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Conditional Cash Transfers to Increase Retention in PMTCT Care, Antiretroviral Adherence, and Postpartum Virological Suppression: A Randomized Controlled Trial

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Background: Novel strategies are needed to increase retention in prevention of mother-to-child HIV transmission (PMTCT) services. We have recently shown that small, incremental cash transfers conditional on attending clinic resulted in increased retention along the PMTCT cascade. However, whether women who receive incentives to attend clinic visits are as adherent to antiretrovirals (ARV) as those who do not was unknown.

Objective: To determine whether HIV-infected women who received incentives to remain in care were as adherent to antiretroviral treatment and achieved the same level of viral suppression at 6 weeks postpartum as those who did not receive incentives but also remained in care.

Methods: Newly diagnosed HIV-infected women at ≤32 weeks gestational age were recruited at antenatal care clinics in Kinshasa, Democratic Republic of Congo. Women were randomized in a 1:1 ratio to an intervention or control group. The intervention group received compensation ($5, plus $1 increment at each subsequent visit) conditional on attending scheduled clinic visits and accepting offered PMTCT services, whereas the control group received usual care. The proportion of participants who remained in care, were fully adherent (took all their pills at each visit) or with undetectable viral load at 6 weeks postpartum were compared across group.

Results: Among 433 women randomized (216 in intervention group and 217 in control group), 332 (76.7%) remained in care at 6 weeks postpartum, including 174 (80.6%) in the intervention group and 158 (72.8%) in the control group, (P = 0.04). Data on pill count were available for 297 participants (89.5%), including 156 (89.7%) and 141 (89.2%) in the intervention and control groups, respectively; 69.9% (109/156) and 68.1% (96/141) in the intervention and control groups had perfect adherence [risk difference, 0.02; 95% CI: −0.06 to 0.09]. Viral load results were available for 171 (98.3%) and 155 (98.7%) women in the intervention and control groups, respectively; 66.1% (113/171) in the intervention group and 69.7% (108/155) in the control group had an undetectable viral load (risk difference, −0.04; 95% CI: −0.14 to 0.07). Results were similar after adjusting for marital status, age, education, baseline CD4 count, viral load, gestational age, and initial ARV regimen.

Conclusions: Although the provision of cash incentives to HIV-infected pregnant women led to higher retention in care at 6 weeks postpartum, among those retained in care, adherence to ARVs and virologic suppression did not differ by study group.

Key Words: conditional cash transfers, PMTCT, retention in care, adherence, virologic, suppression, DR Congo

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INTRODUCTION

The President's Emergency Plan for AIDS Relief (PEPFAR) goal of an AIDS-free generation, re-emphasized in PEPFAR 3.0,[1,2] will not be achieved without substantial improvement in retention along the HIV care continuum among women in maternal and child health (MCH) clinics in resource-limited settings.

Over the past 2 decades, research has identified increasingly effective interventions to prevent HIV transmission and disease progression in infected individuals. Successful antiretroviral therapy (ART) enables HIV-infected people to live longer and remain healthier.[3] Early

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M.Y., H.T., F.B., K.E.M, A.E., designed the study. M.Y., E.W.O., B.K., M.T., and L.W. implemented the study and collected data. M.Y. analyzed the data. M.Y. wrote the first draft of the report with input from H.T., A.E., K.E.M., F.B. All authors contributed to the final report.

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initiation of ART delays the time to AIDS, serious non-AIDS events, and mortality among HIV-infected adults.[4–6] HIV-infected adults on ART who have achieved virologic suppression are 96% less likely to transmit the virus to sexual partners.[7] Moreover, results from the Promise Study showed that the risk of mother-to-child transmission drops to 0.5%–0.6% in pregnant women on ART.[8] Thanks to the progress spurred by the 2011 UNAIDS Global Plan for the Elimination of New HIV Infection Among Children by 2015 and Keeping their Mothers Alive, and an infusion of PEPFAR funding, substantial progress has been achieved in increasing antiretroviral (ARV) availability in low-resource settings, including lifelong ART for pregnant women living with HIV.[9–11] At the end of 2013, 67% of HIV-infected pregnant women worldwide were receiving ARVs for their own health or for the prevention of mother-to-child HIV transmission (PMTCT).[12]

The WHO 2013 guidelines recommend lifelong ART for all HIV-positive pregnant and breastfeeding women regardless of CD4 count (Option B+),[13] effectively transforming MCH clinics into ART centers. However, in part because primary health care systems are set up to primarily deliver episodic acute care, high dropout rates along the HIV continuum of care is a critical issue that is currently limiting the long-term impact of PMTCT programs, particularly in sub-Saharan Africa where 90% of HIV-infected pregnant women live.

Data from early implementation of Option B+ in Malawi showed that about 1 in 6 pregnant women initiated on ART at antenatal care (ANC) registration did not return to the clinic after their initial visit.[14] A recent meta-analysis of women lost to follow-up (LTFU) across the "PMTCT cascade" found that 49% of HIV-infected pregnant women are LTFU between ANC registration and delivery, and 34% of mother-infant pairs are LTFU within 3 months of delivery.[15] Half of all vertical HIV transmissions are now estimated to occur during the breastfeeding period when most of the lactating women are not receiving ARV treatment.[16] In addition, less than 40% of HIV-exposed infants are tested for HIV within the first 2 months of life in priority countries.[12] Without substantial improvements to retention across the PMTCT cascade, the PEPFAR goal of an AIDS-free generation might not be achieved even if all HIV-infected pregnant women were identified and initiated on ART.

Numerous interventions have been proposed to address the retention challenge across the PMTCT cascade. A simple search of clinicaltrials.gov for the term PMTCT shows a number of ongoing or completed studies evaluating strategies such as text messaging, peer support, community health workers, conditional cash transfers, and more. We recently completed a randomized controlled trial evaluating the impact of conditional cash transfers on retention in and uptake of PMTCT services in Kinshasa, Democratic Republic of Congo (DRC). Previous results[17] showed that providing HIV-infected women with small and increasing cash transfers, conditional on attending scheduled clinic visits and accepting available PMTCT services, substantially increases the proportion of women who remain in care and receive available PMTCT services through 6 weeks postpartum. However, as recently demonstrated in a large trial of pre-exposure prophylaxis, adherence to scheduled visits and participation in study procedures when there are incentives conditioned on these specific behaviors do not always translate to adherence to prophylactic treatment.[18] Thus, whether adherence to scheduled PMTCT visits and acceptance of available services translates into better adherence to ART remained to be tested.

This study assessed whether HIV-infected women who received incentives to remain in care were as adherent to ARV treatment and achieved the same level of viral suppression at 6 weeks postpartum as those who did not receive incentives but also remained in care.

METHODS

Study Design and Study Population

Between April 2013 and August 2014, 433 newly diagnosed HIV-infected women, ≤32 weeks pregnant, registering for ANC at 89 clinics in Kinshasa, DRC were recruited and randomized to receive either the standard of care or the standard of care plus small and increasing cash payments. These payments started at $5 and increased by $1 each month, on the condition that the woman attended scheduled clinic visits and, if requested, provided a blood sample for a CD4 count, accepted referral for ART, delivered in a health facility, and provided a blood sample for infant early HIV diagnosis at 6 weeks postpartum. Analysis of the primary endpoints of the trial (retention in and uptake of PMTCT services) has been reported.[17] Only participants who were retained in care through the 6-week postpartum visit were including in this analysis.

Outcomes

Two outcomes were considered for this analysis (1) adherence to ARV drugs, and (2) viral load at 6 weeks postpartum. Adherence was determined by pill counts. On the basis of returned-product [zidovudine (AZT) or ART] counts at each follow-up visit, clinics staff calculated mean adherence as the number of pills not returned divided by the number of days since the previous visit at which products were dispensed. The calculated proportions were recorded in the mother-infant register used by clinics to routinely monitor PMTCT program implementation. At least once per month, study staff visited the clinics and extracted the adherence information from the register into an electronic database. Participants with 100% adherence recorded at all visits were classified as perfectly adherent; those with at least 1 visit with adherence less than 100% were classified as nonadherent.

For viral load, at the time of enrollment, delivery, and 6-week postpartum visit, clinic staff obtained a blood sample from each participant and prepared a dried blood spot [DBS (5 spots of 50 μL of whole blood)] on Whatman paper, dried at ambient temperature for a minimum of 3 hours, and then placed in a Ziploc bag with desiccant packs. Drivers were sent to pick up DBS samples and transport back to study headquarters, where samples were stored at −20°C until they were sent to the National AIDS Reference Laboratory in Kinshasa (LNRS), where viral load was quantified using the

m2000rt Real-Time HIV-1 assay (Abbott, Chicago, IL), with a limit of detection of 40 copies per milliliter The LNRS laboratory had experience with viral load quantification from DBS and performed regular external quality control.[19]

Baseline Covariates

Baseline characteristics considered were participant age in years, marital status (married/cohabitating or other), years of education, gestational age at first ANC registration dichotomized as early (<20 weeks) or not, initial PMTCT regimen (AZT or ART), CD4 count (≤350 or >350 cells/mL), and viral load (undetectable or not) at enrollment. CD4 count was measured as part of routine PMTCT care using the point-of-care Alere Pima Analyser (Alere Technologies, Jena, Germany). DBS samples for viral load were collected as part of the study (after the participant was enrolled, between 2 and 4 weeks after ANC registration).

Statistical Analysis

Proportions of participants in the intervention and control groups who were fully adherent or with an undetectable viral load at 6 weeks postpartum were compared using Pearson's χ^2 tests. Linear risk models were used to estimate unadjusted risk differences (RD) and 95% CI. Generalized estimating equations were used to adjust for potential clustering at the clinic level. Analyses were also adjusted for any baseline characteristic that was found to be imbalanced between groups or hypothesized as a strong predictor of either outcome. All analyses were completed using SAS 9.3 (SAS Institute Inc., Cary, NC). All tests were 2-sided and used a 0.05 significance level.

The study is approved by the Institutional Review Board of the Ohio State University and the Ethical Committee of the Kinshasa School of Public Health. This trial is registered at ClinicalTrials.gov, number NCT01838005.

RESULTS

At 6 weeks postpartum, 332 (76.7%) total participants were retained in care, 80.6% (174/216) of the intervention group and 72.8% (158/217) of the control group ($P = 0.04$). At baseline, participants had a median age of 29 years (interquartile range 25–34) and a median of 10 years of education (interquartile range 8–12). Most participants (83.4%) were married or cohabitating, 19.9% initiated ANC before 20 weeks of gestation, and 23.2% were initiated on ART as the initial PMTCT regimen. Over half (51.8%) of participants had an undetectable viral load, and 44.7% had a CD4 count less than or equal to 350 cells per milliliter. Baseline characteristics did not differ by study group (Table 1).

Overall, pill count data from all clinic visits were available for 297 participants (89.5%), including 156 (89.7%) and 141 (89.2%) of the intervention and control groups, respectively. Among these participants, 69.9% (109/156) in the intervention group and 68.1% (96/141) in the control group were classified as adherent (RD 0.02; 95% CI: −0.06 to 0.09) (Table 2). Initiation of ANC before 20 weeks of gestation was the only baseline characteristic that was statistically associated with adherence (RD −0.18; 95% CI: −0.31 to −0.06). Adjusting for baseline characteristics did not change the association between intervention group and adherence (adjusted RD 0.03; 95% CI: −0.05 to 0.12).

TABLE 1. Characteristics of the 332 Participants Retained in PMTCT Care Through 6 Weeks Postpartum by Study Group

	Study Group		
	Intervention	Control	*P*
Age in years: median (IQR)	29.0 (25.0–34.0)	28.0 (25.0–34.0)	0.4931
Maternal education in years: median (IQR)	10.0 (8.0–12.0)	10.0 (8.0–12.0)	0.6528
Marital status			
Married/cohabiting	146 (84.4)	130 (82.3)	0.6057
Divorced/separated/ widow/never married	27 (15.6)	28 (17.7)	
CD4 count			
≤350	73 (46.2)	58 (57.0)	0.5789
>350	85 (53.8)	77 (43.0)	
Gestational age in weeks: median (IQR)			
<20 wk	36 (20.7)	30 (19.0)	0.6979
≥20 wk	138 (79.3)	128 (81.0)	
Baseline viral load			
Undetectable	89 (52.0)	80 (51.6)	0.9376
Detectable	82 (48.0)	75 (48.4)	
Initial PMTCT regimen			
AZT	37 (21.6)	38 (24.8)	0.4955
ART	134 (78.4)	115 (75.2)	

IQR, interquartile range.

At 6 weeks postpartum, viral load measurements were available for 171 (98.3%) and 155 (98.7%) participants in the intervention and control groups, respectively. Among these participants, 66.1% (113/171) in the intervention group and 69.7% (108/155) in the control group had an undetectable viral load (RD −0.04; 95% CI: −0.14 to 0.07) (Table 3). Undetectable viral load at baseline was a statistically significant predictor of undetectable viral load at 6 weeks postpartum; 84.3% (140/166) of participants with an undetectable viral load at study enrollment had an undetectable viral load at 6 weeks postpartum compared with 50.3% (78/155) of participants with a detectable viral load at baseline (RD 0.34; 95% CI: 0.26 to 0.42). Similarly, participants whose initial PMTCT regimen was ART were more likely to achieve an undetectable viral load at 6 weeks postpartum compared with those who initially received AZT (RD 0.14; 95% CI: 0.01 to 0.26). In multivariable analysis adjusting for all baseline covariates, the adjusted RD comparing the proportions of participants in the study groups with an undetectable viral load at 6 weeks postpartum was −0.01 (95% CI: −0.10 to 0.08).

DNA polymerase chain reaction test results were available for 325 infants; 169 and 156 in the intervention and control groups, respectively. Of those infants, 5 (3.0%) in the intervention group and 6 (3.9%) in the control group tested positive.

TABLE 2. Crude and Adjusted Differences in the Proportions of Participants Who Adhered to Antiretrovirals for the Prevention of Mother-to-Child Prevention at 6 Weeks Postpartum, by Study Group

	Adherence to ARVs			
	Yes (N = 205)*	No (N = 92)*	RD (95% CI)	Adjusted RD (95% CI)†
Group				
Intervention	109 (69.9)	47 (30.1)	0.02 (−0.06 to 0.09)	0.03 (−0.05 to 0.12)
Control	96 (68.1)	45 (31.9)		
Age in years: median (IQR)	28.0 (25.0 to 34.0)	29.5 (25.5 to 34.0)	−0.01 (−0.01 to 0.00)	−0.01 (−0.02 to 0.00)
Maternal education in years: median (IQR)	10.0 (8.0 to 12.0)	10.0 (8.0 to 12.0)	0.00 (−0.01 to 0.02)	0.01 (−0.01 to 0.02)
Marital status				
Divorced/separated/widow/never married	29 (63.0)	17 (37.0)	−0.07 (−0.23 to 0.09)	−0.13 (−0.30 to 0.05)
Married/cohabiting	175 (70.0)	75 (30.0)		
CD4 count				
≤350	80 (70.8)	33 (29.2)	0.06 (−0.06 to 0.19)	0.10 (−0.01 to 0.21)
>350	96 (64.4)	53 (35.6)		
Gestational age in weeks: median (IQR)				
<20 wk	32 (54.2)	27 (45.8)	−0.18 (−0.31 to −0.06)	−0.27 (−0.39 to −0.14)
≥20 wk	173 (72.7)	65 (27.3)		
Baseline viral load				
Undetectable	106 (68.0)	50 (32.0)	−0.02 (−0.13 to 0.09)	0.01 (−0.09 to 0.11)
Detectable	95 (69.9)	41 (30.1)		
Initial PMTCT regimen				
ART	46 (70.8)	19 (29.2)	0.03 (−0.10 to 0.17)	0.03 (−0.10 to 0.17)
AZT	151 (67.4)	73 (32.6)		

*Only participants with available pill counts data were considered. Stratified numbers across level of baseline characteristics might not add to N because of missing data.
†Adjusted for all baseline covariates in the table.
IQR, interquartile range.

DISCUSSION

Data from a pre-exposure prophylaxis trial have shown that, when incentivized, participants may attend study visits and undergo study procedures yet not take their prophylactic drugs.[18] This analysis found that among participants who were successfully retained in care through 6 weeks postpartum, nearly 70% were perfectly adherent to ART but that adherence did not differ between study groups suggesting that providing cash incentives did not influence adherence among those retained in care. Similarly, over two-thirds of women retained in care achieved viral suppression at 6 weeks postpartum, but this did not differ between study groups either, providing further evidence that those who were retained in care as a result of receiving the cash incentive were as adherent to those who would have been retained in care without the incentive.

Incomplete adherence to ART has been found to be associated with a lack of financial support.[20] Subgroup analysis of the primary aims of the trial reported elsewhere[17] found that women in the lower wealth quintiles were more likely to be retained in care if they received the cash incentives. Our findings that there is no difference in adherence by study group suggest that the association between financial support and adherence is mostly mediated through retention. Conditional cash transfers made directly to vulnerable women might increase their control over financial resources and allow them to overcome barriers to clinic attendance such as transportation costs and opportunity costs of time. Adherence to ARVs was not a conditionality for receiving the cash incentives in this study and the cash incentives intervention did not affect adherent behavior among participants retained in care. Given this, more in-depth examinations, including qualitative analyses of the mechanisms by which cash incentive interventions increase desired PMTCT outcomes (retention in care and uptake of services), are needed to (1) enhance our understanding of how these interventions work and (2) improve our ability to design and scale-up similar interventions for PMTCT and other health and social issues.

Over 30% of participants were not adherent to their ARVs, data consistent with what has been observed in HIV-infected women elsewhere.[20] About 69% of women had an undetectable viral load at 6 weeks, a proportion that is similar to the 71% reported in a prospective cohort of pregnant women in Benin.[21] Receiving ART as the initial PMTCT regimen, having an undetectable viral load at baseline, and having started ANC before 20 weeks of gestation were all correlated with viral suppression at 6 weeks postpartum. In late 2014, DRC began rolling out the WHO's Option B+, which will help increase the proportion of pregnant women with an undetectable viral load and lower the risk of mother-to-child transmission. This is a step toward enhanced PMTCT, however, to further optimize PMTCT outcomes, additional efforts are needed to encourage pregnant women to start ANC visits as early as possible. Although 88% of pregnant women in DRC attend at least 1 ANC visit before

TABLE 3. Crude and Adjusted Differences in the Proportions of Participants With an Undetectable Viral Load at 6 Weeks Postpartum, by Study Group

	Undetectable Viral Load at 6 Weeks			
	Yes (N = 221)*	No (N = 105)*	RD (95% CI)	Adjusted RD (95% CI)†
Group				
Intervention	113 (66.1)	58 (33.9)	−0.04 (−0.14 to 0.07)	−0.01 (−0.10 to 0.08)
Control	108 (69.7)	47 (30.3)		
Age in years: median (IQR)	29 (26 to 34)	28 (25 to 35)	−0.00 (−0.01 to 0.01)	0.00 (−0.01 to 0.01)
Maternal education in years: median (IQR)	11 (8,12)	10 (8,12)	0.01 (−0.01 to 0.03)	0.01 (−0.01 to 0.02)
Marital status				
Divorced/separated/widow/never married	36 (66.7)	18 (33.3)	−0.02 (−0.12 to 0.09)	0.04 (−0.07 to 0.15)
Married/cohabiting	185 (68.3)	86 (31.7)		
CD4 count				
≤350	111 (69.8)	48 (30.2)	0.01 (−0.08 to 0.11)	−0.03 (−0.12 to 0.06)
>350	91 (71.1)	37 (28.9)		
Gestational age in weeks: median (IQR)				
<20 wk	48 (73.85)	17 (26.15)	0.08 (−0.05 to 0.20)	0.04 (−0.06 to 0.13)
≥20 wk	173 (66.3)	88 (33.7)		
Baseline viral load				
Undetectable	140 (84.3)	26 (25.2)	0.34 (0.26 to 0.42)	0.32 (0.24 to 0.40)
Detectable	78 (50.3)	77 (49.7)		
Initial PMTCT regimen				
ART	58 (78.4)	16 (21.6)	0.14 (0.01 to 0.26)	0.08 (−0.02 to 0.18)
AZT	158 (64.7)	86 (35.3)		

*Only participants with available viral load result at 6 weeks postpartum were considered. Stratified numbers across level of baseline characteristics might not add to N because of missing data.

†Adjusted for all baseline covariates in the table.

IQR, interquartile range.

delivery, only 17% had their first visit within the first trimester and less than half of them (48%) complete the recommended minimum of 4 visits or more.[22] Implementation science research is needed to further address barriers to timely and optimal utilization of MCH services, including PMTCT in resource poor settings.

In addition to its randomized design, this study has important strengths. All participants provided a DBS for viral load; however, 6 patients were missing results at 6 weeks because of either sample mishandling or inadequacy. Similarly, adherence data were available for a large proportion of participants (90%) and was collected routinely as part of PMTCT monitoring. However, the study also has several limitations. First, the study population was a subset of those initially randomized. Despite that, baseline characteristics remained balanced between study groups, the exchangeability of potential outcomes cannot be guaranteed. Second, we do not know which participants were retained in care specifically because of the monetary incentives they received. It is possible that adherence or virological suppression among these participants in particular is higher than it would be among other participants from the incentive and control groups who were included in this analysis. However, even if this were true, because we are interested in the total population effect of financial incentives on ART adherence and viral suppression, our strategy of comparing all participants who were retained in care seems more appropriate.

In conclusion, the provision of cash incentives to HIV-infected pregnant women led to higher retention in care at 6 weeks postpartum without any evidence of lower rates of adherence to ARVs and virologic suppression than those who did not receive the cash incentive.

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