Financial incentives to increase pediatric HIV testing in Kenya: A pilot randomized trial

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Abstract

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Background

Initiating antiretroviral therapy (ART) prior to the onset of symptomatic disease improves survival in HIV-infected children. However, HIV diagnosis in children is often delayed due to caregiver reluctance to test and financial barriers. A pilot study was conducted to assess acceptability of financial incentives to motivate pediatric testing, and to determine incentive amount and format for a larger efficacy trial.

Materials and Methods

HIV-infected female caregivers at Kisumu County Hospital, Kenya, who had children of unknown HIV status aged 0-12 years, were randomized to receive KSH 500 (~$5), KSH 1000 (~$10) or, KSH 1500 (~$15) payment conditional on child testing within 2 months. At the child HIV testing visit, data on socio-demographics, incentive preference, and impact of testing on health seeking behavior was collected.

Results

Of 1,991 female caregivers screened, 71 (4%) had children of unknown status age 0-12 years, 1,250 (63%) had tested all their children, 506 (25%) had children of unknown status but aged >12, 163 (8%) had no children, and 1 caregiver declined to give information. Of 71 eligible, 60 (85%) were randomized with equal allocation between arms. Forty-four (73%) tested children in the 2-month window; 15 (75%), 14 (70%) and 15 (75%) in the KSH 500, KSH 1000, and KSH 1500 arms, respectively ($p>0.99$). Uptake was significantly higher than in a recent cohort with similar procedures but no incentives (72% vs. 14%, $p<0.001$). Incentives were delivered as cash (55%) or as mobile phone money transfer (45%). A third (36%) preferred incentives to be provided as cash, and 32% had no specific preference. Preferred non-cash incentives included agricultural items (50%), household goods (43%), health services (29%), or food vouchers (21%).

Conclusion

Financial incentives were acceptable and increased pediatric HIV testing in this urban clinic. The similarity between testing rates in the 3 arms warrants evaluation of lower incentive values; a larger efficacy trial comparing testing rates across $0, $1.25, $2.50, $5, and $10 arms began in January 2017.

INTRODUCTION

Early antiretroviral therapy (ART), prior to the onset of symptomatic disease, improves survival, protects neurodevelopment, and reduces the risk of opportunistic infections in HIV-infected children[1-3]. However, many African children are diagnosed only after they become symptomatic, limiting the benefits of ART[4]. There is a large burden of undiagnosed pediatric HIV infection in Africa[5,6]; in Kenya, less than half of those children with HIV-infected caregivers have been tested[7].

While prevention of mother-to-child transmission (PMTCT) and early infant diagnosis (EID) systems are well developed with high uptake, there are few systematic strategies to test older HIV-exposed children for HIV before they become symptomatic. Older children may have missed testing during PMTCT because they were born before programmatic scale-up, or they may have dropped out of the PMTCT cascade[8]. Index case testing—testing the children of HIV-infected caregivers—reveals a high prevalence among those children tested, but uptake is generally low[9,10]. HIV-infected caregivers cite fear, denial, guilt, and financial constraints as barriers to testing their children[11,12]. To reach the first 90 of the 90-90-90 UNAIDS goals for children, innovative strategies are required to optimize efficient strategies to identify HIV-infected children early and link them to care[13].

Financial incentives (FI) have been evaluated in various randomized trials to motivate desired health behaviors[14-16]. FIs increased uptake of male circumcision among hard-to-reach men in Kenya[14]. In Kenyan children, uptake of full childhood immunization was increased by text messaging and FI[15]. Among mothers in the Democratic Republic of Congo, FI increased completion of PMTCT visits and reduced loss to follow-up[16]. In adults and adolescents, there is evidence that FI interventions increase uptake of HIV testing [17,18], but there are no current studies using FI to motivate testing of younger children. Additionally, testing children for HIV is

unique in that children lack autonomy over care-seeking and healthcare decision-making, yet require urgent testing.

FI may motivate testing by offsetting costs associated with bringing a child to clinic—including lost wages, transport costs, and childcare costs; previously cited by caregivers as barriers to pediatric HIV testing[12]. FI may also address non-financial barriers by putting emphasis on the immediate benefit of testing and increasing the sense of urgency for a caregiver to initiate testing[20]. Small FI may motivate caregivers who are willing to test their children, but have not yet taken action to test, to act. However, small FI are unlikely to motivate those facing strong emotional or psychological barriers to take action. If effective, FI may be a useful intervention to reach untested older children and facilitate linkage to care. No previous studies that have evaluated the impact of FI on pediatric HIV testing.

A pilot randomized trial was conducted to determine feasibility of using FI to improve uptake of pediatric HIV testing and to identify the optimal incentive values and format for a larger randomized controlled trial (RCT).

METHODS

Ethical approval: This study was approved by Kenyatta National Hospital (KNH)/University of Nairobi (UoN) Ethics and Research Committee (ERC) (P774/12/2015) and the University of Washington (UW) Institutional Review Board (IRB) (50526-J), and is registered at *clinicaltrials.gov* (NCT02931422). At recruitment, HIV-infected caregivers provided oral consent for assessment of eligibility and randomization; caregivers provided written consent for child HIV testing at the HIV testing visit. Children age 7 years and above were given the opportunity to provide written assent for participation, according to caregiver wishes.

Study design: The FIT study was a pilot un-blinded randomized trial of conditional cash incentives valued at KSH 500 (~$5), KSH 1000 (~$10) or, KSH 1500 (~$15) to motivate pediatric HIV testing, among HIV-infected female adults with children of unknown HIV status. This pilot study was designed to be formative for the larger study and was not powered to compare testing rates between arms or to include an un-incentivized control arm.

Study arm incentive values: Incentive amounts were calculated using pediatric HIV testing cost data collected in a previous study conducted in an urban population in Nairobi, Kenya[10]. The KSH 500 level reflected the 75th percentile of transportation costs incurred for child HIV testing visits; the KSH 1000 level reflected the 75th percentile of transportation costs and one day of lost wages; the KSH 1500 level reflected the 75th percentile of transportation costs and 2 days of lost wages. These values reflect direct non-medical costs (KSH 500 arm); direct non-medical and indirect costs (KSH 1000 arm); and direct non-medical, indirect costs, and additional amount (KSH 1500 arm).

Randomization: Randomization was conducted with block sizes of 12 generated using STATA version 14.2 ralloc.ado v3.7.5 by a statistician who was not involved in study procedures. Arms were allocated using a 1:1:1 ratio. Study investigators were blinded to the values of the sequence in the block. Treatments were assigned as pre-prepared scratch cards (Figure 1), ordered in the sequence of treatment assignments and arranged by block.

Setting: The study was conducted at the Kisumu County Hospital (KCH) in Kisumu, Kenya, a county hospital that serves a predominantly urban population. Caregivers were recruited from the Patient Support Center (PSC), which provides free HIV care. Recruitment began on September 29, 2016 and HIV testing visits were completed on January 23, 2017.

Recruitment & eligibility: Recruitment was conducted by clinic staff, who gave a brief introduction to the study and assessed eligibility. Recruiters attempted to screen every female adult attending the PSC to assess eligibility, and counted the number of individuals who declined screening. Caregivers were considered eligible if they were female and had children in their care under the age of 13 years of unknown HIV status. Children were considered of unknown status if they had never been tested *or* had tested negative during infancy but had no confirmatory negative test at 18 months or post-cessation of breastfeeding. The pilot study was restricted to HIV-infected female caregivers to maximize sample homogeneity; the larger RCT includes both male and female caregivers.

Eligible participants were invited to pick a scratch card from a bag and reveal their randomized incentive value (Figure 1). Each caregiver picked only one scratch card, even if they had more than one child requiring testing. Caregivers were informed that payment of the incentive was contingent upon completion of child testing and that cards expired after 2 months. The expiration date was written on the back of the card. Individual "extensions" were allowed to accommodate boarding school holidays, although no late bookings were requested. Randomization took place in the same physical space and directly following eligibility assessment to limit drop offs due to time and space transfer noted in previous studies[10]. Reasons for ineligibility and reasons for not being randomized were recorded systematically.

Scheduling for HIV testing: At recruitment, caregivers were encouraged to book a testing appointment, and were asked to bring the scratch card to the visit. Names or phone numbers of those willing to provide this information were collected in a log book, and linked to the scratch card number for retrieval in case the card was lost or damaged. No other demographic or clinical information was collected to limit barriers to randomization and increase external validity. Participants missing their testing appointments were contacted by phone and rescheduled a

maximum of 2 times. Participants who presented for testing outside the expiry date of their scratch card were referred to local programmatic staff for testing and were considered "non-testers" in the study.

HIV testing visit: Detailed caregiver and child socio-demographic information, PMTCT and HIV testing history, and caregiver perceptions about a child's HIV status were collected prior to performing the HIV test. Children were tested for HIV according to Kenyan National Guidelines using 2 rapid tests for children over 18 months[21] and HIV DNA PCR for children under 18 months. After HIV testing, a post-test survey was conducted to determine preference for different types of incentives, real costs incurred by caregivers in seeking testing, and previous health seeking behavior when the child had minor illnesses. Reimbursements were made via mobile money transfers largely using the MPESA platform[22], or by cash if the participant chose cash or did not have an existing money transfer account.

Sample size considerations: This pilot study randomized 60 HIV-infected female caregivers. The number of participants was selected to inform incentive levels for use in a larger efficacy trial, refine incentive disbursement procedures and data collection tools for a larger trial. The study was not powered to detect differences in uptake of testing based on FI arms with this sample size.

Statistical analysis: The primary study outcome was HIV testing within 2 months of randomization. Secondary outcomes included preference for incentive type and what the test meant for them in terms of future care seeking behavior. Uptake of testing between arms was compared using log binomial regression. Time to testing was estimated using Kaplan Meier survival analysis and compared between arms using the log-rank test and Cox proportional hazards regression. Participant characteristics among those caregivers who tested children

were summarized using medians, interquartile ranges, and proportions. Data were analyzed using STATA 14 software (Stata Corporation, College Station, Texas, USA).

RESULTS

Recruitment and randomization: Of 1,991 female caregivers screened, 71 (4%) had children of unknown status age 0-12 years. Of the 1,920 (96%) not eligible, 1,250 (63%) reported that all their children had previously been tested for HIV, 506 (25%) had children of unknown status but all were aged >12, 163 (8%) had no children, and 1 caregiver declined to give information. Sixty (85%) of the 71 eligible participants were randomized. Of the 11 (15%) not randomized, the mother was not the primary caregiver in 7 cases (64%), 2 (18%) were already scheduled for infant HIV testing by PCR at the PMTCT clinic, 2 (18%) needed more time to think before testing their children and never returned to the study clinic. A total of 60 female caregivers were randomized, 20 in each of the $5, $10, and $15 arms (Figure 2).

Uptake of testing: Overall, (73%) randomized caregivers brought their children for testing: 75%, 70%, and 75% in the $5, $10 and $15 arms, respectively (Table 1). There was no difference in the proportion testing comparing the $5 and $10 arm and the $5 and $15 arm (RR 0.93 [95% CI 0.64, 1.37, p=0.74] and RR 1.0 [95% CI 0.70, 1.43 p=>0.99]. Of the 16 caregivers who did not test their children, 10 (63%) missed their appointments and could not be reached by phone for rescheduling, 2 (13%) said they were not ready for child testing, 2 (12%) reported they were no longer the primary caregiver or could not access the children, 1 (6%) reported their children had already tested elsewhere, and 1 (6%) who had an 11 year old child, reported their child did not want to be tested for HIV.

For the 44 caregivers who tested children, a total of 53 children were tested for HIV (mean: 1.2 children tested per adult, range 1-3) with 1 child testing HIV positive (HIV prevalence 1.8%

[95%CI=0.05, 9.7]). The number of children tested per adult was comparable between arms. Median age of children tested was 9 years (IQR=5, 11), and was similar between arms (Table 2). Median time to testing was 6 days from randomization (IQR=1, 20) and did not differ by arm (Figure 3).

Characteristics of caregivers who presented for child testing: Of the 44 caregivers who tested children, 54% were married, and 30% were widowed. Almost all (98%) were on ART for a median duration of 24 months. Nearly all of those with partners (93%) had disclosed their HIV status, and 57% reported knowing their partners were HIV positive (Table 2). The 44 caregivers had a total of 85 children who were of unknown HIV status. Of these, 58 (68%) were in the study age range and 53 (91%) were tested in the study. Of the 5 children who were eligible for testing in the study but were not brought for testing, caregivers reported not thinking those children were HIV positive (2), no time to test them (2) and fear of questions related to HIV testing (1). Of the 27 children of unknown status whose age was above the study age range, median age was 16 years (IQR 14-19).

Potential impact of child HIV testing on care seeking: Before testing, caregivers who presented for child testing were asked if they thought their children would test positive or negative. Thirty percent of caregivers believed their children were HIV positive and 43% thought they were negative; 27% could not predict. Only one child tested positive in the study, and their caregiver had thought they were negative. Forty-one percent of caregivers reported that they had avoided seeking health care for minor illnesses for their children for fear of a HIV test, and 61% stated that they were more likely to seek care for their children in the future, now that they knew their child's status (Table 3).

Operational considerations: Among 44 caregivers who tested children, 20 (45%) and 24 (55%) received their FI amounts via mobile money transfer services and cash, respectively. Caregivers who presented for child testing were asked what format they preferred to receive incentives. The largest number preferred cash (36%), but a large proportion (32%) did not note any specific preference; of the 14 who did not prefer cash, agricultural items (50%), household goods (43%), health services (29%), or food vouchers (21%) were preferred. Among the caregivers who returned to test their children, only 1 (2%) did not return with the randomization card as it was accidentally destroyed, and 19 (43%) had to reschedule their testing appointment at least once.

DISCUSSION

FI motivated high uptake of pediatric HIV testing in female caregivers of children of unknown status. Most caregivers reported that knowing the child's status would make them more likely to bring children to the clinic for other medical issues. Together, these data suggest the use of FI for pediatric testing is feasible and acceptable in this population, and that confirmation of a child's HIV status may have broader benefits for improving child health.

Uptake of index case testing observed in this pilot study with FI was significantly and substantially higher than that in un-incentivized index case testing reported in a previous study by the same study team in Nairobi (14%)[10] and at the same site in Kisumu (12%) (*Wagner, manuscript in preparation*). Indeed, the testing rate observed in this pilot study (73%) is the highest among index case testing studies of caregiver/child dyads in routine clinical settings to date. A systematic review of pediatric HIV testing strategies described a wide range of index case testing interventions, ranging from simple interventions with cards inserted in medical files[23] to complex interventions with assisted disclosure and counseling services for the whole family[24]. The pooled estimated uptake of index case testing was 52%[9], and the highest uptake among studies that did not use a select population already enrolled in an RCT was 59%[25]. The

high uptake rate in the present study suggests that FI could hold promise for increasing uptake of testing, but a larger trial is needed to determine intervention effectiveness.

The values of FI offered in this pilot were determined based on real costs of testing in another Kenyan urban site (Nairobi) and thus were able to address the substantive barrier that cost presents to testing children[12]. The 75th percentile of direct costs and direct and indirect costs in the same site, was KSH 350 (~$3.50) and KSH 650 (~$6.50) (*Wagner, manuscript in preparation*), and was lower than the costs used to calculate incentive values for the pilot study. This data was unavailable at that time and reflects a lower cost of living in this population and geographical area. The Gross National Income (GNI) per capita in Kenya was $3,070USD in 2015 (World Bank 2015)[26], but varies widely across urban and rural sites in Kenya, and similar programs in other settings will need to consider local salaries and cost of living. Because there was no detectable difference in the rates of testing between arms, the ongoing larger RCT for efficacy will include a wider range of FI ($1.25, $2.50, $5, and $10 USD), as well as an un-incentivized control arm, in order to estimate efficacy, determine the minimum FI conferring maximum testing uptake, and enable cost-effectiveness analyses.

In this predominantly urban population, a third of caregivers preferred cash incentives to other formats; this preference may not be generalizable to rural settings where agricultural items or vouchers for services may hold greater value. A cash incentive was selected for this trial due to the exchangeability of cash, as well as the increased costs associated with procuring and distributing non-cash incentives. Other programs seeking broader benefits (increased household economy, increased food stability) have utilized agricultural or livestock incentives and may warrant consideration for rural settings[27,28]. The ongoing, multi-site RCT will assess preference for incentive format in a wider array of sites including semi-rural and rural clinics.

Logistically, our study provided important lessons for feasible scale-up. Despite concerns over trading of cards, or caregivers re-testing children of known status or children not their own, there were no instances of deception discovered by the study team. A large number of cash transfers were made using mobile money transfer methods, addressing concerns of handling large amounts of money in the clinic and facilitating accounting. However, accountability issues may be of greater concern during a larger testing campaign that runs for a longer period of time.

A major strength of this study was that randomization was conducted at recruitment, prior to completing a lengthy written informed consent procedure and incurring large drop off associated with traditional RCTs. A previous study conducted by this team noted large drop off (86%) between determination of eligibility, referral and HIV testing[10]. This innovative approach to randomization allowed estimation of testing uptake by having the largest and most valid denominator of eligible caregivers randomized and offered testing. However, it is still uncommon for research studies to include this type of denominator, making head to head comparisons of uptake between studies challenging. Other studies have reported testing rates using a denominator of those agreeing to enroll in a study, which may artificially inflate the enrolled study population with caregivers who are already open to testing their children and results in overestimates of testing uptake. Were *et al* reported an index case testing uptake of 99% in a population enrolled in a separate RCT and accepting family testing; this rate is much higher than other studies enrolling from HIV clinics[29].

Nearly a quarter of caregivers who were screened were not eligible to participate in the study because they only had adolescents or older children who were of unknown HIV status. Previous studies have found gaps in HIV testing for perinatally infected adolescents who commonly present with HIV associated chronic illness at hospitalization[4,18,30]. While the study initially sought to test all children <18 years, ethical issues of caregiver/child consent, disclosure,

unknown route of transmission, and potentially discordant caregiver/child wishes limited feasibility to include this population in the intervention. However, it is clear that innovative strategies to access adolescents outside the usual provider initiated testing and counselling (PITC) approaches, to include them in index testing, and offer HIV testing are urgently needed[18,30]. FI interventions, assisted caregiver disclosure and targeted testing for adolescents may be beneficial.

The population randomized was generalizable to the eligible source population; only one screened individual who was eligible declined participation. Almost two thirds of those who were eligible but were not randomized were not currently the primary caregiver of their child(ren); this has implications for the population to which this type of intervention might be applicable. Even among those randomized, 5 children who met eligibility criteria were not tested, suggesting the FI range offered in this study did not overcome all social, emotional, and economic barriers in women that were willing to test. Challenges caregivers experience in testing children, who cannot self-present and who fully rely on caregivers to assess HIV risk and present them for HIV testing, have been described previously[6,11].

An important novel finding of this study that warrants further exploration is that 41% of caregivers had previously avoided care for their children due to fear of an HIV test. This suggests that parental anticipation of PITC may be acting as deterrent to care-seeking for children of HIV-infected caregivers, and targeted counseling on this issue could be beneficial for caregivers receiving HIV care. Indeed, 61% of caregivers noted they would now be more likely to bring their children for other medical services now that they knew their status, suggesting HIV testing can have substantial and immediate benefit for both HIV-positive and negative children.

Prevalence of HIV in this population (1.8%) was lower than reported in other studies utilizing index case testing (7.4% to 8.4%)[9,10] with only 1 child testing positive for HIV. Notably, this pilot study was conducted in a clinic where the same study team had recently completed index case testing of adults in care[10], and additionally had undergone recent family-based HIV testing rapid results initiative campaigns by the Kenya National AIDS/STI Control Program. For this reason, both the testing uptake and HIV prevalence may be lower in this population because caregivers with HIV positive children, or those who were more easily motivated to test with counselling alone, had already been removed from the source population.

The study had some important limitations. Although testing uptake is estimated among all eligible caregivers screened, the absence of data collection among those individuals who were randomized but did not complete testing prevents direct comparison of socio-demographic, caregiver risk assessment, and child characteristics between testers and non-testers. Although the team made every effort to track cards and avoid testing of children of known status, it is possible that some cards switched hands, or some children were tested for HIV that did not need testing, and this was undetected by the study team; such activity would be expected to inflate testing rates upward and bias HIV prevalence rates downward. A larger-scale program would need to consider the level of “unnecessary testing” that would be acceptable in order to implement the intervention. Higher incentives than the values tested here may motivate more caregivers to test; however, it is unclear whether a national program could support such high payouts given Kenya’s GNI and resource constraints. It was clear that some families had additional children requiring testing, and the FI provided here may not have been sufficient to overcome the interpersonal or economic barriers needed to test these children; additional approaches may be needed for larger families and for older children and adolescents.

CONCLUSION

In conclusion, the FI intervention was demonstrated to have high acceptability, high feasibility, and high overall uptake of pediatric HIV testing. Lessons learned were used to revise incentive values and refine procedures for a larger RCT, which began recruitment in January 2017 and will complete recruitment in June 2018.

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Figure 1: Study scratch card

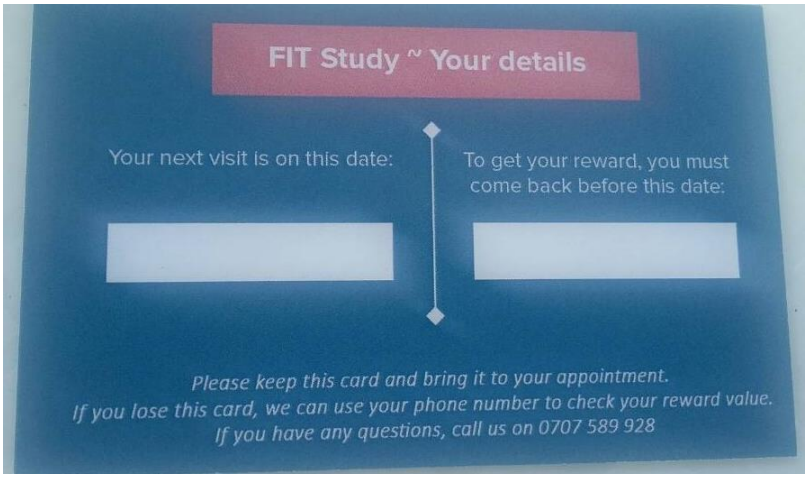

Figure 2: Trial profile: Recruitment, randomization, and child HIV testing

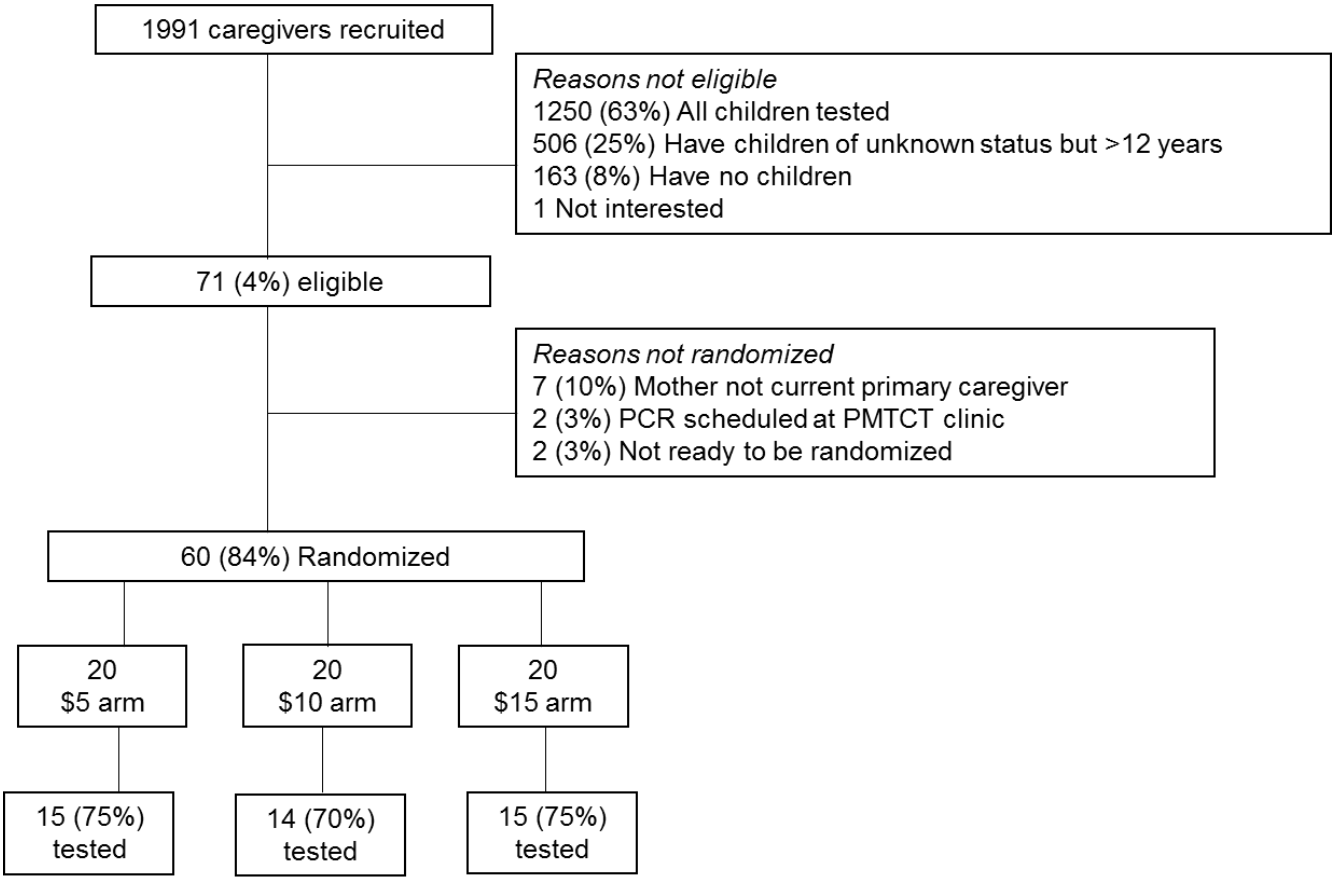

Figure 3: Time to testing by arm

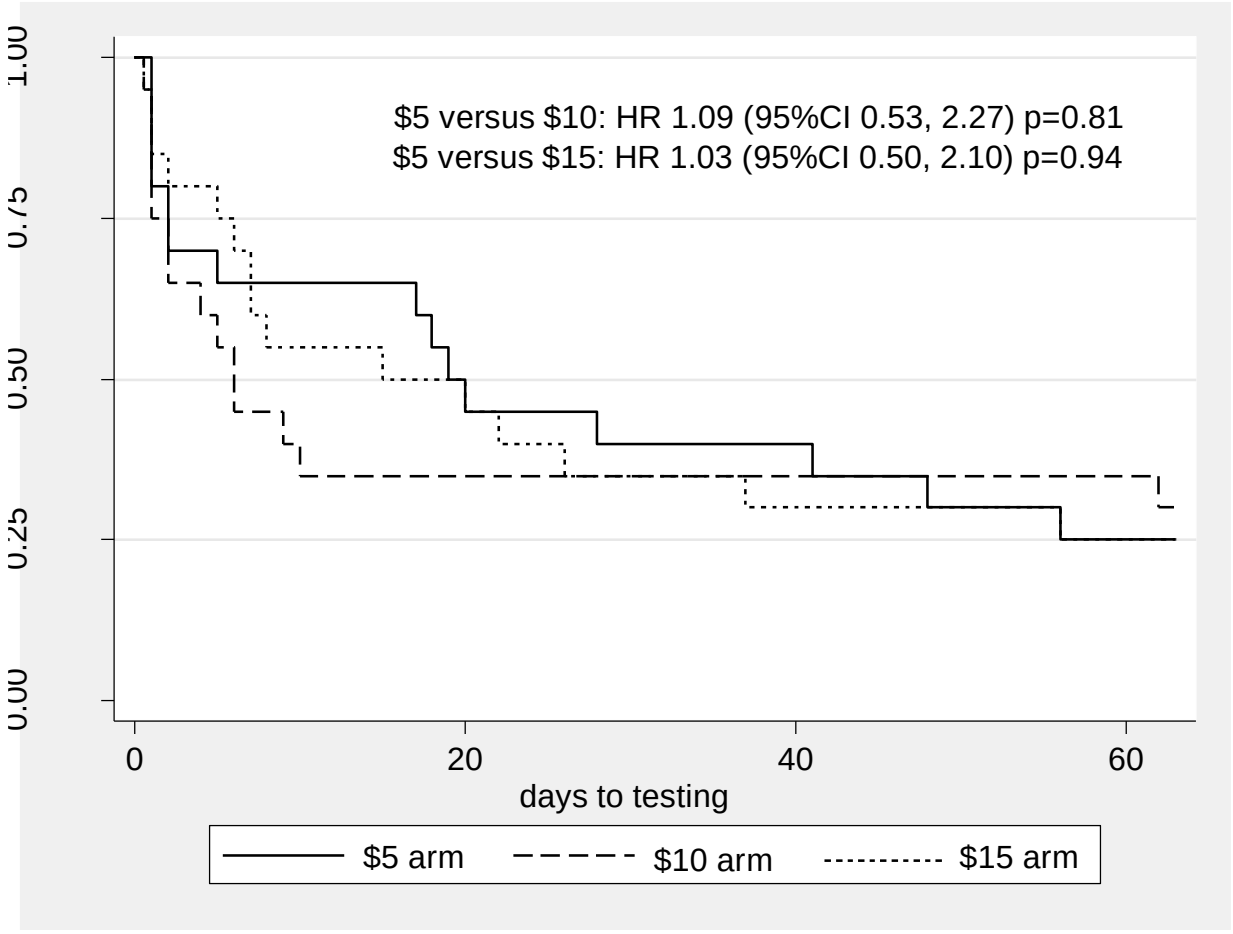

Table 1: Testing uptake, age and number of children, and days to testing by randomization arm

	All	$5 arm (N=20)	$10 arm (N=20)	$15 arm (N=20)
Completed testing (%)	44 (73%)	15 (75%)[c]	14 (70%) [c]	15 (75%) [c]
95%CI	60-84%	51-91%	46-88%	5-91%
Number children tested[a]	53	18	17	18
Median children tested per adult[1] (range)	1 (1, 3)	1 (1, 2)	1 (1, 2)	1 (1, 3)
Median age of children tested (range)[b]	9 (5, 11)	8.5 (4, 10)	8 (6, 10)	10.5 (6, 11)
Median days to testing (IQR)	6 (1, 20)	17 (1, 28)[d]	3 (1, 6)[d]	7 (2, 22) [d]

[a] N=44 [b] N=54

[c]$5 vs $10 RR 0.93, (95%CI=0.64, 1.37 p=0.74); $5 vs $15 arm, RR 1.0 (95%CI 0.70, 1.43 p=>0.99)

[d]Log-rank *$5 vs $10:* 1.09 (0.53, 2.27), *$5 vs $15,* 1.03 (0.50, 2.10)

Table 2: Characteristics of enrolled caregivers

	All N (%) / median (IQR) N=44	$5 arm n (%) / median (IQR) N=15	$10 arm n (%) / median (IQR) N=14	$15 arm n (%) / median (IQR) N=15
Age	30.5 (28, 38)	30 (25, 36)	32.5 (29, 36)	33 (29, 40)
Years of education	8 (7, 10)	8 (7, 10)	8 (7, 10)	8 (7, 10)
Marital status				
Unmarried	3 (7%)	1 (7%)	1 (7%)	1 (7%)
Divorced/Separated	4 (9%)	4 (27%)	0	0
Married (monogamous)	19 (43%)	7 (47%)	7 (50%)	5 (33%)
Married (polygamous)	5 (11%)	1 (7%)	2 (14%)	2 (13%)
Widowed	13 (30%)	2 (13%)	4 (29%)	7 (47%)
On ART	43 (98%)	15 (100%)	13 (93%)	15 (100%)
Months in HIV care	24 (3, 61)	24 (3, 85)	4.3 (1.8, 31)	36.5 (3, 61)
Among those with partners (n=28)				
Disclosed HIV status to partner	26 (93%)	9 (90%)	9 (100%)	8 (89%)
Partner HIV positive	16 (57%)	6 (60%)	5 (56%)	5 (59%)

* includes cost of transport for self, child(ren), meal for the day, child care costs

Table 3. Previous beliefs, health seeking and impact on care seeking

	n (%) **N=44**
Prior to testing, believed child HIV status was	
HIV positive	13 (30%)
HIV negative	19 (43%)
Truly no prediction	12 (27%)
Previously avoided seeking child health care for fear of HIV test	18 (41%)
Impact on future health care seeking behavior	
More likely to seek health care for child after test	27 (61%)
Less likely to seek health care for child after test*	1 (2%)
Learning status does not change health seeking behavior	16 (36%)

*reported by one caregiver of a child who tested HIV negative

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