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# Facility HIV Self-Testing in Outpatient Departments: An Assessment of Characteristics and Concerns of Outpatients Who Opt Out of Testing in Malawi

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**Background:** Facility HIV self-testing (HIVST) in outpatient departments can dramatically increase testing among adult outpatients. However, it is still unclear why populations opt out of facility HIVST and reasons for opt out. Using data from a parent facility HIVST trial, we sought to understand individual characteristics associated with opting out of facility HIVST and reported reasons for not testing.

**Methods:** Exit surveys were conducted with outpatients aged  $\geq 15$  years at 5 facilities in Central and Southern Malawi randomized to the facility HIVST arm of the parent trial. Outpatients were eligible for our substudy if they were offered HIVST and eligible for HIV testing (ie, never previously tested HIV positive and tested  $\geq 12$  months ago or never tested). Summary statistics and multivariate regression models were used.

**Results:** Seven hundred seventy-one outpatients were included in the substudy. Two hundred sixty-three (34%) opted out of HIVST. Urban residency (adjusted risk ratios [aRR] 3.48; 95% CI: 1.56 to 7.76) and self-reported poor health (aRR 1.86; 95% CI: 1.27 to 2.72) were associated with an increased risk of opting out. Male participants had a 69% higher risk of opting out (aRR 1.69; 95%

CI: 1.14 to 2.51), with risk being 38% lower among working male participants. Primary reasons for not testing were feeling unprepared to test (49.4%) and perceived low risk of HIV infection (30.4%)—only 2.6% believed that HIVST instructions were unclear, and 1.7% were concerned about privacy.

**Conclusion:** Working, risky sexual behavior, rural residence, and good self-rated health were positively associated with opting out of HIVST among outpatients. Strategies to address internalized barriers, such as preparedness to test and perceived need to test, should be incorporated into facility HIVST interventions.

**Key Words:** HIV/AIDS, sub-Saharan Africa, HIV self-testing, barriers to care, outpatient department

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## INTRODUCTION

In 2014, the Joint United Nations Programme on HIV/AIDS set ambitious targets to curb the HIV epidemic by 2030. The accelerated “Fast Track” target proposes that 95% of those infected with HIV know their status, 95% of those with a known HIV-positive status initiate antiretroviral treatment, and 95% of those on treatment reach viral suppression.<sup>1</sup> Despite the increased visibility and access to HIV testing services in sub-Saharan Africa, acceptability and uptake of HIV testing is still suboptimal.<sup>2,3</sup> In Malawi, 88% know their status, with an estimated 90% of women living with HIV know their HIV status, whereas only 85% of men living with HIV know their status.<sup>4</sup> Youth also experience lower testing coverage.<sup>5</sup> Remaining barriers to testing uptake must be addressed to reach the first 95%, particularly for men and youth.

Provider-initiated testing and counseling within health facilities remains a primary source of testing in the region<sup>6</sup> and in Malawi.<sup>4</sup> For generalized epidemics, outpatient settings will likely continue to be a particularly important venue for implementing mass testing strategies because outpatient departments (OPD) are frequented by adult men, women, and youth seeking acute care.<sup>7</sup> However, HIV testing coverage in outpatient settings is low, with data showing that only 11%–18% of eligible outpatients tested<sup>8,9</sup> and positivity rates have declined as the proportion of individuals living with HIV who are already diagnosed has increased over time.<sup>10</sup> Primary barriers to outpatient testing include overburdened health care

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workers, lack of private spaces to conduct HIV testing in busy clinics,<sup>11</sup> and the human resources required to provide ample testing coverage—1 study in Malawi found that personnel costs contributed the overwhelming majority of costs associated with facility testing.<sup>12</sup> In addition, extended wait times to access HIV testing may deter outpatients from testing because HIV testing is often not integrated into routine outpatient consultations.

HIV self-testing (HIVST), whereby individuals can test themselves without supervision from health care workers, is a highly acceptable strategy to address traditional barriers to HIV testing.<sup>13,14</sup> HIVST provides private, convenient, and fast HIV testing services, potentially addressing the lack of privacy and long wait times common in traditional provider-initiated testing and counseling.<sup>15,16</sup> The strategy also allows for increased testing volumes with fewer human resource inputs because outpatients can test themselves, without one-on-one supervision from a health care worker (HCW). HIVST has been associated with an increased testing uptake among outpatients in Malawi.<sup>17</sup> However, there are limited data on specific barriers to using HIVST and the characteristics of those who opt out of HIVST services.<sup>18</sup> Knowing which populations are more likely to opt out of HIVST will allow for a better understanding of who is still missing from HIVST strategies and what additional innovations are required to reach them.

To our knowledge, only 1 study has examined factors associated with actual HIVST use and found that men with lower risk behavior and women with lower education and wealth were less likely to use community-based HIVST.<sup>18</sup> Literature from traditional blood-based testing (ie, provider testing) show that men, youth, and individuals with high levels of perceived HIV-related stigma, low perceived risk of HIV infection, time conflicts, and perceived lack of privacy and confidentiality are all more likely to opt out of testing.<sup>19</sup> However, it is unclear whether factors associated with opt out for blood-based provider testing remain salient for HIVST use because HIVST should address many of the barriers associated with traditional HIV testing.

In this article, we conducted a secondary analysis using data from our cluster-randomized trial of facility-based HIVST in outpatient settings in Malawi to examine characteristics and concerns of adult outpatients who opted out of HIVST.

## METHODS

### Study Design

#### Study Design and Setting

This is a cross-sectional study using data from a cluster-randomized trial aimed to assess the impact of facility-based HIVST among adult outpatients compared with standard of care and optimized standard of care.<sup>9,20</sup> Participants were recruited from 15 health facilities located in high HIV prevalent areas in central and southern Malawi. Facilities represented a mixture of facility types, namely, district hospital, mission hospital, and health center. Constrained randomization was used to allocate 1:1:1 facility to 3 arms:

(1) standard provider-initiated testing and counseling per the national guidelines; (2) optimized provider-initiated testing with additional training and job aids for health workers to improve testing implementation; and (3) facility-based HIVST whereby OraQuick ADVANCE HIV I/II self-testing kits were distributed during adult outpatient services for use while waiting to see a provider. Details about the parent trial are provided in the primary article.<sup>9</sup> In this article, we focus on data from outpatients in the facility HIVST arm. Facilities in the HIVST intervention arm were spread across central (n = 3) and southern (n = 2) Malawi and varied by facility type: district hospital (n = 1), mission hospital (n = 1), and large health center (n = 3).

### Study Procedures and Participants

Facility HIVST was offered to adult outpatients during waiting periods for routine outpatient consultations and included 5 components: (1) health talk about the importance of HIV testing and pretest counseling conducted by a facility-based HIV counselor; (2) HIVST demonstration conducted by study staff; (3) opt out HIVST kit distribution to all outpatients  $\geq 15$  years of age (HIVST kit offered to every outpatient), with support for kit use provided as needed (the intervention was designed to optimize unassisted HIVST and only provide assistance to those who needed it); and (4) private spaces for HIVST kit interpretation; and (5) an opportunity to disclose their HIVST result to study staff or outpatient providers. Clients who chose to disclose were given posttest counseling, and for those tested HIV positive, HIV linkage services (escorting the client to the antiretroviral (antiretroviral treatment) department within the health facility) were provided. All activities beside kit interpretation took place in OPD waiting spaces, facilitating mass HIVST kit distribution by a limited number of staff. Most outpatients often waited hour(s) to access outpatient services,<sup>20</sup> allowing ample time to receive and use HIVST kits.

Outpatients  $\geq 15$  years of age were encouraged to use HIVST kits if they had never tested HIV positive, had not tested for HIV within the past 12 months, and were comfortable using a self-test kit in the OPD waiting space. Adult outpatients opted in for HIV testing by raising their hand to request a HIVST kit (they did not have to leave the waiting area). Those who received an HIVST kit were encouraged to use the kit immediately and interpret test results before seeing the health care provider for routine outpatient services. Locked boxes were available at all exit points of OPDs to facilitate disposal of HIVST kits.

In the parent trial, a subset of adult outpatients was systematically recruited by research assistants to complete an exit survey (recruiting every 10th outpatient leaving the OPD). Survey eligibility criteria included:  $\geq 15$  years of age, receipt of outpatient services on the day of the survey, receipt of all health services planned for that day (including any HIV-related services), and being able and willing to provide oral consent.<sup>9</sup> In this article, we included participants who (1) were in the HIVST arm; (2) reported being offered HIVST kits (ie, they had the opportunity to test); and (3) reported never testing HIV positive or having tested  $> 12$  months ago (hereafter referred to as “in need”

of testing) before being enrolled in the trial. We exclude outpatients tested <12 months ago to align with the Ministry of Health guidelines around who within the general population should test for HIV—therefore, everyone in our sub-sample should have been tested on the day of the intervention.

### Study Exposure, Outcomes, and Covariates

The exit survey included 6 primary domains: (1) sociodemographics, (2) previous use of HIV services and test results, (3) sexual risk behavior, (4) health services received that day (including HIV testing and treatment), (5) perceived acceptability of the intervention, and (6) the presence of any adverse events associated with the intervention. All surveys were completed in the local language (Chichewa) and lasted ~20 minutes.

The exposure for this study was being offered an HIVST kit on the day they visited the health facility by an HCW, measured using the participant’s self-report during the exit survey. A binary variable was used to assess whether a participant was offered an HIVST kit. Participants who were not offered and were therefore not exposed are excluded from this study. We also excluded participants who had missing data on the exposure (n = 130; 14%)—participants with missing data on the exposure did not differ by key demographic characteristics (gender, age, and marital status).

The primary outcome of interest was refusing to use an HIVST kit when offered a kit by an HCW. The outcome was self-reported by the participant and measured as a binary (yes/no) variable. We documented reasons for refusing to use HIVST kit after being offered by an HCW.

We considered a variety of potential factors that could influence refusal to use an HIVST kit based on other literature on HIV testing uptake.<sup>9</sup> We categorized factors that could hinder usage of HIVST kit into 3: demographic factors, health factors, and previous sexual behavior. Demographic factors considered included the following: gender, marital status (binary defined as currently married or being in a steady relationship), education level attended (categorized as none, primary level, and secondary or higher level), working for pay in the past 7 days (binary), and the type of residential area (rural vs urban). Health factors considered included: self-rated health at the time of the survey (dichotomized into good/very good and poor/very poor), previously seeking health services (defined as attended a health facility in the past 6 months), and never tested for HIV before (showing potential willingness for HIV testing more generally). We used a combined variable to measure sexual risk behavior: an additive variable including (1) condomless sex with a nonprimary partner in the past 12 months and (2) more than 2 sexual partners in the past 12 months. Applicable survey questions are in Appendix A, Supplemental Digital Content, <http://links.lww.com/QAI/C179>.

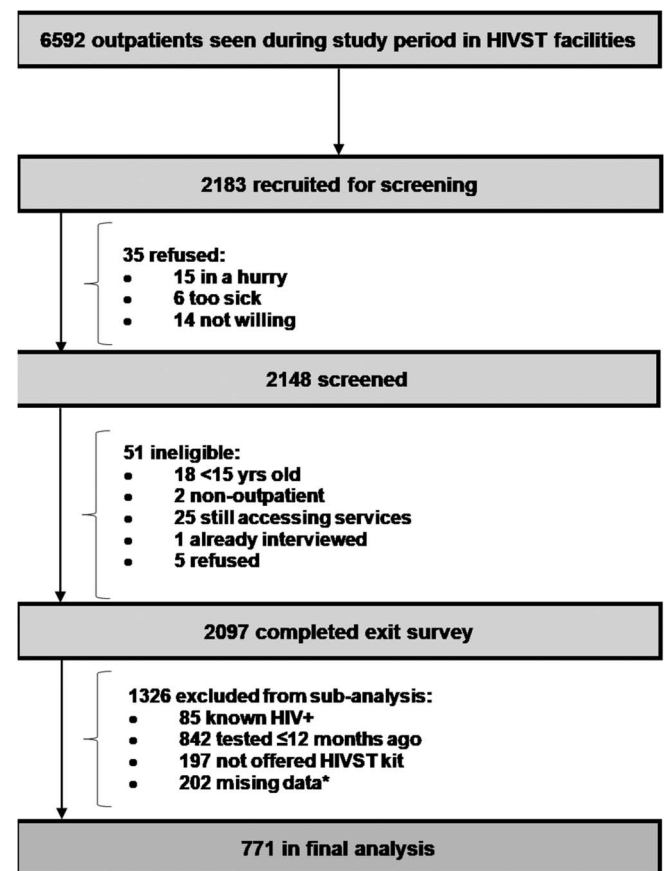
### Analysis

We used descriptive statistics to characterize study participants. Categorical variables were analyzed using frequencies and percentages, with differences between those who used HIVST kits and those who refused assessed using  $\chi^2$  test.

Age was collected as a continuous variable and was collapsed into a categorical variable (adolescents [aged 15–24 years] vs adults [aged 25 years or older]) using priori knowledge of categories used in routine HIV programs.

In this study, the primary outcome was very common (>10%); therefore, we assessed factors associated with the risk of opting out of HIVST kit using regression analysis. In univariate analysis, we estimated the effect of each covariate separately on the risk of opting out after adjusting for the fixed effects of clustering at facility level. The association between opting out of HIVST and covariates was then examined in a multivariate regression model to control for confounding effects of each variable on the other.

We examined the association between opting out of HIVST and the covariates using a gender-stratified analysis. Although the univariate analysis of the association between opting out of HIVST and gender showed weak evidence of differences by gender (Wald  $\chi^2$  P-value = 0.0713), there are significant gender differences across the HIV care cascade in Malawi.<sup>21</sup> Therefore, gender-stratified analysis was deemed necessary to investigate any gender differences in the association between opting out of HIVST and the covariates. We then concluded our analysis with a gender-stratified



\*Individuals were not asked if they were offered HIVST, therefore they are excluded from the analyses

FIGURE 1. Flowchart for study enrollment.

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description of reported barriers to facility-based HIVST among those who opted out of testing. Respondents were allowed to report multiple barriers to facility-based HIVST; all reported barriers are pooled together for analysis.

within the past 12 months; and 197 of 1326 (14.9%) were not offered HIVST during their OPD visit. We included 771 outpatients ( $\geq 15$  years of age) in the analysis: 508 (66%) users and 263 (34%) opted out (Fig. 1).

## Ethical Approval

The main trial was approved by the National Health and Sciences Research Committee in Malawi, the Institutional Review Board at the University of California Los Angeles (Los Angeles, CA) NCT03271307, and Pan African Clinical Trials (PACTR201711002697316).

## RESULTS

Between September 12, 2017, and February 23, 2018, 2183 outpatients attended a facility randomized to the HIVST arm. Among these, 2148 (98.4%) were screened, and 2097 (96.1%) completed an exit survey. In total, 1326 participants who completed an exit survey were excluded from the analysis: 85 of 1326 (6.4%) had tested HIV positive before enrolling in the study; 842 of 1326 (63.5%) tested for HIV

## Baseline Characteristics of Participants

Overall, 304 (39%) were male and 467 (61%) were female (Tables 1, 2). Participants were 25 years or older (495; 64%), married or in a steady relationship (564; 73%), had completed primary education (424; 59%), did not work in the past 7 days (557; 72%), and were resident in rural areas (568; 74%). Among the participants, 533 (69%) reported good or very good self-rated health, 501 (65%) had visited a health facility in the past 6 months, and 204 (27%) had never tested for HIV. In total, 209 (27%) were categorized as having high risky sexual behavior.

Baseline characteristics showed significant differences by gender ( $P = 0.05$ ). Approximately, 34% (93) of the male participants had completed secondary or a higher education level compared with 14% (63) of the female participants. Male participants reported working in the past 7 days (38% vs 21%) and were resident in urban areas (35% vs 21%). Female

**TABLE 1.** Demographic Characteristics of Participants by Sex (n = 771)

Variable, n (%)	Total N = 771 (%)	Female n = 467 (61%)	Male n = 304 (39%)	P
<b>Demographics</b>				
Age group				
15–24 years old	276 (35.8)	155 (33.2)	121 (39.8)	
25+ years old	495 (64.2)	312 (66.8)	183 (60.2)	0.061
Marital status				
Not married	207 (26.9)	126 (27.0)	81 (26.6)	
Married/steady relationship	564 (73.1)	341 (73.0)	223 (73.4)	0.918
Education level				
None	135 (18.9)	116 (26.4)	19 (6.9)	
Primary	424 (59.3)	260 (59.2)	164 (59.4)	
Secondary or higher	156 (21.8)	63 (14.4)	93 (33.7)	<0.001
Worked in past 7 d				
No	557 (72.2)	367 (78.6)	190 (62.5)	
Yes	214 (27.8)	100 (21.4)	114 (37.5)	<0.001
Area of residence				
Rural	568 (73.7)	371 (79.4)	197 (64.8)	
Urban	203 (26.3)	96 (20.6)	107 (35.2)	<0.001
<b>Health services</b>				
Self-rated health				
Good/very good	533 (69.1)	325 (69.6)	208 (68.4)	
Poor/very poor	238 (30.9)	142 (30.4)	96 (31.6)	0.731
Visited a health facility in the past 6 mo				
No	270 (35.0)	127 (27.2)	143 (47.0)	
Yes	501 (65.0)	340 (72.8)	161 (53.0)	<0.001
Previous HIV test status				
Tested for HIV	567 (73.5)	366 (78.4)	201 (66.1)	
Never tested for HIV	204 (26.5)	101 (21.6)	103 (33.9)	<0.001
<b>Sexual risk behavior†</b>				
Low-risk behavior	562 (72.9)	386 (82.7)	176 (57.9)	
High-risk behavior	209 (27.1)	81 (17.3)	128 (42.1)	<0.001

\*† test P value.

†Defined as having condomless sex with an unknown partner or having 2 or more sexual partners.

**TABLE 2.** Demographics Characteristics of Participants Who Used and Opted out (n =771)

Variable, n (%)	Total N = 771 (%)	Used HIVST n = 508 (66%)	Opted out of HIVST n = 263 (34%)	$\chi^2$ P
<b>Demographics</b>				
<b>Gender</b>				
Female	467 (61)	328 (65)	139 (53)	0.002
Male	304 (39)	180 (35)	124 (47)	
<b>Age group</b>				
15–24 years old	276 (36)	171 (34)	105 (40)	0.086
25+ years old	495 (64)	337 (66)	158 (60)	
<b>Marital status</b>				
Not married	564 (73)	377 (74)	187 (71)	0.356
Married/steady relationship	207 (27)	131 (26)	76 (29)	
<b>Education level</b>				
None	135 (19)	93 (20)	42 (17)	0.065
Primary	424 (59)	289 (61)	135 (56)	
Secondary or higher	156 (22)	91 (19)	65 (27)	
<b>Worked in past 7 days</b>				
No	557 (72)	352 (69)	205 (78)	0.011
Yes	214 (28)	156 (31)	58 (22)	
<b>Area of residence</b>				
Rural	568 (74)	419 (82)	149 (57)	<0.001
Urban	203 (26)	89 (18)	114 (43)	
<b>Health services</b>				
<b>Self-rated health</b>				
Good/very good	533 (69)	374 (74)	159 (60)	<0.001
Poor/very poor	238 (31)	134 (26)	104 (40)	
<b>Visited a health facility in the past 6 months</b>				
No	270 (35)	181 (36)	89 (34)	0.621
Yes	501 (65)	327 (64)	174 (66)	
<b>Previous HIV test status</b>				
Tested for HIV	567 (74)	386 (76)	181 (69)	0.033
Never tested for HIV	204 (26)	122 (24)	82 (31)	
<b>Sexual risk behavior†</b>				
Low-risk behavior	562 (73)	365 (72)	197 (75)	0.366
High-risk behavior	209 (27)	143 (28)	66 (25)	

\*t test P value.

†Defined as having condomless sex with an unknown partner or having 2 or more sexual partners.

participants were more likely to report visiting a health facility (340; 73%) and previously testing for HIV (366; 78%) than male participants (161; 53% and 103; 34% respectively). Approximately, 40% (128) male participants were categorized as having risky sexual behavior compared with 17% (81) female participants.

### Characteristics of Opting out of HIVST

Among participants who opted out, 124 (47%) were male and aged 25 years or older (158; 60%) (Table 3). Less than one-quarter of participants who opted out (58; 22%) worked in the past 7 days and 43% (114) resided in urban areas. Approximately, 60% (159) of the participants who opted out reported good health and more than two-thirds (181; 69%) had an HIV test in the past 6 months (Fig. 2).

In univariable analysis, working in the past 7 days significantly ( $P = 0.05$ ) reduced the risk of opting out by more than one-third (RR 0.61; 95% CI: 0.46 to 0.80), whereas

urban residency increased the risk of opting out by approximately four-fold (RR 3.60; 95% CI: 1.38 to 9.37). Adjusting for the confounding effects of each variable on the other, several variables showed strong associations with opting out. The risk of opting out increased by more than two-thirds among male participants (adjusted risk ratios [aRR] 1.69; 95% CI: 1.14 to 2.51). Participants who had worked in the past 7 days had more than 50% reduction risk of opting out (aRR 0.48; 95% CI: 0.39 to 0.58) compared with those who did not work. Urban residency (aRR 3.48; 95% CI: 1.56 to 7.76) and self-reported poor health (vs good health) (aRR 1.86; 95% CI: 1.27 to 2.72) were associated with an increased risk of opting out of HIVST (Fig. 3).

### Gender Stratified Characteristics Associated With Opting out of HIVST

Among female participants, the risk of opting out reduced by more than one-third (risk ratios [RR] 0.64; 95%

**TABLE 3.** Risk Ratio Comparing Participants Who Refused HIVST With Those Who Used (n =771)

Variable n (%)	Opted out of HIVST n = 263 (34%)	Univariable RR		aRR	
		RR	95% CI	aRR	95% CI
<b>Demographics</b>					
<b>Gender</b>					
Female	139 (52.9)	Ref		Ref	
Male	124 (47.1)	1.63†	0.96 to 2.76	1.69‡	1.14 to 2.51
<b>Age group</b>					
15–24 years old	105 (39.9)	Ref		Ref	
25+ years old	158 (60.1)	0.76	0.51 to 1.16	0.98	0.62 to 1.56
<b>Marital status</b>					
Not married	76 (28.9)	Ref		Ref	
Married/steady relationship	187 (71.1)	0.85	0.52 to 1.40	1.02	0.81 to 1.29
<b>Education level</b>					
None	42 (17.3)	Ref		Ref	
Primary	135 (55.8)	1.03	0.72 to 1.49	1.01	0.61 to 1.65
Secondary or higher	65 (26.9)	1.58	0.51 to 4.88	0.92	0.51 to 1.66
<b>Worked in past 7 days</b>					
No	205 (78.0)	Ref		Ref	
Yes	58 (22.0)	0.61§	0.46 to 0.80	0.48§	0.39 to 0.58
<b>Area of residence</b>					
Rural	149 (56.7)	Ref		Ref	
Urban	114 (43.3)	3.60‡	1.38 to 9.37	3.48§	1.56 to 7.76
<b>Health services</b>					
<b>Self-rated health</b>					
Good/very good	159 (60.5)	Ref		Ref	
Poor/very poor	104 (39.5)	1.83†	0.97 to 3.45	1.86§	1.27 to 2.72
<b>Visited a health facility in the past 6 months</b>					
No	89 (33.8)	Ref		Ref	
Yes	174 (66.2)	1.08	0.79 to 1.49	1.16	0.90 to 1.49
<b>Previous HIV test status</b>					
Tested for HIV	181 (68.8)	Ref		Ref	
Never tested for HIV	82 (31.2)	1.43	0.67 to 3.05	1.26	0.56 to 2.83
<b>Sexual risk behavior*</b>					
Low-risk behavior	197 (74.9)	Ref		Ref	
High-risk behavior	66 (25.1)	0.86	0.61 to 1.20	0.79	0.55 to 1.15

\*Defined as having condomless sex with an unknown partner or having 2 or more sexual partners.

†P value < 0.1.

‡P value < 0.05.

§P value < 0.001.

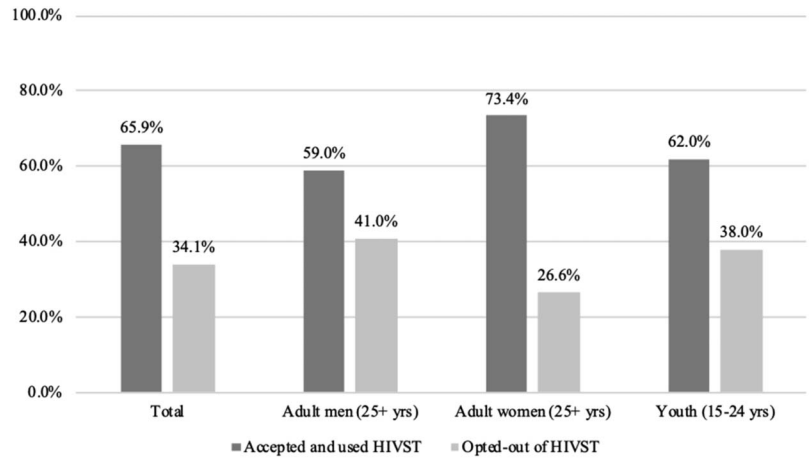
CI: 0.47 to 0.87) in participants aged 25 years or older and approximately 60% (RR 0.41; 95% CI: 0.30 to 0.56) in participants who worked in the past 7 days. Urban residency increased the risk of opting out by four-fold (RR 4.08; 95% CI: 1.62 to 10.31). In multivariable analysis, the associations observed in univariable analysis among female participants were sustained, except age and education level attained. Female participants aged 25 years or older or those who completed secondary or higher education had an approximately 30% reduction in the risk of opting out (aRR 0.70; 95% CI: 0.36 to 1.39 and aRR 0.73; 95% CI: 0.31 to 1.73)—these associations were not significant.

The risk of opting out was approximately 38% (RR 0.72; 95% CI: 0.53 to 0.98) lower among male participants who worked. Male participants were more likely to opt out if they resided in urban areas (RR 2.82; 95% CI: 1.03 to 7.72),

reported poor health (RR 2.1; 95% CI: 1.64 to 2.68), and had visited a facility in the past 6 months (RR 1.58; 95% CI: 1.13 to 2.21). High-risk sexual behavior significantly reduced the risk of opting out by 44% (RR 0.56; 95% CI: 0.37 to 0.85) among male participants. In multivariable analysis, being married and working in the past 7 days significantly reduced the risk of opting out (aRR 0.63; 95% CI: 0.43 to 0.91 and aRR 0.59; 95% CI: 0.50 to 0.71 respectively). Male participants who reported poor health (aRR 2.27; 95% CI: 1.88 to 2.74) and visited a health facility in the past 6 months (aRR 1.57; 95% CI: 1.35 to 1.84) had a higher risk of opting out (Tables 4, 5).

### Reasons for Opting out of HIVST

Approximately half of the participants cited “not being ready to test” as a reason for opting out (Table 6). Other



**FIGURE 2.** Proportion of outpatients who opted out of HIVST (n = 771).

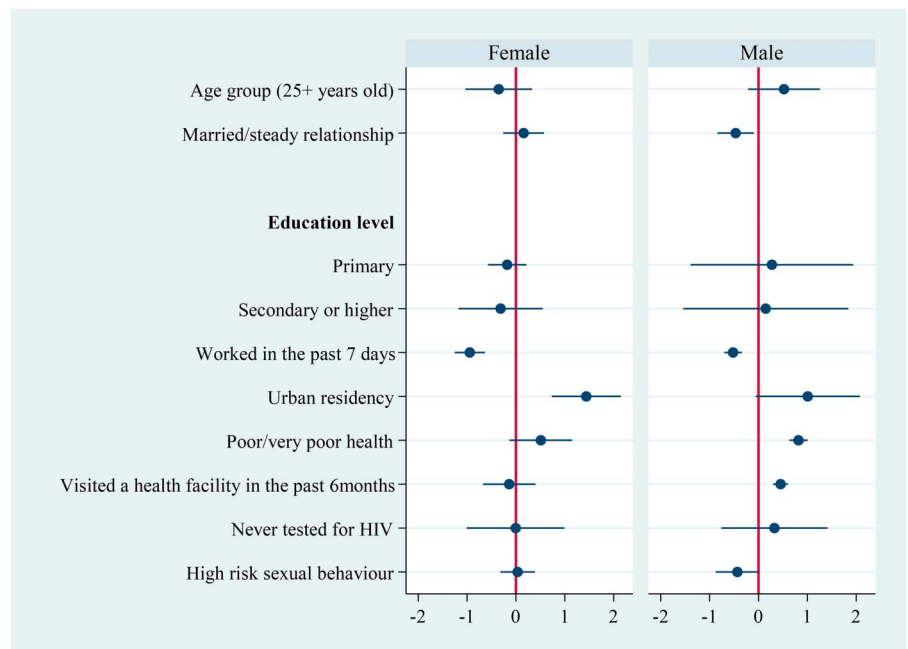
reasons for opting out included “not seeing the need to test” (30%) and “being busy” (11%). Men were more likely to cite “not needing a test” as a reason for opting out than women (34% vs. 27%, *P* value = 0.250) and being too busy (15% vs 9%, *P*-value = 0.134).

### DISCUSSION

Using data from a facility HIVST trial in Malawi, we found that 34% of all adult outpatients in need of testing (defined as never tested HIV positive and never tested or tested > 12 months ago) opted out of facility HIVST, although testing coverage was significantly higher than the standard of care provider-initiated testing and counseling.<sup>17</sup> Those working for pay were less likely to opt out of HIVST, whereas those residing in urban residence, being males, and those with self-rated poor health were more likely to opt out

of testing services. Among women being an adult was associated with opting out of testing compared with men. When examining reasons for opting out of HIVST, traditional facility-based barriers to HIV testing were rarely cited, such as loss of confidentiality or privacy, wait times, or provider attitudes,<sup>22–24</sup> highlighting that facility HIVST strategies can overcome many facility-based barriers to testing.

An analysis by subpopulations showed that for both men and women, working was associated with uptake of HIVST. Specifically for men, being married and in a steady relationship was negatively associated with opting out of testing. In addition, in men, a previous visit and the number of visits to the facility positively affected opting out of facility-based HIVST. Men with poor self-rated health and visiting the facility may be more preoccupied with their current health concerns, reducing their desire to test. Other literature shows



**FIGURE 3.** Forest plot of risk ratios of participants who refused HIVST by sub-population (n = 771).



**TABLE 4.** Risk Ratios of Participants Who Refused HIVST by Subpopulation (n =771)

Variable n (%)	Female		Male	
	RR (95% CI)	aRR (95% CI)	RR (95% CI)	aRR (95% CI)
<b>Demographics</b>				
Age group				
15–24 year old	Ref	Ref	Ref	Ref
25+ years old	0.64§ (0.47 to 0.87)	0.70 (0.36 to 1.39)	1.02 (0.47 to 2.21)	1.69 (0.81 to 3.52)
Marital status				
Not married	Ref	Ref	Ref	Ref
Married/steady relationship	1.08 (0.74 to 1.58)	1.17 (0.77 to 1.77)	0.62 (0.28 to 1.36)	0.63‡ (0.43 to 0.91)
Education level				
None	Ref	Ref	Ref	Ref
Primary	0.87 (0.71 to 1.06)	0.84 (0.56 to 1.24)	1.10 (0.27 to 4.41)	1.32 (0.25 to 6.97)
Secondary or higher	1.42 (0.48 to 4.22)	0.73 (0.31 to 1.73)	1.35 (0.31 to 5.99)	1.56 (0.21 to 6.28)
Worked in the past 7 days				
No	Ref	Ref	Ref	Ref
Yes	0.41§ (0.30 to 0.56)	0.39§ (0.29 to 0.53)	0.72‡ (0.53 to 0.98)	0.59§ (0.50 to 0.71)
Area of residence				
Rural	Ref	Ref	Ref	Ref
Urban	4.08§ (1.62 to 10.31)	4.22§ (2.08 to 8.54)	2.82‡ (1.03 to 7.72)	2.74* (0.94 to 7.97)
<b>Health services</b>				
Self-rated health				
Good/very good	Ref	Ref	Ref	Ref
Poor/very poor	1.65 (0.64 to 4.26)	1.66 (0.88 to 3.16)	2.10§ (1.64 to 2.68)	2.27§ (1.88 to 2.74)
Visited a health facility in the past 6 months				
No	Ref	Ref	Ref	Ref
Yes	0.94 (0.67 to 1.32)	0.87 (0.51 to 1.49)	1.58‡ (1.13 to 2.21)	1.57§ (1.35 to 1.84)
Previous HIV test status				
Tested for HIV	Ref	Ref	Ref	Ref
Never tested for HIV	1.26 (0.51 to 3.12)	0.99 (0.37 to 2.70)	1.44 (0.51 to 4.06)	1.39 (0.47 to 4.12)
<b>Sexual risk behavior†</b>				
Low-risk behavior	Ref	Ref	Ref	Ref
High-risk behavior	0.99 (0.82 to 1.21)	1.03 (0.73 to 1.48)	0.56‡ (0.37 to 0.85)	0.65* (0.42 to 1.01)

\**t* test *P* value.  
 †Defined as having condomless sex with an unknown partner or having 2 or more sexual partners.  
 ‡Significant at 95% confidence level.  
 §Significant at 99% confidence level.

similar perceptions among outpatient men, showing that men may want to resolve their current health concerns before testing.<sup>25,26</sup> This presents an important opportunity for HIVST programs to adapt pretest counseling strategies to educate outpatients, especially men, about the link between HIV and poor health, emphasizing that HIV testing is part of their outpatient consultation visit and important for improving their immediate and long-term health concerns. However, in women, being 25+ years was positively associated with opting out of testing compared with men both young and adults. Although reasons are not clear as to why adult women opted out of testing, a qualitative study in Malawi showed that concern for nonvoluntary disclosure of the testing results in the open spaces is a barrier for adult women to pick up HIVST. Provision of private spaces as part of HIVST programs for viewing results is crucial to encourage shy adult women test for HIV.<sup>27</sup>

Our study observed higher risk of opting out among urban populations as compared with rural residents for both

men and women. This is consistent with other HIV testing studies that report low uptake of testing among urban populations across the region.<sup>28–30</sup> Reasons for this association are unclear and deserve further attention. Additional efforts to reach urban populations may be needed, such as tailored messaging and counseling that directly motivates urban populations.

Individuals who felt ill were more likely to opt out of HIVST than those who felt healthy at the time of the survey. Other literature from Malawi shows that individuals with acute symptoms may wish to resolve their most pressing health concern before testing for HIV.<sup>21,24</sup>

This population may benefit from being able to take HIVST kits home to use at times and locations that are convenient for them, when they are not preoccupied with acute illness that is immediately bothering them.

Finally, it is encouraging that working populations and those who report risky sexual behavior, especially men, were less likely to opt out of facility HIVST. Working

**TABLE 5.** Risk Ratios of Participants Who Refused HIVST by Age (n = 771)

Variable n (%)	15–24 Year Old		25+ Years Old	
	aRR	95% CI	aRR	95% CI
<b>Demographics</b>				
Gender				
Male	Ref		Ref	
Female	1.02	0.50 to 2.08	2.33§	1.47 to 3.70
Marital status				
Not married	Ref		Ref	
Married/steady relationship	0.80	0.53 to 1.21	1.11	0.72 to 1.69
Education level				
None	Ref		Ref	
Primary	0.38*	0.13 to 1.07	0.97	0.52 to 1.79
Secondary or higher	0.33*	0.10 to 1.09	0.89	0.34 to 2.34
Worked in the past 7 days				
No	Ref		Ref	
Yes	0.36§	0.21 to 0.61	0.52§	0.36 to 0.75
Area of residence				
Rural	Ref		Ref	
Urban	4.36§	1.99 to 9.57	3.22‡	1.18 to 8.79
<b>Health services</b>				
Self-rated health				
Good/very good	Ref		Ref	
Poor/very poor	1.68§	1.30 to 2.18	1.98‡	1.08 to 3.63
Visited a health facility in the past 6 months				
No	Ref		Ref	
Yes	1.11	0.65 to 1.91	1.22	0.93 to 1.62
Previous HIV test status				
Tested for HIV	Ref		Ref	
Never tested for HIV	1.91	0.62 to 5.94	0.83	0.41 to 1.68
<b>Sexual risk behavior†</b>				
Low-risk behavior	Ref		Ref	
High-risk behavior	0.83	0.43 to 1.58	0.72	0.36 to 1.45

\**t* test *P* value.

†Defined as having condomless sex with an unknown partner or having 2 or more sexual partners.

populations are often less likely to use traditional testing services as compared with nonworking groups because of conflicting work schedules and time constraints,<sup>31</sup> and

**TABLE 6.** Reasons for Opting out of Facility-Based HIVST (n = 263)

Variable, n (%)	Total N = 263 (%)	Female n = 139 (53%)	Male n = 124 (47%)
Not ready to test	130 (49)	69 (49)	61 (49)
Do not need to test	80 (30)	38 (27)	42 (34)
Too busy	30 (11)	12 (9)	18 (15)
Missed HIVST demonstration	24 (9)	15 (11)	9 (7)
Other*	13 (5)	8 (6)	5 (4)

\*Instructions not clear on how to use HIVST, privacy concerns, feeling too sick to use HIVST on the day.

individuals with risky sexual behavior are often at an increased risk of HIV, making it a critical group to reach with HIVST.

Our findings provide insight into perceived barriers to facility HIVST among those who opt out of HIVST. We found that traditional facility-based barriers to testing were removed with the implementation of facility HIVST. Traditional barriers to facility HIV testing, such as fear of unwanted disclosure and stigma, lack of privacy, and time constraints,<sup>32</sup> were reported by only a small handful of respondents who opted out of HIVST. Our findings corroborate other studies showing that HIVST removes many barriers inherent to conventional methods of HIV testing,<sup>33</sup> suggesting that facility HIVST in outpatient waiting spaces is acceptable, even among outpatients who chose not to test.

However, HIVST is not a magic bullet. We found that internalized barriers to HIV testing still remain. In our study, the 2 most common reasons for opting out of facility HIVST were not ready to test (49.4%) and perceived low risk of HIV infection (30.4%). Individual readiness to test is an important factor influencing decisions to test or not. Individuals may not feel prepared to test due to an array of reasons, including fear of a positive test result, limited knowledge about the benefits of early treatment and living with HIV, and fear of stigma.<sup>13,33</sup> To increase acceptance of facility HIVST, further sensitization or motivational messaging may be needed.

Our study has several limitations. First, because of high patient volumes in the selected facilities, not all outpatients were surveyed. Although systematic sampling was employed to recruit outpatients for surveys, some clients may have been missed leading to potential selection bias as those who were surveyed might be different to those who were not. Second, participants may have experienced social desirability bias whereby they underreported barriers to facility HIVST, knowing that HIVST was the primary outcome being studied. Research assistants who conducted surveys did not implement the facility HIVST intervention; however, it is impossible to ensure that participants did not still feel some level of social desirability bias. The full limitations of the parent trial have been documented elsewhere.<sup>9</sup>

## CONCLUSION

Facility HIVST in OPD was largely acceptable in Malawi. Characteristics associated with opting out of testing varied by sex and age but included urban residence, poor self-rated health, not working, and no risky sexual behavior within the past 12 months in men. However, for women, age was a predictor to opting out of testing. Supply side barriers to HIV testing were largely removed by HIVST, but internalized barriers related to preparedness to test and perceived need to test still remained. Future facility HIVST strategies may require integrating HIVST into other services, for example, antenatal clinics and voluntary medical male circumcision, client-targeted HIVST testing, and further sensitization activities to increase client preparedness for testing and their awareness of HIV risk.

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