

Modeling the Cost-Effectiveness of Home-Based HIV Testing and Education (HOPE) for Pregnant Women and Their Male Partners in Nyanza Province, Kenya

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Introduction: Women in sub-Saharan Africa face a 2-fold higher risk of HIV acquisition during pregnancy and postpartum and the majority do not know the HIV status of their male partner. Home-based couple HIV testing for pregnant women can reduce HIV transmission to women and infants while increasing antiretroviral therapy (ART) coverage in men. However, the cost-effectiveness of this program has not been evaluated.

Methods: We modeled the health and economic impact of implementing a home-based partner education and HIV testing (HOPE) intervention for pregnant women and their male partners in a region of

Western Kenya (formally Nyanza Province). We used data from the HOPE randomized clinical trial conducted in Kisumu, Kenya, to parameterize a mathematical model of HIV transmission. We conducted an in-country microcosting of the HOPE intervention (payer perspective) to estimate program costs as well as a lower cost scenario of task-shifting to community health workers.

Results: The incremental cost of adding the HOPE intervention to standard antenatal care was \$31–37 and \$14–16 USD per couple tested with program and task-shifting costs, respectively. At 60% coverage of male partners, HOPE was projected to avert 6987 HIV infections and 2603 deaths in Nyanza province over 10 years with an incremental cost-effectiveness ratio (ICER) of \$886 and \$615 per disability-adjusted life year averted for the program and task-shifting scenario, respectively. ICERs were robust to changes in intervention coverage, effectiveness, and ART initiation and dropout rates.

Conclusions: The HOPE intervention can moderately decrease HIV-associated morbidity and mortality by increasing ART coverage in male partners of pregnant women. ICERs fall below Kenya's per capita gross domestic product (\$1358) and are therefore considered cost-effective. Task-shifting to community health workers can increase intervention affordability and feasibility.

Key Words: HIV counseling and testing, sub-Saharan Africa, cost-effectiveness, males, pregnant, PMTCT

(*J Acquir Immune Defic Syndr* 2016;72:S174–S180)

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Related presentations: Sharma M, Farquhar C, Kinuthia J, Osofi A, Asila V, Parikh S, Krakowiak D, Gone A, Barnabas R.V. Cost of home HIV testing and education for male partners of pregnant women in Kenya. [Poster] HIV Pathogenesis, Treatment and Prevention (IAS), Vancouver, BC, July 20, 2015.

The authors have no funding or conflicts of interest to disclose.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.jaids.com).

C.F. and R.B. conceived of the analysis. M.S. conducted the microcosting and cost-effectiveness analyses. R.Y. and M.S. conducted the modeling. MS wrote the manuscript with input from C.F., R.Y., D.K., J.K., A.O., V.A., M.G., J.M., and R.B.

This study was approved by the Kenya Ethics Review Committee and the University of Washington Human Subjects Division.

Clinicaltrials.gov registry: NCT01784783.

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INTRODUCTION

HIV is one of the most serious health and economic challenges in sub-Saharan Africa (SSA), where over 70% of the world's new HIV infections occur.¹ Pregnant and postpartum women in SSA have particularly high rates of HIV acquisition; cohort studies report HIV incidences ranging from 2.3 to 7.6 per 100 person-years during pregnancy and postpartum,^{2–5} more than 2-fold higher than in nonpregnant women.⁶ This increased risk persists after adjustment for sexual behavior, which suggests that biological factors including hormonal or immunological changes during pregnancy may play a role in heightening susceptibility.⁶ With fertility rates around 5 children per woman in SSA, this can translate into 10 or more years of increased risk. HIV-infected women in East Africa also face more than 7-fold higher risk of maternal mortality compared with uninfected pregnant women,⁷ and

approximately 17% of HIV-infected mothers in SSA transmit HIV to their infants.⁸

Although pregnant women have high rates of HIV testing coverage in SSA largely due to antenatal testing, they are less likely to know the HIV status of their male partners. For example, in Kenya, during 2013, 88% of pregnant women were tested for HIV, whereas only 4.5% of their male partners underwent testing in the previous 12 months.^{8,9} This is a significant problem in generalized epidemic settings, because persons are most likely to become infected in stable partnerships. A modeling analysis using sexual behavior survey data from 18 countries in SSA suggests that HIV transmission within couples is largely transmitted from men to women, and men are more likely than women to become infected by someone other than their main partner, both of which indicate that interventions to reduce HIV in women will likely need to target men as well.¹⁰

As facility-based HIV testing and counseling (HTC) has not achieved high testing coverage in male partners of pregnant women in SSA, novel testing interventions are needed.^{11,12} Community-based HTC is a promising strategy that achieves high uptake and identifies asymptomatic HIV-positive individuals at higher CD4 counts than facility HTC.^{13,14} One form of community HTC, home-based HIV couple counseling for pregnant women and their male partners, can attain high HIV testing coverage in both pregnant women and their partners. Couple HIV testing and disclosure has been shown to increase women's adherence to both antiretroviral therapy (ART) and prevention of mother to child transmission regimens, including Option B+ (lifelong ART for HIV-infected pregnant women).¹⁵⁻¹⁷ Increasing HIV testing in males reduces transmission to their female partners, while also averting morbidity and mortality in men associated with late ART initiation. Men are less likely than women to undergo HIV testing, less likely to start ART, and more likely to seek care at advanced disease stages, interrupt treatment, and die on ART.¹⁸ Antenatal clinic attendance is high (95.4% of pregnant women in Kenya, 2012), indicating the potential to achieve high coverage of male partners.¹⁹ However, home-based couple counseling for pregnant women is resource intensive, and its cost-effectiveness (ie, value for money) has not been well evaluated. We used a mathematical model to assess the cost-effectiveness of providing home-based partner education and HIV testing (HOPE) to couples as a part of routine antenatal care in Western Kenya. Primary cost and effectiveness data were collected from the HOPE study, a randomized controlled trial conducted in Kisumu, Kenya, in which couples either received the HOPE intervention (HOPE arm) or written invitations for male partners to attend clinic (INVITE arm). In addition to HIV education and testing, couples in the HOPE arm received information on facility delivery, exclusive breastfeeding, family planning, and voluntary medical male circumcision. In this analysis, we project the health and economic impact of implementing the HOPE intervention in the former Nyanza Province, a region in Western Kenya with high HIV prevalence (15.1%). From an implementation science perspective, we sought to translate the HOPE clinical trial results into projections of HIV burden averted and costs incurred under realistic program scale-up. Our analysis can be useful to policy makers charged with implementing evidence-based HIV interventions that maximize health benefits within a fixed budget.

METHODS

Home-Based Partner Education and Testing (HOPE) Intervention

Costs and effectiveness data were obtained from the HOPE intervention, a randomized controlled trial conducted from September 2013 to June 2015 in Kisumu, Kenya. Study design and outcomes are described in detail in this supplement.²⁰ Briefly, 601 pregnant women in stable partnerships were enrolled when they presented for antenatal care at Kisumu County Hospital and randomized to HOPE (intervention) or INVITE (control) arm. Couples in the intervention arm received a home visit in which study staff (health advisors) screened male partners and offered couples HIV counseling and testing. Health advisors also administered a standardized health education intervention on the importance of facility delivery, exclusive breastfeeding, family planning, and methods to prevent HIV transmission. Women in the INVITE arm were asked through written invitation to bring their partners to the clinic for couple HIV testing. The study compared uptake of male partner HIV testing, condom use, facility delivery, exclusive breastfeeding, HIV transmission to infants and mothers, and contraceptive use in the 2 arms. Outcomes were assessed at 6 weeks and again at 6 months after delivery. The HOPE intervention was found to increase male partner testing by more than 2-fold (relative risk: 2.1, 95% confidence interval: 1.81 to 2.42) and identified more HIV serodiscordant couples (13%) compared with the INVITE arm (4%). The HOPE intervention was not associated with an increase in intimate partner violence or other adverse events.²⁰

Mathematical Model

We adapted a previously published dynamic HIV transmission model to include pregnancy states.²¹ The model was parameterized with epidemiologic data from the former Nyanza Province and calibrated to fit HIV incidence and prevalence from that region. The model simulates the natural history of HIV/AIDS using 3-month time steps. Men and women are stratified by 5-year age group (0–59 years), sexual activity (low, medium, and high), circumcision status, viral load (6 stages), and CD4 count (6 stages). Sexual behavior is assumed to change over time as individuals age. Susceptible individuals can acquire HIV and transition to acute infection. CD4 count declines over time based on clinical estimates from a prospective cohort.²¹ Persons on ART have a 96% reduction in transmission risk.²² Disability weights are assigned to each HIV state.²³ In addition to background mortality, HIV-positive individuals face a disease-specific mortality that varies by age and CD4 count.²⁴ Persons on ART are assumed to have the same mortality rates as those who are uninfected.²⁵ Dropout of ART occurs yearly and individuals are assumed to return to the CD4 count and viral load status they had before initiating ART. The model estimates the force of HIV infection as a function of sexual mixing (by age and sexual activity), proportion of HIV-infected individuals, circumcision, and HIV transmission probability. HIV-positive women who are not on ART have

a probability of transmitting HIV to their infants. Changes in the population over time are estimated using a system of ordinary differential equations that are solved in MATLAB version 2015a using 4th-order Runge–Kutta methods.²⁶ Before projecting the impact of the HOPE intervention, the model was calibrated to reflect the age-specific and overall HIV prevalence from Nyanza province and CD4 distribution and ART coverage from Kenya. Additional details about the model, parameters, and calibration results are available in the Supplemental Digital Content, <http://links.lww.com/QAI/A828>.

Status Quo and Intervention Scenarios

For the status quo (no intervention) scenario, we modeled the impact of continued facility HIV testing and ART expansion at current scale-up rates.²⁷ In the intervention scenario, HOPE is added to the status quo scenario with 60% coverage of male partners of pregnant women, based on coverage from the trial. However, as coverage could either be higher or lower if implemented as a government program, we conducted sensitivity analyses varying coverage from 40% to 80%. We assumed that the HOPE intervention increased the ART initiation rate for HIV-positive male partners by 2.1-fold (the increase in male partner HIV testing found in the clinical trial).²⁰

Microcosting

A detailed microcosting was conducted following established guidelines for costing HIV interventions.^{28,29} Primary cost data were collected from budgets, expense reports staff, and local expert interviews. Costs were divided into mutually exclusive categories of: personnel, transportation, equipment, supplies, buildings and overhead, start-up, and phones and data monitoring. Time and motion studies were conducted over 3 weeks (June 10–30, 2014) to record staff time spent on intervention activities (eg, conducting HTC, tracing male partners, traveling to couples' homes). Research time (administering informed consent, reimbursements, etc) and other research cost were removed from the programmatic costs. The time and motion studies and interviews with staff were used to inform efficiency assumptions about the mean number of couples that could be tested per day. Capital costs, software development, and start-up cost (staff hiring, training, and community mobilization) were annualized assuming a 5-year useful life expectancy discounted annually at 3%. Costs were inflated to 2014 US dollars (USD) using the Kenya consumer price index. Total program costs were divided by the number of couples tested by HIV status under each scenario to determine the cost per person tested. Other costs including facility HIV testing, ART, and HIV/AIDS-related hospitalizations were estimated from the literature^{30–32}; additional information is available in the Supplemental Digital Content, <http://links.lww.com/QAI/A828>.

Cost-Effectiveness Analysis

We calculated the incremental cost-effectiveness ratio (ICER) for adding the HOPE intervention to standard

antenatal care for disability-adjusted life years (DALYs) averted over 10 years. The ICER is measured as the additional cost divided by the additional health benefit of the intervention strategy compared with the next less costly strategy (the status quo). Consistent with health economic conventions, we considered the intervention to be very cost-effective if the ICER is less than Kenya's 2014 GDP per capita (1358 USD).³³ We used a 10-year time horizon as is common in cost-effectiveness analyses of HIV prevention.^{34,35}

Sensitivity Analyses

To explore the impact of key assumptions on our findings, we conducted sensitivity analyses varying coverage, costs, intervention effectiveness, projected ART expansion, and task-shifting from health advisors to community health workers. We also evaluated a scenario in which the HOPE intervention increased adherence to Option B+ as studies found that couple HIV testing and disclosure increases women's adherence.¹⁵

RESULTS

Microcosting

Costs were estimated for 2 scenarios: (1) a higher cost program model, reflecting the staff cadre of the research study—nurses enrolling pregnant women into the intervention, highly trained health advisors administering the intervention, and higher cost supplies including research-compatible mobile phones, and (2) a lower-cost task-shifting model in which nurses and health advisors are replaced with community health workers, the field coordinator is replaced with a community health worker manager, the data manager is reduced to a half-time position, and lower cost supplies are used (Table 1). Results of the time and motion observations showed that the HOPE educational component and couple HTC together take approximately 1 hour per couple (15–30 minutes longer for couples with discordant HIV status who require additional counseling). After accounting for travel time to participant's home, follow-ups, paperwork, and other staff responsibilities, we estimated that health advisors could test 3 couples per day. Staff were assumed to work 7 hours per day for 215 days per year (after accounting for holidays, vacation, and sick time). Supply costs per person tested included gloves, HIV screening test kit, and alcohol swabs. Additional supplies for HIV-positive persons included confirmatory test, and tie breaker test (assumed to be used in 5% of all HIV-positive cases). Supply wastage was assumed to be 5%. Transport costs included motorcycles used to travel to participants homes to conduct the intervention. Economic costs were estimated for donated goods, including hospital space. Incremental costs per couple tested were estimated separately for HIV discordant and concordant couples as the former required more staff time for counseling. Costs per couple tested ranged from \$31–37 for the program model and \$14–16 for the task-shifting model. Staff salaries represented the bulk of the costs (65%–70%) (Table 1).

TABLE 1. Unit Costs for the HOPE Intervention Per Couple Tested (2014 USD)

	Program Model			Task-Shifting Model		
	Concordant HIV–	Concordant HIV+	Discordant	Concordant HIV–	Concordant HIV+	Discordant
Personnel	22.90	22.90	25.45	9.27	9.27	10.30
Transportation	2.16	2.16	2.40	2.16	2.16	2.40
Equipment	0.17	0.17	0.18	0.17	0.17	0.19
Supplies	3.63	7.65	6.27	0.53	0.89	0.79
Buildings and overhead	0.96	0.96	1.07	0.96	0.96	1.07
Start-up	0.44	0.44	0.49	0.27	0.27	0.30
Data capture and use	0.52	0.52	0.57	0.44	0.44	0.49
Total (per couple tested)	30.78	34.80	36.43	13.81	14.17	15.55

The task-shifting model replaces professional counselors with community health workers (CHWS), lower cost mobile phones.

Model Estimated Health and Economic Impact of the HOPE Intervention

In the base-case scenario, assuming the HOPE intervention increased male partner ART initiation by 2.1-fold and achieved 60% coverage of male partners, the model estimated that 6987 incident HIV infections and 2603 deaths would be averted over a 10-year time horizon (Table 2). Discounted incremental costs of adding the HOPE intervention to standard of care (ART expansion) were \$14.3 million USD over 10 years with program model and \$9.9 million USD with the task-shifting model. The ICER for adding HOPE to standard of care was \$886 and \$615 USD per DALY averted for the program and task-shifting model, respectively. ICERs were

similar with changing intervention coverage (40%–80%), although health benefits varied, as expected. At 40% coverage of male partners, HIV infections and deaths averted were reduced to 4659 and 1734, respectively, whereas 80% coverage was estimated to avert 9134 HIV infections and 3594 deaths. Lower intervention linkage to ART increased the ICER to \$1076 and \$730 for the program and task-shifting model, respectively, although ICERs were still below the threshold of Kenya’s GDP per capita. Lower intervention linkage to ART at 60% coverage achieved greater reductions in HIV infections and deaths than higher intervention ART linkage at lower (40%) coverage. Similarly, higher HOPE coverage (80%) averted more HIV infections and deaths

TABLE 2. Health and Economic Impact of the HOPE Intervention Under Base-Case Assumptions and Sensitivity Analyses

	Current ART Scale-up	HOPE Intervention*								
		Base-Case	Lower Intervention Coverage (40%)	Higher Intervention Coverage (80%)	30% Lower Intervention Linkage to ART	30% Higher Intervention Linkage to ART	50% Lower ART Dropout	50% Higher ART Dropout	Lower Baseline ART Initiation	5% Increased Uptake of Option B+
Total HIV infections	301,870									
Total deaths†	275,469									
Total DALYs	2,514,475									
HIV infections averted‡	—	6987	4659	9314	5480	8289	7293	6385	6398	8445
Deaths averted‡	—	2603	1734	3474	2040	3090	2614	2539	2502	3304
DALYs averted	—	16,192	10,788	21,601	12,651	19,270	16,282	15,769	15,268	20,419
Incremental costs program model (millions)	—	14.3	9.6	19.1	13.6	15	14.5	14.1	13.9	15.3
Incremental costs task-shifting model (millions)	—	9.9	6.6	13.3	9.2	10.6	10.0	9.7	9.5	10.9
ICER program model (\$/DALY averted)	\$240	\$886	\$886	\$885	\$1076	\$778	\$888	\$892	\$911	\$749
ICER task-shifting model (\$/DALY averted)	\$240	\$615	\$614	\$614	\$730	\$549	\$616	\$616	\$621	\$533

*Costs and infections are over 10-year time horizon. Incremental costs and DALYS associated with each strategy are discounted. HOPE intervention is added to current ART expansion. Percent coverage refers to coverage of male partners of pregnant women. Costs are in 2014 USD.

†All deaths, not only those related to HIV/AIDS.

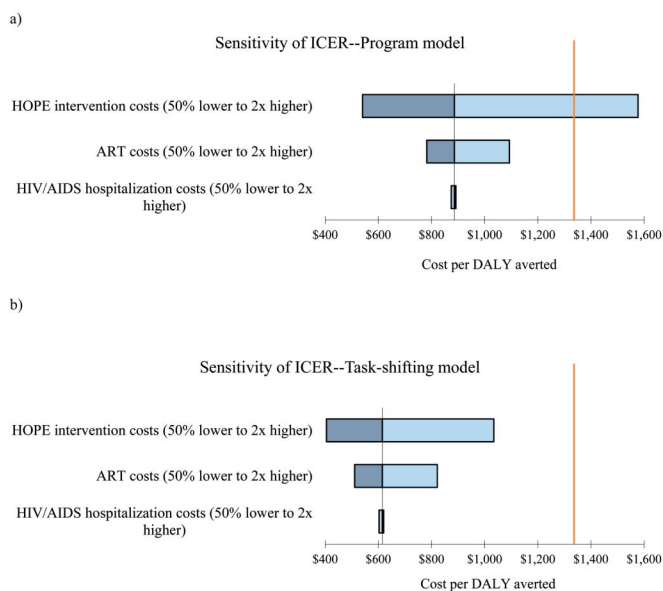
‡Discounted health benefits.

compared with 60% coverage with higher ART linkage. The ICERs were robust to changes in ART dropout although intervention health benefits were lower at increased dropout rates. Because ART expansion in the next 10 years is uncertain, we assessed a scenario in which ART was rolled out at a lower rate (lower baseline ART initiation); this decreased intervention health benefits and resulted in higher ICERs—although they remained below the threshold of Kenya's GDP per capita. We also assessed a scenario in which undergoing couple HIV testing through the HOPE intervention increased women's initiation of Option B+. Results showed that increasing Option B+ initiation by just 5% yielded the highest benefits and lowest ICERs of all strategies at 60% coverage; ICERs were \$749 and \$533 for the program and task-shifting model, respectively. Overall, the HOPE intervention was projected to achieve 8% population coverage per year, as 14% of women are pregnant annually and 60% of couples would receive the HOPE intervention.

Figure 1 displays tornado diagrams of the sensitivity of ICERs for the program (1a) and task-shifting cost model (1b) to changes in the cost of HOPE, ART, and HIV/AIDS-related hospitalization. ICERs for both cost models were most sensitive to HOPE intervention costs, with the ICER exceeding the GDP for the program model at twice the intervention costs. ICERs were less sensitive to ART costs; higher ART costs resulted in less attractive (higher) ICERs and lower ART costs resulted in lower ICERs. The ICERs were least sensitive to hospitalization costs, which were inversely related to ICERs.

DISCUSSION

Women in Kenya attend antenatal care at rates over 90% and the majority are tested for HIV.¹⁹ However, they



*Orange line represents Kenya's GDP per capita, the threshold utilized for cost-effectiveness.

FIGURE 1. Tornado diagram of ICERs with varying costs. Orange line represents Kenya's GDP per capita, the threshold used for cost-effectiveness.

continue to experience disproportionately high HIV incidence, partially because of the lack of HIV testing and linkage for their male partners.⁹ Scaling up the HOPE intervention in the former Nyanza Province, Kenya can cost-effectively reduce HIV infections in pregnant women and their partners while averting morbidity and mortality associated with late initiation of ART in both sexes. Because men present to health care facilities at later stages of HIV and have lower ART linkage and poorer clinical outcomes, they are more likely to transmit HIV to their female partners.³⁶ Additionally, morbidity and mortality in men has a negative economic impact on women and their children. The HOPE intervention can identify HIV-positive men earlier in the course of their illness and link them to care before they infect their pregnant partners.

The projected health benefits of the HOPE intervention varied depending on the coverage achieved, the intervention's ability to link male partners to ART, and the baseline levels of ART initiation and dropout. However, the ICERs were robust to changes in these parameters and remained very cost-effective (Table 2). ICERs were most sensitive to increases in intervention costs, with the program model exceeding the cost-effectiveness threshold of Kenya's GDP per capita at double intervention costs (Fig. 1). However, the detailed microcosting completed as part of the analysis increases our confidence in the estimated costs. Furthermore, the task-shifting model remained cost-effective despite increased intervention costs. In addition, if the HOPE intervention increases women's adherence to ART, as found in previous studies, the health benefits increase substantially and the ICERs become more attractive.¹⁶

Scaling up the HOPE intervention will likely be more affordable if implemented under a task-shifting model as staff salaries account for the majority of program costs. Training community health workers to conduct health interventions is an increasingly used strategy in SSA; community health workers can fill in service gaps caused by the shortage of health care professionals and deliver health care to rural areas more efficiently.³⁷ Integrating health interventions is another way to reduce program costs. For example, community health workers can deliver the HOPE intervention along with diabetes and hypertension screening. Integrating services can also reduce the stigma associated with an HIV testing intervention.³⁸ Additionally, a tiered program can be implemented in which women are given a few weeks to bring their partner into the clinic for testing. Those who do not present to the clinic can be followed up at home. Furthermore, a risk score could be developed to identify male partners who are less likely to come to the clinic so they can be traced at home. Such a score has been developed for HIV intimate partner notification in Malawi and has been shown to have good sensitivity and specificity.³⁹ Additionally, the HOPE intervention can be used to identify serodiscordant couples to target pre-exposure prophylaxis (PrEP), further integrating HIV services and decreasing costs. Finally, the HOPE intervention can be implemented within the context of home or mobile HTC for the general population. Although HOPE is cost-effective, it has a limited population-level impact on HIV burden as it is targeted to a specific portion of the population.

Overall, it is projected to reach 8% population coverage annually and reduce approximately 2.5% of HIV infections in Nyanza over 10 years. Therefore, it should be combined with community-based HIV interventions that have been found to be cost-effective in other settings.³⁵

The strengths of our analysis include obtaining primary cost and effectiveness data from a randomized controlled trial in Nyanza, Kenya. Our results should be interpreted within the context of our limitations. We assume that male partners testing HIV-positive through the HOPE intervention have the same rate of linkage to ART as facility testing. Community-based testing can result in lower linkage rates because it is conducted outside the health care system.⁴⁰ If implemented, the HOPE intervention should be monitored for linkage, and community health workers will likely need to conduct follow-up home visits or make phone calls to encourage reluctant partners to link to care. However, if the HOPE intervention increases adherence to ART and prevention of mother to child transmission, health benefits could be greater than projected. The effectiveness estimates were obtained from a randomized controlled trial that used highly trained and closely monitored health advisors. If the HOPE intervention is scaled up through a government program, effectiveness may decrease if counselors were less able to persuade reluctant male partners to undergo testing, or were less efficient in delivering the intervention. We explored a scenario of low intervention effectiveness (only 30% increase in linkage to ART) and HOPE remained cost-effective with the task-shifting scenario, although the intervention with full program costs exceeded Kenya's GDP per capita (Supplemental Digital Content, <http://links.lww.com/QAI/A828>). As expected, the health benefits were considerably lower. This highlights the importance of follow-up to ensure linkage to care. Additionally, implementing standardized training and monitoring for community health workers would be essential in maintaining intervention fidelity. Currently, community health workers in Kenya are not trained to conduct HTC. Therefore, efficiency may be lower than expected during the first few years of the intervention as community health workers solidify their HIV testing skills. Indeed, the translation of a clinical trial to real-world implementation poses significant challenges, and the HOPE intervention would be most successful if it is integrated into other health interventions and uses community health workers instead of higher cadre staff.

In conclusion, we find the HOPE intervention to be a cost-effective method to reduce HIV disease burden in Nyanza, Kenya. Our results are similar to previous analyses that have found community-based HIV counseling and testing in SSA to be cost-effective.^{35,41} Although absolute costs will vary, our results are likely generalizable to other regions of SSA with a similar HIV epidemic profile.

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