observation over the 2-year duration of follow-up, or

247   17.1/100 PYO if you exclude those who never returned for any follow up visits. The findings

248   from our study build on reports from previous work conducted on these and other similar

249   populations around Lake Victoria. Retention rates of 85% (12) and 77% (11) were reported

250   in two other fisher folk cohorts in which participants were followed up in community-based

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251   clinics. Our study differs from these studies in three main aspects firstly, these studies (11-13)

252   differed from our study in that they reported their retention as proportions, while our study is

253   reporting a dropout rate over the two year period. Though the difference may be modest, a

254   proportion will typically overestimate drop out compared to a rate (i.e., 30.1% of our study

255   participants dropped out, but our rate was 25.3 drop outs per 100 PYO). Secondly the study

256   retention for some of the studies (11, 12) were performed in the fishing communities whereas

257   our study activities were at a distant study clinic, and thirdly some also (11, 13) reported their

258   retention over a period of 1 year compared to 2 years in our study.

259   The observed high rate of drop out at the month 3 may point to the fact that some participants

260   were willing to enrol but were simply unwilling to return for any follow up. This finding

261   suggests for the adoption of a lead-in type of enrolment scheme for clinical trials involving

262   participants from these fishing communities.

263   Even though we provided reimbursement for transportation and time, as well as free STI

264   treatment, this may not have been adequate to overcome the hurdles of having to travel to a

265   distant research site. Distance from home could have affect retention in follow up. In a

266   cohort study conducted among discordant couples in Kenya, it was discovered that

267   participants who were living 5-10 kilometres away from the clinic were twice as likely to

268   have follow-up interruptions compared to those living less than 5 kilometres(16). Although

269   no differences were observed in dropout rates between the different fishing communities, it is

270   possible that the distance from the fishing communities to the clinic could have contributed to

271   the drop out.

272   We found that persons who had lived in the community for a relatively short time were more

273   likely to drop out of the study. This findings is consistent with those of previous studies in

274   Uganda fishing communities (11) (12). It is likely that being in a community for a shorter

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275 period of time is a proxy for people who are more likely to be migratory and who tend to

276 move between different islands and landing sites usually following the seasonal fishing

277 seasons (17). I think this would be a good spot to talk about enrolment village and distance

278 to masaka study clinic, and if we did/did not see any relationships

279 Women may also be less likely to be retained, because they usually have time demanding

280 roles within a family including care for sick family members, provision of care for children

281 and food. It is possible too that some women are commercial sex workers and who might

282 move from place to place depending on the demand for their services. Women will therefore

283 find difficulty in taking time off to come to the clinic. Since it is important to ensure that men

284 and women are equally engaged in HIV vaccine efficacy trials, efforts need to be made to

285 increase female enrolment and retention in clinical trials within these communities.

286 Participation of women from the fishing communities can potentially be improved by

287 involvement of individuals or groups in the community who have ample rapport with them,

288 such as, their spouses, brothel owners, bar and lodge owners.

289 The observation that younger participants are more likely to drop out. This finding is similar

290 to what was observed in the previous studies (11, 12) and may be due to the fact that young

291 people possibly haven't settled in any stable relationship/occupation and are still moving in

292 search of greener pastures.

293 The strength of this study included longer duration of follow up with frequent clinic visit in a

294 set up with an already established infrastructure suitable for HIV vaccine efficacy trials. This

295 builds on the previous studies that provided retention data but from follow up at clinics

296 established within the fishing communities.

297 Our study had some limitations. Firstly, we were often not able to document the specific

298 reasons why participants dropped out, other than some data on relocation. This information

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299   could have probably provided more insight on the specific reasons for dropping out.

300   Secondly, at the initial contact with potential participants in the fishing communities, we did

301   not collect data on those who attended meetings but who did not later attend screening visits

302   at the Masaka study clinic, nor did we collect data on those who attended screening at the

303   clinic but were not enrolled (aside from reason they were not enrolled), thus we were unable

304   to make comparisons between enrolled and non-enrolled persons. Thirdly, we did not collect

305   data on breastfeeding or pregnancy among the females, which may have also been barriers

306   for participation and retention, since these may affect ones travel to and from the study clinic.

307

Conclusions

309   Although we demonstrate ability to enrol participants in this longitudinal cohort, the high

310   dropout rate especially in the first three months is a point of concern. Inclusion of volunteers

311   into clinical trials to evaluate products such as vaccine candidates would require delayed

312   enrolment and consider an initial pre-screening period of approximately 2-3 months,

313   requiring potential volunteers to attend more than one screening visit to establish

314   commitment. Particular attention for retention should be paid to the participant categories

315   identified as being a risk of dropping out such as female, younger, lower educated and

316   participants with short duration of stay in the community.

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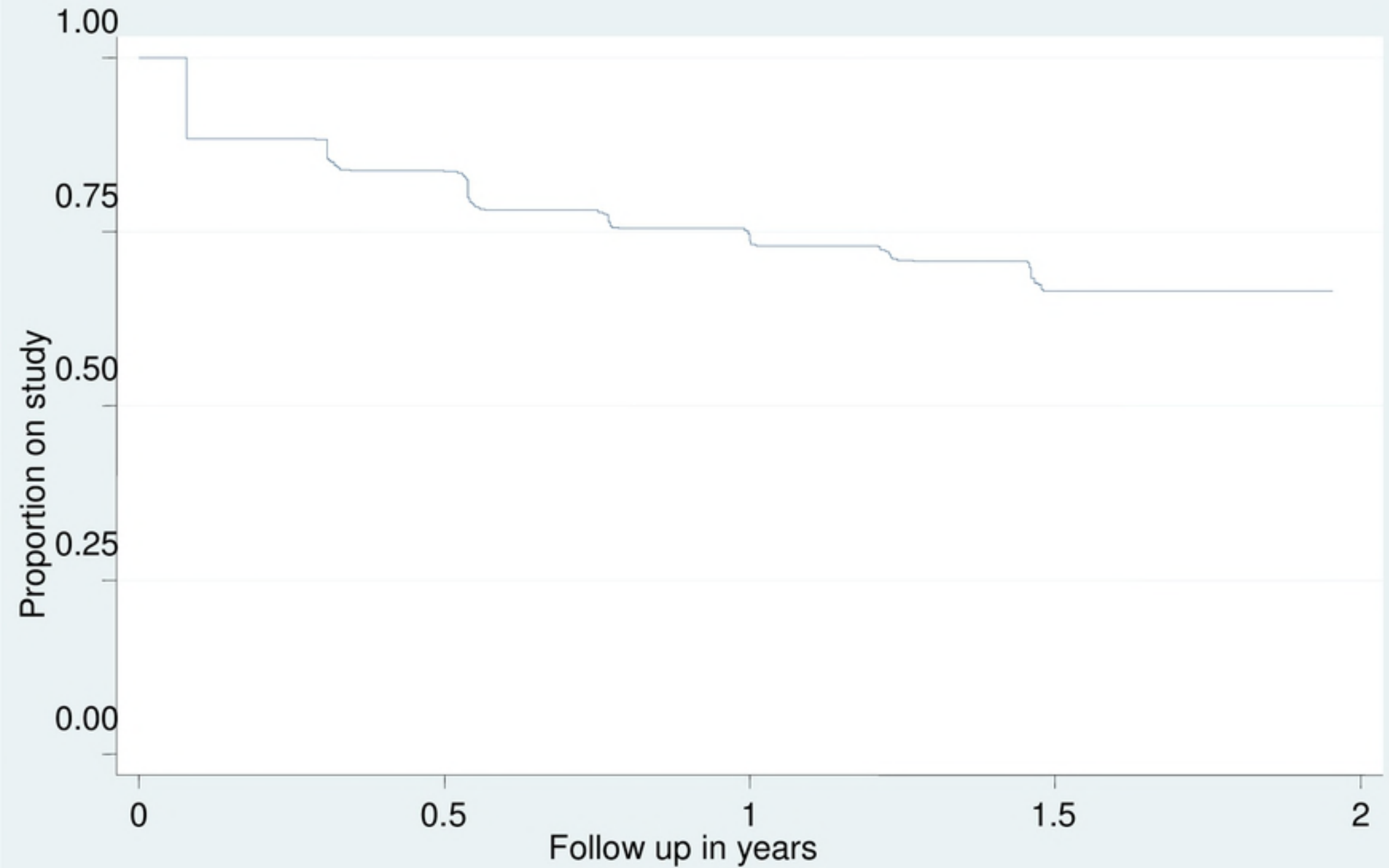17.   Nunan F. Mobility and fisherfolk livelihoods on Lake Victoria: implications for vulnerability and risk. Geoforum. 2010;41(5):776-85.

Figure 1. Kaplan Meier plot of volunteer attrition over time