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Understanding patient-level costs of weekly isoniazid-rifapentine (3HP) among people living with HIV in Uganda

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SUMMARY

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BACKGROUND: Twelve weeks of weekly isoniazid and rifapentine (3HP) prevents TB disease among people with HIV (PWH), but the costs to people of taking TB preventive treatment is not well described.

METHODS: We surveyed PWH who initiated 3HP at a large urban HIV/AIDS clinic in Kampala, Uganda, as part of a larger trial. We estimated the cost of one 3HP visit from the patient perspective, including both out-of-pocket costs and estimated lost wages. Costs were reported in 2021 Ugandan shillings (UGX) and US dollars (USD; USD1 = UGX3,587)

RESULTS: The survey included 1,655 PWH. The median participant cost of one clinic visit was UGX19,200 (USD5.36), or 38.5% of the median weekly income. Per visit, the cost of transportation was the largest component (median: UGX10,000/USD2.79), followed by lost income (median: UGX4,200/USD1.16) and food (median: UGX2,000/USD0.56). Men reported greater income loss than women (median: UGX6,400/USD1.79 vs. UGX3,300/USD0.93), and participants who lived further than a 30-minute drive to the clinic had higher transportation costs than others (median: UGX14,000/USD3.90 vs. UGX8,000/USD2.23).

CONCLUSION: Patient-level costs to receive 3HP accounted for over one-third of weekly income. Patient-centered approaches to averting or defraying these costs are needed.

Keywords

tuberculosis preventive treatment; human immunodeficiency virus; cost analysis; people living with HIV

People living with HIV (PWH) experience a high burden of TB; in 2020, 16% of global TB deaths occurred among PWH.[1] TB preventive treatment (TPT) reduces TB risk and mortality in PWH, independent of antiretroviral therapy or CD4 count.[2–6] Twelve weeks of isoniazid and rifapentine (3HP) is a short-course TPT regimen with similar efficacy, fewer adverse events, and higher treatment completion than 6–9 months of daily isoniazid.[7–9] In 2018, the WHO recommended 3HP as an option for TPT.[10] Despite the availability of effective regimens, however, global implementation of TPT has been suboptimal. Between 2005 and 2020, only 13 million of the world's estimated 37.7 million PWH were started on TPT.[1,11]

One major barrier to broader scale-up of short-course TPT is its cost, including the high cost of rifapentine.[12] Less widely considered, however, are the costs to people taking TPT.[13–16] Owing to early evidence suggesting that direct observation of treatment may lead to higher levels of completion,[17] 3HP is sometimes given under direct observation – often at substantial cost to patients. Even when self-administered, multiple clinic visits may be required for refills or adverse event management. Each clinic visit for TPT may incur expenses for transportation and food and may result in lost wages. These financial disincentives may adversely impact TPT completion. Understanding patient-level costs associated with 3HP is therefore essential to fully evaluate the feasibility and real-world effectiveness of directly observed 3HP. Furthermore, if financial incentives are considered to address patient costs of TPT, it is important to understand the appropriate level of reimbursement. We therefore conducted a patient-level costing survey among PWH who initiated 3HP at a large urban HIV/AIDS clinic in Kampala, Uganda.

METHODS

This study was conducted at the Mulago Immune Suppression Syndrome (ISS; i.e., HIV/AIDS) Clinic in Uganda. Located in Kampala, the Mulago ISS clinic is the largest HIV clinic in Uganda, providing comprehensive care to more than 16,000 registered PWH. We performed a costing survey among PWH who were started on 3HP at the Mulago ISS clinic between July 2020 and July 2022. This study was embedded within a randomized trial assessing strategies for delivering short-course TPT (3HP Options Trial; Clinicaltrials.gov NCT03934931). The detailed protocol for the trial has been described elsewhere.[18]

Briefly, PWH who were 18 years or older without signs of active TB and who lived within 25 km of the clinic were eligible to participate. Participants were randomized 1:1:1 to one of three study arms to receive 3HP by the following delivery strategies: facilitated directly observed therapy (DOT), facilitated self-administered therapy (SAT), and patient choice between DOT and SAT, guided by a shared decision-making aid. All participants ingested their first dose under direct observation at the enrollment visit. Participants who were randomized to the DOT arm were asked to return to the clinic on a weekly basis to ingest the remaining doses under direct observation for 11 weeks. Participants randomized to the SAT arm were initially provided with a 4-week supply (doses 2–5) of 3HP and received weekly toll-free automated interactive voice response (IVR) dosing reminders and adverse event check-in phone calls via a digital adherence technology (99DOTS, Everwell Health Solutions, Bengaluru, India). Participants in the SAT arm were asked to return at 6 weeks for adverse event management, receive their medication refill (doses 7–11), and schedule their Week 12 clinic visit at which they would take their final dose under direct observation.

During the enrollment visit, we surveyed all study participants and collected information about their income, out-of-pocket expenses for the clinic visit, transportation costs to the clinic, and time spent for the visit. Ten percent of participants in each arm were randomly selected for follow-up surveys at Week 6 to assess any costs associated with adverse events, any changes in costs to attend clinic visits, and participants' self-reported assessment of the per-visit reimbursement that they would consider "fair". At each clinic visit, a fixed reimbursement was provided to all participants. The reimbursement amount was 15,000 Ugandan shillings (UGX15,000 = 4.18 US dollars, USD) when recruitment began in July 2020. In response to concerns about the impact of the COVID-19 pandemic on transportation costs, we doubled compensation to UGX30,000 (= USD8.36) in August 2020. In November 2020, the reimbursement level was readjusted to UGX20,000 (= USD5.58), which was maintained until the end of recruitment and follow-up. In the present analysis, we evaluated the stability of transportation costs over the post-COVID period by assessing trends in self-reported transportation costs.

We estimated the patient-level cost of one clinic visit per person (regardless of study arm) by adding out-of-pocket costs and estimated lost wages. Out-of-pocket costs of clinic visits were estimated by self-report and were organized into five categories: transportation, additional food, child care, expenses for accompanying caregivers or family members, and other out-of-pocket costs. We used participants' self-reported weekly wages and work hours to calculate each participant's hourly wage. We multiplied this estimated hourly wage by participants' self-reported time spent on travel and clinical encounters (i.e., removing any research-specific costs) to estimate potential lost income. We compared this estimate to a survey question (asked at enrollment) in which participants were asked to directly estimate their wages lost for the clinic visit and used the latter in the sensitivity analysis. We did not include insurance payments, as only 5% of individuals in Uganda had health insurance in 2020.[19] Costs for adverse reaction management were estimated by adding self-reported out-of-pocket expenses for hospitalization, outpatient care, calls to healthcare workers, laboratory testing, and medications, and lost wages incurred from time spent managing adverse reactions.

Ugandan shillings were converted to US dollars using the average exchange rate in 2021, as reported by the World Bank (USD1 = UGX3,587.05).[20] We compared costs across three sets of a-priori defined categories: 1) sex; 2) age (dichotomized at 40 years, based on the median age of 42 years), and 3) a binary measure of distance from the clinic (requiring more or less than 30 min on a motorized transport). To calculate this latter measure, we used self-reported one-way transit time and primary mode of transport to estimate whether the person lived within a 30 min ride of the clinic using motorized transport. For people who walked or used a bicycle to the clinic, we used 90 min as a proxy for this threshold. Given the expectation of non-normality, we used the non-parametric Mann–Whitney *U*-test to estimate *P* values for comparisons across continuous variables. All reported *P*-values are two-sided, with statistical significance defined as a two-sided alpha <0.05. All analyses were performed using Stata v16.1 (Stata Corp, College Station, TX, USA). This study was approved by the Institutional Review Boards at the University of California San Francisco, CA, USA; Makerere University College of Health Sciences School of Public Health, Kampala, Uganda; and the Uganda National Council for Science and Technology, Kampala, Uganda.

RESULTS

A total of 1,655 PWH were enrolled in the trial and participated in the baseline survey. Characteristics of study participants are given in Table 1. Participants spent a median of 1 h (interquartile range [IQR] 0.5–1.3) for a one-way trip to the clinic, and two-thirds (68%) of participants lived within an estimated 30-min ride of the clinic using motorized transport. The median total cost of one clinic visit was UGX19,200, or USD5.36 per person receiving 3HP (Table 2), accounting for 38.5% of self-reported median weekly income (UGX50,000/USD13.94 per visit). Transportation was the largest cost component (median: UGX10,000/USD2.79 per visit), followed by lost income (median: UGX4,200/USD1.16 per visit), and food (median: UGX2,000/USD0.56 per visit). Despite the intervening COVID-19 pandemic, those who attended clinic visits did not report a substantive change in the median cost of transportation over calendar time (Figure 1). Participants' self-reported income loss (median: UGX3,000/USD0.83) was lower than their income loss estimated based on expended time (median: UGX4,200/USD1.16). Men reported higher costs of attending the clinic than women (median: UGX21,500/USD5.99 vs. UGX18,200/USD5.06; $P < 0.001$), a difference driven primarily by income loss (median: UGX6,400/USD1.79 vs. UGX3,300/USD0.93; $P < 0.001$). Older (≥40 years) participants had slightly higher costs than younger participants (UGX19,600/USD5.45 vs. median UGX18,500/USD5.16; $P = 0.029$). Participants who were residing in areas that required at least 30 min of motorized transport reported higher transportation costs than those living closer to the clinic (median: UGX14,000/USD3.90 vs. UGX8,000/USD2.23; $P < 0.001$). Figure 2 illustrates costs of attending the clinic according to sex, age group, and distance to the clinic.

For the Week 6 follow-up survey, 157 participants were randomly selected, and 156 (99%) study participants completed the survey. When asked to estimate a “fair” level of compensation per clinic visit, these participants reported a median of UGX20,000 (IQR 15,000–30,000)/USD5.58 (IQR 4.18–8.36) – similar to the estimated cost per clinic visit above (median: UGX19,200/USD5.36). Most respondents (133 of 138 who answered the question, 96%) stated that ‘fair’ compensation should include transportation fees, followed by compensation for food on the visit day ($n = 42$, 30%), and compensation for income loss due to missed work ($n = 19$, 14%). Of 156 respondents, 33 (21%) reported that they had received insufficient compensation to cover the costs incurred during their clinic visit; relative to their peers, these participants did not differ by time of enrollment but did report higher transportation costs (median: UGX12,000, IQR 10,000–20,000/USD3.35, IQR 2.79–5.58 vs. UGX10,000, IQR 8,000–14,000/USD2.79, IQR 2.23–3.90; $P = 0.015$).

Overall, 23 survey participants (15%) reported having experienced adverse reactions to 3HP. Twelve of these participants (8%) sought medical care, and nine (6%) incurred associated costs. One participant was hospitalized for 7 days due to acute liver injury that resulted in a total incurred cost of UGX796,800/USD222.13. Largely reflecting this one event, the mean cost for adverse reaction management was UGX42,114/USD11.74 per participant reporting any adverse reaction and UGX6,209/USD1.73 per person receiving 3HP (i.e., including those with no adverse reactions).

DISCUSSION

In this survey of 1,655 PWH receiving 3HP at a large urban HIV/AIDS clinic in Kampala, we found that the cost for a participant to make a single visit to receive 3HP was over USD5, accounting for more than one-third of participants’ self-reported weekly income. Costs were higher for men (due to greater income loss) and people living further from the clinic (due to higher transportation costs). These findings highlight the fact that the financial burden borne by people taking TPT could act as a major barrier to effective implementation and delivery of 3HP, particularly among populations with poorer existing access to care. Innovative approaches to avert or defray these costs will be important if short-course TPT such as 3HP is to be more broadly scaled up in this population.

In this study, transportation costs accounted for more than half of the total patient-level cost of 3HP. As such, participants who lived further from the clinic bore greater costs of clinic attendance – suggesting that this population may warrant special attention in any effort to overcome financial barriers to TPT delivery. As we restricted our study to people living within 25 km, we expect that costs could be higher for those living in remote rural settings, where clinics with TB services are further away. Beyond transportation, income loss was the other major component of participant costs, and men reported greater income loss than women. Costs for adverse reaction management were not high for the average participant but were catastrophic for one participant who required a week of hospitalization. Any scheme to address costs of TPT should account for rare, but potentially, extreme costs due to adverse events.

Our study results highlight that TPT, especially when implemented with DOT, can be costly for people in urban Kampala. A prior randomized trial assessing 3HP delivery strategies showed that DOT was associated with higher treatment completion than SAT, particularly in South Africa[17] although subsequent trials in Africa have found high completion levels with SAT.[21] In the parent trial for this survey, we found very high (>90%) completion across all arms, but participants received financial compensation for each clinic visit to facilitate their TPT experience.[22] Given that the cost to attend clinic for TPT was over one-third of participants' median weekly income, DOT is likely to be cost-prohibitive for many PWH in settings such as ours. Person-centered approaches that do not require clients to incur such costs are likely to be critical to TPT scale-up efforts. Such approaches might include direct financial compensation for clinic visits (as in this study) and/or facilitated SAT approaches such as home-based management with community health workers,[23] or implementation of digital adherence technologies.[24] Further research into the implementation and effectiveness of such approaches in different cultural and economic contexts should be a high priority.

Our study had several limitations. Because our study population primarily consisted of individuals who lived within 25 km of a major urban clinic, our findings may not generalize to rural areas or other clinic setups. For example, whereas transportation costs accounted for over half of all costs in this study, this may not be true for clinics to which most people walk. Our study population was relatively young (median age 42 years) with well-controlled HIV (99% virally suppressed, defined as HIV viral load <1,000 copies/mL). Thus, only a fraction of people reported costs for caregivers and other guardians, which may not generalize to settings in which clients have a greater burden of comorbidities and require additional personnel support. While we observed that transportation costs remained stable during the post-pandemic study period, we were unable to document increases that likely occurred during the pandemic.

We estimated income loss using self-reported weekly income, which may have over- or under-estimated actual income loss. In this study, most participants were only informally employed; as such, actual income loss may have been lower than estimated here. For example, some participants may have been able to reorganize their work schedules, and visits could theoretically be offered outside of business hours, although such visits are uncommon in Uganda and not offered at Mulago ISS Clinic. Even in such cases, however, time spent attending clinic could have been used to generate additional income, and including lost income is recommended in patient cost surveys for TB.[25] As part of this research study, participants were provided with medications and clinical care free of charge; in other settings, these fees may represent substantial additional costs of TPT. Finally, we limited our analysis to patient-level costs to represent the patient perspective. A full cost-effectiveness analysis should consider healthcare and other societal costs as well.

In summary, this survey of 1,655 PWH in Kampala, Uganda, illustrates the high costs to people receiving short-course TPT. The average per-visit cost for TPT was over USD5, more than one-third of participants' median weekly income. The primary cost components were transportation and income loss; as such, participants living further from clinic and men bore higher-than-average costs and might be at risk for loss to follow-up under programmatic conditions. Innovative solutions to avert and overcome the high cost of short-course TPT are required if this life-saving intervention is to be brought to scale in low-income populations.

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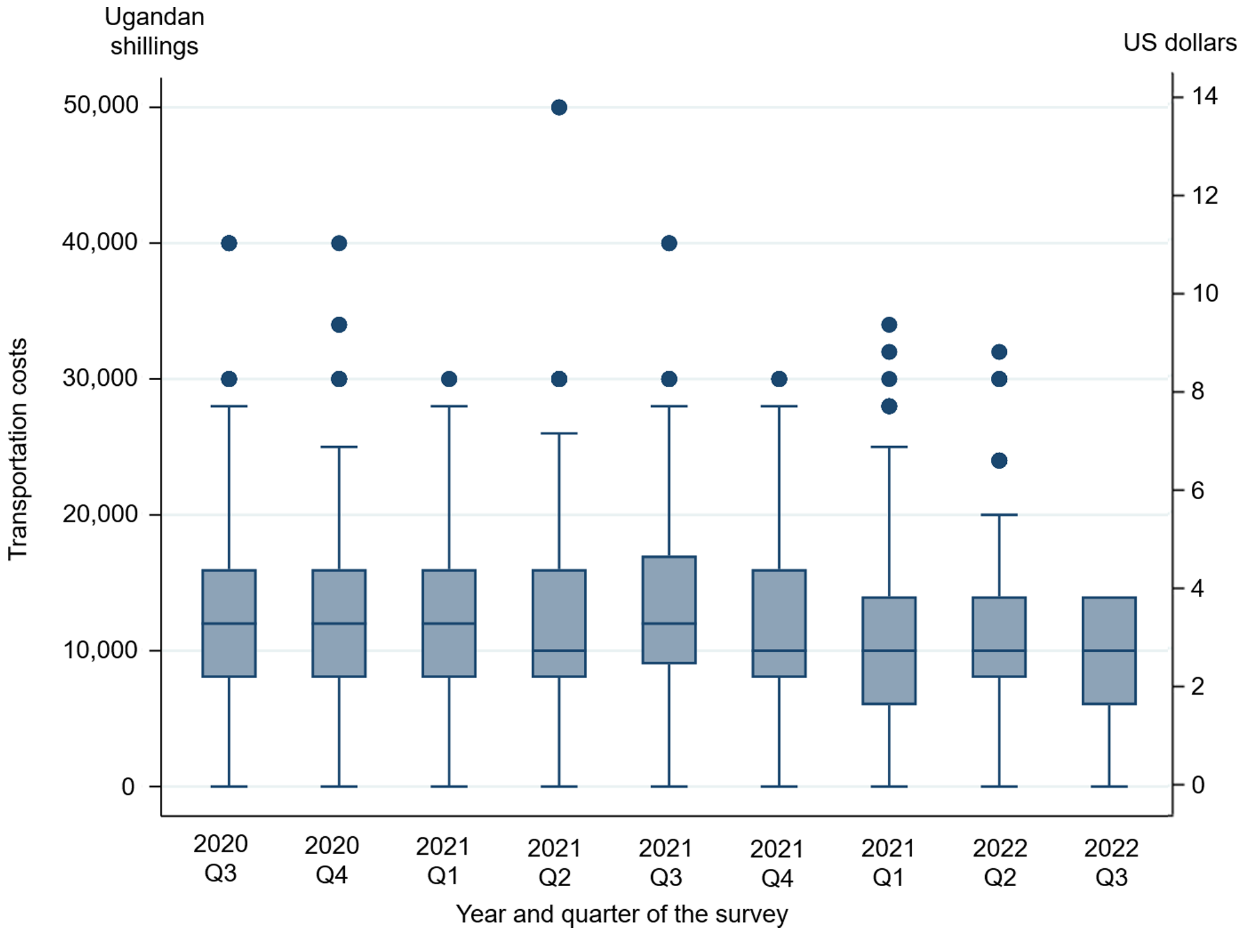

Figure 1.

Temporal trend in transportation cost during the study period. The box plot illustrates self-reported two-way transportation costs to the clinic over calendar time among people with HIV started on 12 weeks of isoniazid and rifapentine (3HP) at a large urban HIV clinic in Kampala, Uganda (survey period: July 2020–July 2022). Each box represents the distribution of transportation costs with IQRs (25^{th} and 75^{th} percentiles of measurements) across study participants who were surveyed within each quarter (labeled Q on the *x*-axis). Horizontal bars within the box represent the median cost, and outliers are shown as dots. In August 2020, the compensation level for each clinic visit was increased to account for the rise in transportation costs due to COVID-19 pandemic; 51 (3%) participants enrolled before this adjustment. The median transportation cost at the beginning of the study (the third quarter of 2020) was UGX12,000 (IQR 8,000–16,000)/USD3.35 (IQR 2.23–4.46), compared to UGX10,000 (6,000–14,000)/USD2.79 (IQR 1.67–3.90) at the end of the study (the third quarter of 2022).

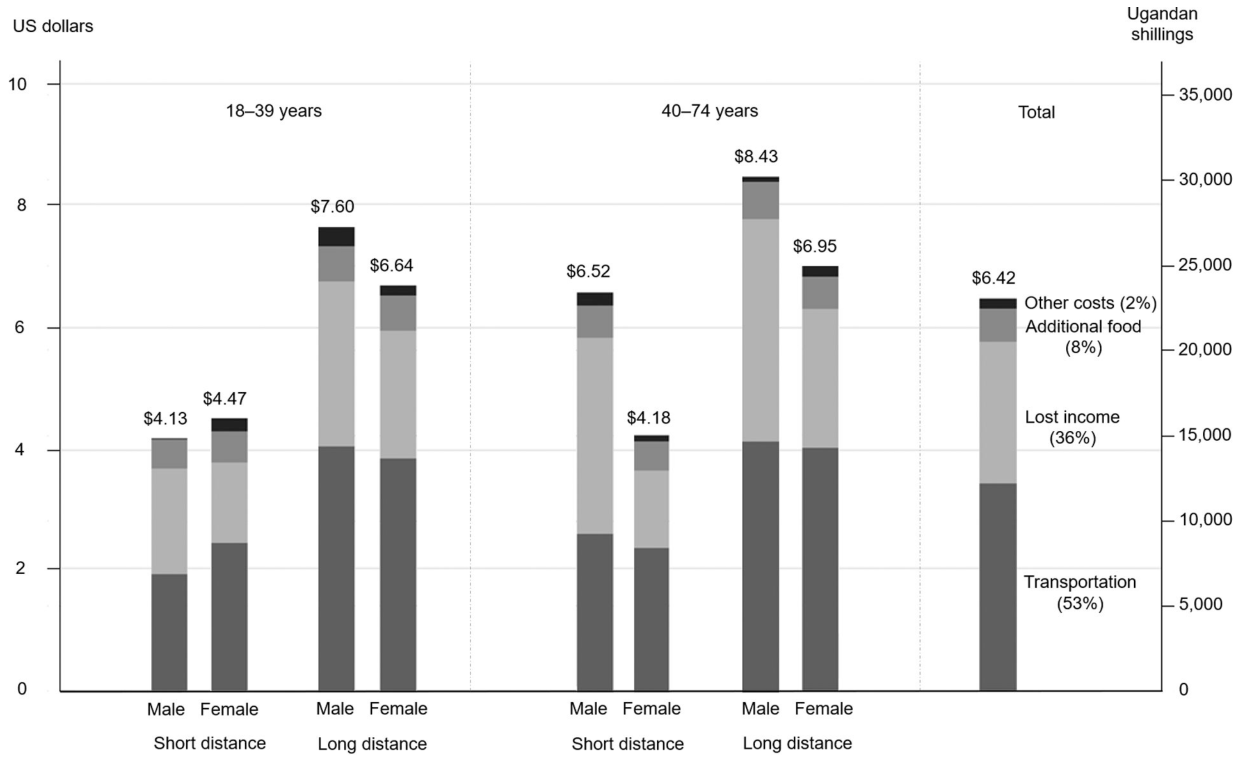

Figure 2.

Mean patient-level costs for one visit to receive TPT, according to age, sex, and distance to clinic. Stacked bars show the mean total cost per clinic visit to receive short-course TPT in an urban Ugandan clinic, according to age (older or younger than 40 years), sex, and distance to the clinic (short: <30-min ride on motorized transit, long: ≥30-min ride on motorized transit). The far-right column represents the mean total cost per clinic visit across all participants. Divisions within bars illustrate the components of those costs, with transportation (bottom division) and income loss (second from bottom division) representing over 89% of total costs. Expenses for additional food (second from top division) and other costs (topmost division, including childcare cost, cost for accompanying person, and other unclassified costs) were responsible for 8% and 2% of total costs, respectively. There were differences in patient-level costs per clinic visit by sex and distance to the clinic, with men reporting greater income losses (mean: UGX11,400/USD3.19) than women (mean: UGX6,900/USD1.91) and people living further from clinic reporting greater transport costs (mean: UGX13,900/USD3.88) than people living within 30 min ride of the clinic (mean: UGX8,500/USD2.37). TPT = TB preventive treatment; UGX = Ugandan shilling; USD = US dollar.

Table 1

Characteristics of participants receiving TB preventive treatment with weekly isoniazid and rifapentine (3HP) in an urban Ugandan clinic

	Enrollment survey (*n* = 1,655) *n*/*N* (%)	**Follow-up survey (*n* = 156) *n*/*N* (%)**
Age, years, median [IQR]	42 [36–48]	41.5 [36–48]
Sex		
Female	1,122 (68)	111 (71)
Male	533 (32)	45 (29)
Years HIV-positive, median [IQR]	10.1 [6.0–13.7]	9.7 [7.1–12.8]
Years on ART, median [IQR] *	9.1 [5.6–12.6]	8.6 [6.2–11.7]
CD4 count, cells/mm^3, median [IQR]	473 [318–656]	490 [345–682]
HIV viral load <1000 copies/mL	1,627/1,647 (99)	156/156 (100)
Prior TB		
No	1,354 (82)	129 (83)
Yes	301 (18)	27 (17)
Education		
None	139 (8.4)	20 (12.8)
Primary	782 (47.3)	71 (45.5)
Secondary	600 (36.3)	56 (35.9)
Tertiary or higher	126 (7.6)	8 (5.1)
Vocational	7 (0.4)	1 (0.6)
Weekly income, UGX, median [IQR]	50,000 [25,000–100,000]	52,500 [20,000–110,000]
Weekly income, USD, median [IQR]	13.94 [6.97–27.88]	14.64 [5.58–30.67]
Employment		
Unemployed	230 (14)	21 (14)
Temporary/informal worker	396 (24)	35 (23)
Hired worker	204 (12)	17 (11)
Self-employed worker	815 (50)	82 (53)
Travel distance to the clinic †		
<30-min drive	533 (32)	49 (31)
≥30-min drive	1,118 (68)	107 (69)

*All participants were taking antiretroviral therapy.

†For people who walked or used a bicycle, 90 min were used as a threshold.

IQR = interquartile range; ART = antiretroviral therapy; UGX = Ugandan shilling; USD = US dollar.

Table 2

Patient-level cost of each clinic visit among people with HIV receiving short course TB preventive treatment

	Participants with corresponding cost *n* (%)	Costs/person reporting expenses Median [IQR]		Costs/person receiving 3HP Median [IQR]		Costs/person receiving 3HP Mean ± SD	
		UGX	**USD**	**UGX**	**USD**	**UGX**	**USD**
Transportation	1,562/1,654 (94.4)	12,000 [9,000–16,000]	3.34 [2.51–4.46]	10,000 [8,000–16,000]	2.79 [2.23–4.46]	12,200 ± 6,800	3.39 ± 1.88
Lost income	1,392/1,652 (84.3)	5,300 [2,800–10,000]	1.47 [0.77–2.79]	4,200 [1,800–8,800]	1.16 [0.50–2.44]	8,300 ± 22,100	2.32 ± 6.15
Additional food	1,293/1,655 (78.1)	2,000 [2,000–3,000]	0.56 [0.56–0.84]	2,000 [1,000–3,000]	0.56 [0.28–0.84]	2,000 ± 1,500	0.54 ± 0.41
Childcare	102/1,654 (6.2)	3,300 [2,000–5,000]	0.91 [0.56–1.39]	0 [0–0]	0 [0–0]	300 ± 2,700	0.09 ± 0.75
Cost for accompanying person(s)	12/1,655 (0.7)	14,500 [8,000–17,500]	4.04 [2.23–4.88]	0 [0–0]	0 [0–0]	100 ± 1,500	0.03 ± 0.41
Other costs*	34/1,655 (2.1)	5,000 [4,000–10,000]	1.39 [1.12–2.79]	0 [0–0]	0 [0–0]	200 ± 1,400	0.04 ± 0.39
Total cost	1,647/1,651 (99.8)	19,300 [13,500–27,000]	5.37 [3.76–7.53]	19,200 [13,500–27,000]	5.36 [3.76–7.53]	23,000 ± 24,500	6.42 ± 6.82

*Other costs include expense for work coverage (22/34), indirect income loss from missed business (1/34), and unspecified costs (11/34).

IQR = interquartile range; SD = standard deviation; UGX = Ugandan shilling; USD = US dollar.