Effect of facility-based HIV self-testing on uptake of testing among outpatients in Malawi: a cluster-randomised trial

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Summary

Background HIV self-testing increases testing uptake in sub-Saharan Africa but scale-up is challenging because of resource constraints. We evaluated an HIV self-testing intervention integrated into high-burden outpatient departments in Malawi.

Methods In this cluster-randomised trial, we recruited participants aged 15 years or older from 15 outpatient departments at high-burden health facilities (including health centres, mission hospitals, and district hospitals) in central and southern Malawi. The trial was clustered at the health facility level. We used constrained randomisation to allocate each cluster (1:1:1) to one of the following groups: standard provider-initiated testing and counselling with no intervention (provider offered during consultations), optimised provider-initiated testing and counselling (with additional provider training and morning HIV testing), and facility-based HIV self-testing (Oraquick HIV self-test, group demonstration and distribution, and private spaces for interpretation and counselling). The primary outcome was the proportion of outpatients tested for HIV on the day of enrolment, measured through exit surveys with a sample of outpatients. Analyses were on an intention-to-treat basis. The trial is registered with ClinicalTrials.gov, NCT03271307, and Pan African Clinical Trials, PACTR201711002697316.

Findings Between Sept 12, 2017, and Feb 23, 2018, 5885 outpatients completed an exit survey—2097 in the HIV self-testing group, 1951 in the standard provider-initiated testing and counselling group, and 1837 in the optimised provider-initiated testing and counselling group. 1063 (51%) of 2097 patients in the HIV self-testing group had HIV testing on the same day as enrolment, compared with 248 (13%) of 1951 in the standard provider-initiated testing and counselling group and 261 (14%) of 1837 in the optimised provider-initiated testing and counselling group. The odds of same-day HIV testing were significantly higher in the facility-based HIV self-testing group compared with either standard provider-initiated testing and counselling (adjusted odds ratio 8·52, 95% CI 3·98–18·24) or optimised provider-initiated testing and counselling (6·29, 2·96–13·38). Around 4% of those tested in the standard provider-initiated testing and counselling and optimised provider-initiated testing and counselling groups felt coerced to test, and around 1% felt coerced to share test results. No coercion was reported in the facility-based HIV self-testing group.

Interpretation Facility-based HIV self-testing increased HIV testing among outpatients in Malawi, with a minimal risk of adverse events. Facility-based HIV self-testing should be considered for scale-up in settings with a high unmet need for HIV testing.

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Introduction

HIV testing is crucial for the UNAIDS 90-90-90 goals to be reached,[1] yet only 76% of HIV-positive individuals in countries in east and southern Africa are aware of their status.[2] HIV self-testing, whereby individuals perform and interpret their own HIV test, is an effective strategy to improve HIV testing coverage, especially among hard-to-reach populations such as men and adolescents.[3–6] Current HIV self-testing strategies have focused on community-based distribution modalities, resulting in a high uptake of testing because of the private and convenient nature of self-testing.[7] However, there is an urgent push to scale up HIV self-testing strategies throughout the region,[8] with nearly all countries in east and southern Africa developing or recently adopting HIV self-testing policies.

Scale-up of HIV self-testing in low-resource settings is challenging because of insufficient infrastructure and human capital throughout the region, challenges with monitoring and evaluation of HIV self-test use, and low antiretroviral therapy (ART) initiation among people who test positive through HIV self-testing strategies.[9] Incorporating HIV self-testing into existing facility-based health services might be an important additional strategy to facilitate scale-up. Facility-based HIV self-testing could improve the efficiency of facility-based

Research in context

Evidence before this study

Inadequate HIV testing coverage remains the biggest barrier to reaching UNAIDS 90-90-90 goals. HIV self-testing is an effective strategy to improve HIV testing coverage, especially among hard-to-reach populations, such as men and adolescents. However, evidence-based, low-cost strategies to scale up HIV self-testing remain scarce. Facility-based distribution of HIV self-testing could be one strategy to increase access with minimal resource use. This strategy could be particularly beneficial in outpatient departments, where HIV testing coverage has been historically low. We searched PubMed for studies published from Jan 1, 2000, up to Nov 20, 2018, with the search terms "HIV" and "self-test" or "self-testing" and "outpatient departments" or "health facility", with no language restrictions. Our search did not identify any evaluations of facility-based HIV self-testing up to the search end date.

Added value of this study

Our study adds to the literature on HIV self-testing and, to our knowledge, is unique in evaluating this strategy in busy outpatient facilities in resource-limited settings. We found that facility-based HIV self-testing in the outpatient department significantly increased the proportion of outpatients tested for HIV, with 51% of all outpatients tested compared with 13% for standard provider-initiated testing and counselling. Our strategy markedly improved testing coverage for men and adolescents and, overall, more than doubled the absolute number of individuals newly diagnosed with HIV. To our knowledge, our study documents one of the first HIV self-test strategies to show high rates of antiretroviral therapy initiation (70% compared with the reported 29–45% in most HIV self-test studies).

Implications of all the available evidence

We found that facility-based HIV self-testing in the outpatient department is an effective strategy for increasing testing coverage among outpatients in resource-limited settings, such as Malawi. Facility-based HIV self-testing might provide the greatest benefit in congested, high-burden health facilities, where human resource constraints limit the reach of traditional provider-initiated testing.

testing services, as patients can use HIV self-testing while waiting for other health services; improve ART initiation, as users are already at the facility and can easily access additional services; promote quality assurance, as users have direct access to trained HIV testing providers at the facility; and reduce costs associated with HIV self-testing through distribution that can be easily incorporated into the routine tasks of facility-based staff.

Facility-based HIV self-testing might be particularly useful in high-burden outpatient departments, which are often overcrowded and understaffed, where patients can experience considerable wait times; in Malawi, the median wait time to see a health-care provider is 4 hours.[10] Furthermore, traditional provider-initiated testing and counselling in outpatient department settings is scarce, with low testing coverage.[11–13] Barriers to testing in outpatient department settings include a paucity of HIV testing staff available for individual testing and counselling, little availability of private spaces, and insufficient integration of care, whereby outpatients referred for HIV testing must actively seek services in a separate HIV department.[11] Facility-based HIV self-testing might be a critical addition to provider-initiated testing and counselling strategies and might overcome traditional barriers to testing by allowing outpatients to test themselves while waiting for routine services.

We aimed to assess the efficacy, acceptability, and cost of facility-based HIV self-testing among outpatients in Malawi compared with standard and optimised provider-initiated testing and counselling. This study adds to the growing number of trials on HIV self-testing in sub-Saharan Africa and, to our knowledge, provides a novel perspective by examining whether HIV self-testing can be integrated alongside facility-based health services in high-burden outpatient departments.

Methods

Study design and participants

In this cluster-randomised trial, we recruited participants from 15 outpatient departments at high-burden health facilities (including district hospitals, mission hospitals, and health centres) in central and southern Malawi. In outpatient departments, services are offered for adults with either acute illnesses or non-communicable diseases (NCDs). Typical acute illnesses include febrile syndromes, cough, diarrhoea, dehydration, and minor injuries. Common NCDs include hypertension and diabetes. Services for pregnant women, children younger than 5 years, and emergency or inpatients were provided in different departments and therefore these individuals were not included in our study. Outpatients were encouraged to opt out of facility-based HIV self-testing if they met any of the following exclusion criteria: ever tested positive for HIV, tested negative for HIV in the past month, felt uncomfortable using HIV self-testing in the outpatient department, and were younger than 15 years. The intervention was designed to offer multiple reasons for opting out to avoid inadvertent status disclosure of those who declined to take an HIV self-testing kit. This study was approved by the National Health and Sciences Research Committee in Malawi and the Institutional Review Board at the University of California Los Angeles, Los Angeles (CA, USA).

Randomisation and masking

The trial was clustered at the health facility level. We used constrained randomisation to allocate each cluster (1:1:1) to one of the following groups: standard provider-initiated testing and counselling with no intervention, optimised provider-initiated testing and counselling, whereby additional training and job aids were provided to health workers to improve testing and counselling implementation and early morning HIV testing was offered to patients within the outpatient department, and facility-based HIV self-testing, whereby OraQuick ADVANCE HIV I/II self-testing kits (OraSure Technologies; Bethlehem, PA, USA) were distributed to outpatients to use in clinic waiting spaces. Clusters were constrained by the following covariates: facility type (hospital or health facility), ownership (government or mission), and region (central or southern; appendix p 1). Random assignment was done by the project statistician using a computer-generated sequence of random numbers, and outputs were shared with the Ministry of Health of Malawi, district-level governance, and medical providers at participating sites.

Procedures

Figure 1 shows the procedures for each study group. Although HIV testing is recommended for all outpatients in Malawi, as per national guidelines, referrals for testing are based on provider discretion. In the standard provider-initiated testing and counselling group, no additional support was provided. Outpatients were referred to a separate HIV department for HIV testing. All HIV tests were done according to national guidelines by a certified HIV testing counsellor with a fingerstick blood sample and Determine 1/2 (Abbott Laboratories; Chicago, IL, USA) tests. Positive tests were confirmed using Uni-Gold (Trinity Biotech; Bray, Ireland). Counselling was provided before and after testing. Confirmed HIV-positive individuals were referred to the facility's ART clinic,

See Online for appendix

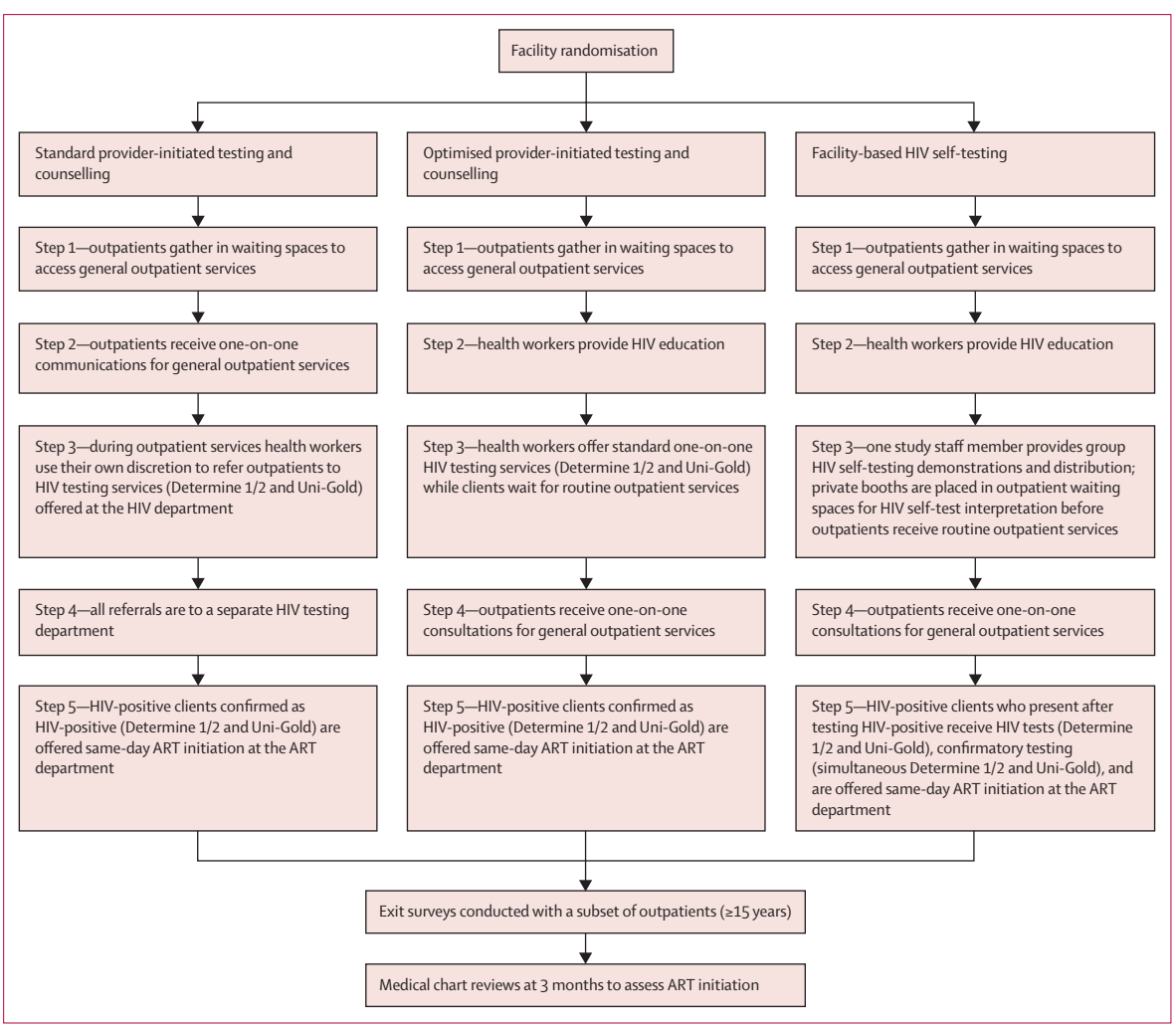

Figure 1: **Study procedures by intervention**
ART=antiretroviral therapy.

where they received additional verification testing for quality control (parallel Determine 1/2 and Uni-Gold tests) and were offered same-day ART initiation.

The aim of the optimised provider-initiated testing and counselling group was to improve implementation of provider-initiated testing and counselling in the outpatient department. Refresher provider-initiated testing and counselling training and job aids were provided to outpatient health-care workers at these facilities. HIV testing was integrated within the outpatient department and offered in the mornings before consultations began by certified HIV testing counsellors. One or two counsellors and one or two private spaces were available for morning testing. Services included a 10 min group health talk about the importance of HIV testing and one-on-one counselling before and after HIV testing. Standard procedures for HIV testing (Determine 1/2 and Uni-Gold) were used. HIV-positive clients received confirmatory HIV testing and were offered same-day ART initiation.

The facility-based HIV self-testing intervention included the following five components: a 10 min health talk to all outpatients about the importance of HIV testing; a 15 min Oraquick HIV self-testing demonstration, including group pre-counselling; HIV self-test distribution for use in outpatient department waiting spaces and, if needed, assistance from a trained study staff member with a background equivalent to a typical Malawian HIV diagnostic assistant; private spaces (temporary cardboard standing booths) for interpretation of HIV self-test results before receiving routine heath consultations; and optional post-test counselling and referral to additional HIV services for those who chose to disclose their HIV self-testing result.

One study staff member demonstrated, distributed, and assisted with the use of HIV self-testing kits in outpatient department waiting spaces. Group HIV self-testing demonstrations occurred when there were large groups of outpatients in the waiting space, supplemented by small group talks when there were fewer people, allowing one health worker to distribute HIV self-testing kits to a large number of people in a small amount of time.

Pre-counselling and the need for confirmatory HIV testing was explained during the health talk before kit distribution. Disclosure of HIV self-test results was voluntary, but outpatients were encouraged to discuss their result with the health-care provider during routine outpatient services. Outpatients who tested HIV-positive with HIV self-testing and disclosed their status entered the national testing algorithm (Determine 1/2 followed by Uni-Gold, and confirmatory testing before ART initiation). Those who disclosed their HIV self-test result and were confirmed to be HIV-positive were offered same-day ART initiation.

Locked boxes were available at all exit points of the outpatient departments for disposal of self-test kits. Outpatients were instructed not to take unused test kits home. Those who accepted a kit but decided not to use it could drop the unused kit into the locked box. Meetings with local community leaders and stakeholders were held before implementation of the intervention to familiarise them with the HIV self-testing kits and avoid confusion and misconceptions about the kits.

Cost analysis

We used a microcosting (bottom-up) approach from the provider perspective to assess study cost in each trial group using the HIV Counselling and Testing costing tool developed by the Health Economics and Epidemiology Research Office in South Africa.[14] All resources used for HIV testing services were captured from five representative health facilities. Resource costs included testing consumables and equipment, staff costs, staff training, shared costs (eg, cleaning, stock taking, data capturing, HIV counselling, and testing staff scheduling), and overhead costs (including building maintenance and utilities). We then averaged HIV counselling and testing costs across all five facilities and reported SDs around these costs (appendix p 2). Additional information about the composition of consumables can be found in the appendix (p 3). To estimate the additional cost per test of the optimised provider-initiated testing and counselling group, we divided the total additional training costs incurred and divided this by the number of people tested during the study period. In the HIV self-testing group, the cost of research assistants providing demonstrations was factored into the personnel time and divided by the total number of people who tested with an HIV self-test. The costs of training, community sensitisation, and cardboard booths were also divided by the total number of people who tested with an HIV self-test in this study. These study-related costs (training, staff members, booth, and HIV self-test kits) were determined from service provider reports and research study procurement records and added to the cost of the standard HIV testing and counselling algorithm.

In the standard provider-initiated testing and counselling and optimised provider-initiated testing and counselling group, we assumed confirmatory testing and costs related to confirmatory testing for those who tested positive. Since HIV self-testing is considered a screening tool, those who screen positive are assumed to go through the full facility-based testing algorithm (two HIV tests—Determine 1/2 and Uni-Gold—followed by confirmatory testing for those who tested positive) and incur the related costs. We did not assume overhead costs for those who tested negative in the HIV self-test group as the testing space would be occupied by the same individuals regardless of the presence of HIV. We did assume overhead costs for those who tested positive and underwent the standard HIV testing algorithm within the facility. The cost of ART initiation itself was not included in the final production cost or the total cost to initiate one new client on ART. Total testing-related costs per test completed, per newly diagnosed HIV-positive individual,

and per person initiated onto ART were calculated by study group. All costs are reported in 2017 US$.

Outcomes

The primary outcome was the proportion of outpatients tested for HIV on the day of enrolment. Secondary outcomes were HIV positivity among those tested, ART initiation at 3 months among newly diagnosed outpatients, acceptability of facility-based HIV self-testing, the presence of adverse events, such as coercion to test or share test results, and costs.

Primary and secondary outcomes were measured with a one-time, anonymous exit survey done with participants after all outpatient and HIV services were received. Because of facility workload and client flow it was not possible to survey all outpatients attending facilities. We used a systematic sampling strategy to recruit outpatients for the exit survey. Research assistants approached every tenth client they saw exiting the pharmacy (representing the last service received during clinical care) until the target sample size was reached. If an individual was found to be ineligible or declined to participate, the next participant exiting the pharmacy was approached. A different proportion of outpatients was sampled at each site because of varied patient volumes between sites. Staff recruited throughout clinic hours and every clinic working day, ensuring clients receiving services in morning and afternoon hours were represented. Survey eligibility criteria included age 15 years or older, 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 consent. Eligible individuals gave oral consent.

The exit survey included the following six domains: sociodemographics, previous use of HIV services and test results, sexual risk behaviour, health services received that day (including HIV testing and treatment), acceptability of the intervention, and the presence of any adverse events associated with the intervention. No identifiers were collected. Exit surveys lasted around 20 min. Recruitment, oral consent, and exit surveys were done at the health facility by trained research assistants who were not involved in the intervention to minimise social desirability bias in self-reported responses.

For the purpose of determining ART initiation, participants who reported testing HIV-positive on the day of enrolment were asked to provide written informed consent and give multiple identifiers, such as name and physical address. Identifiers were also used for chart reviews to determine whether participants initiated ART within 3 months of study enrolment. Facility-based data clerks reviewed clinical records at study facilities and

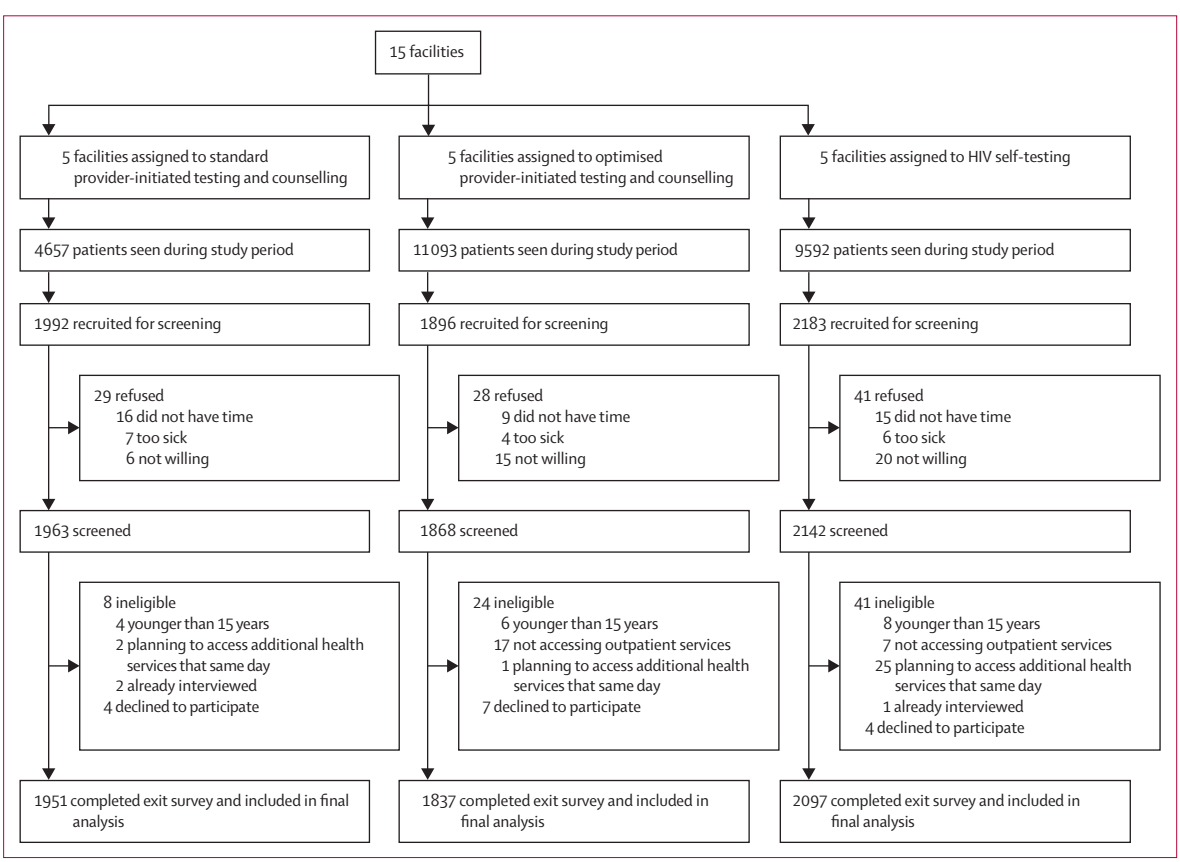

Figure 2: **Trial profile**

	Standard provider-initiated testing and counselling (n=1951)	Optimised provider-initiated testing and counselling (n=1837)	Facility-based HIV self-testing (n=2097)
Demographics			
Sex			
Female	1327 (68%)	1002 (55%)	1304 (62%)
Male	624 (32%)	835 (45%)	793 (38%)
Age, years	32·5 (21–40)	34·5 (22–43)	32·1 (22–40)
Schooling completed, years	4·2 (2–6)	4·3 (2–6)	4·2 (2–6)
Literate*	1285 (66%)	1332 (71%)	1432 (68%)
Married	1344 (69%)	1296 (71%)	1293 (62%)
Services received			
Reason for visit			
Injury	58 (3%)	95 (5%)	99 (5%)
Malaria	90 (5%)	55 (3%)	162 (8%)
Sexually transmitted infection	105 (5%)	146 (8%)	37 (2%)
General illness	1659 (85%)	1378 (75%)	1661 (79%)
Non-communicable disease	53 (3%)	190 (10%)	144 (7%)
Self-rated health			
Very good	96 (5%)	178 (10%)	237 (11%)
Good	1017 (52%)	917 (50%)	1198 (57%)
Poor	794 (41%)	676 (37%)	535 (26%)
Very poor	44 (2%)	66 (4%)	127 (6%)
Previous use of health services			
Health-care visits in the past 6 months, n	1·7 (0–3)	2·3 (0–3)	1·8 (0–3)
HIV services			
Never tested for HIV	317 (16%)	237 (13%)	275 (13%)
Tested ≤12 months ago	1041 (53%)	971 (53%)	1044 (50%)
Tested >12 months ago	593 (30%)	629 (34%)	778 (37%)
Previously tested HIV-positive	174 (9%)	185 (10%)	127 (6%)
Sexual risk behaviour			
More than two sexual partners in the past 12 months	102 (5%)	137 (7%)	179 (9%)
Condomless sex with a non-stable partner	112 (6%)	145 (8%)	145 (7%)
Region			
South	1371 (70%)	991 (54%)	1272 (61%)
Central	580 (30%)	846 (46%)	825 (39%)

Data are n (%) or mean (IQR) unless otherwise indicated. *Measured by asking participants to read a simple literacy card.

Table 1: **Baseline characteristics**

surrounding facilities (42 facilities in total) to account for participants who might have initiated ART at a facility other than the one at which they tested HIV-positive. Information was collected on whether clients initiated ART and, among those who did initiate, date and location of initiation.

Statistical analysis

We estimated our sample size assuming a fixed number of clusters (k) and an equal number of clusters per arm (k=5). Based on previous HIV testing prevalence among outpatients,[15] we assumed an equal number of participants per cluster (n=400) for a total sample size of 2000 participants per group (6000 total). Assuming an overall type I error of 0·05 and an intracluster correlation of 0·004, the sample size provided at least 90% power to detect differences in HIV testing of 5% in the standard provider-initiated training and counselling group, 10% in the optimised provider-initiated training and counselling group, and 20% in the HIV self-testing group. We used the Bonferroni correction to account for multiple comparisons.

We used CONSORT standards for reporting trial outcomes.[16] All analyses were prespecified based on the protocol, which has been published previously.[17] Descriptive statistics (mean, SD, median, IQR, and frequency distribution) were generated for demographic and clinical information to characterise the study population. We used intention-to-treat principles for the primary outcome analysis (the proportion of outpatients tested). We used mixed effects models to evaluate the treatment effects on all outcomes, with the fixed effect of treatment assignment and the random effects of study sites, to account for correlations within clusters. This method works well in situations where the number of observations per cluster is large[18] and for unequal cluster sizes.[19] We also did sensitivity analyses on the uptake of HIV testing, excluding clients who were not in need of testing (such as clients who were tested despite a previous positive test result and clients who had tested HIV-negative within the past month or 3 months). We did additional mixed effects analyses for each outcome of interest by including fixed effect covariates of sex, age, age squared, marital status, and number of years of schooling completed.

Analyses were done with R version 3.5.3. The trial is registered with ClinicalTrials.gov, NCT03271307, and Pan African Clinical Trials, PACTR201711002697316. The full study protocol is described elsewhere.[17]

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between Sept 12, 2017, and Feb 23, 2018, 22 342 outpatients received health services and 6071 (27%) were recruited for an exit survey (figure 2). 98 (2%) of 6071 refused to be screened. 73 (1%) of 5973 screened outpatients did not meet eligibility criteria and an additional 15 (<1%) outpatients declined to participate. Therefore, 5885 outpatients completed an exit survey (figure 2). Because of facility workload and client flow it was not possible to survey all outpatients attending facilities. Furthermore, because patient volume varied between sites, a different proportion of outpatients was sampled at each site

	Standard provider-initiated testing and counselling	Optimised provider-initiated testing and counselling	Facility-based HIV self-testing	Facility-based HIV self-testing *vs* standard provider-initiated testing and counselling		Facility-based HIV self-testing *vs* optimised provider-initiated testing and counselling	
				Adjusted OR (95% CI)*	Adjusted OR (95% CI)†	Adjusted OR (95% CI)*	Adjusted OR (95% CI)†
Tested for HIV on day of enrolment	248/1951 (13%)	261/1837 (14%)	1063/2097 (51%)	8·89 (4·17–18·94)	8·52 (3·98–18·24)	6·85 (3·23–14·52)	6·29 (2·96–13·38)
Subset analysis by demographics							
Male adult (≥25 years)	57/417 (14%)	87/583 (15%)	230/493 (47%)	7·90 (3·62–17·27)	7·46 (3·35–16·59)	5·91 (2·85–12·29)	5·57 (2·64–11·75)
Female adult (≥25 years)	105/792 (13%)	79/672 (12%)	452/838 (54%)	8·81 (3·80–20·46)	7·74 (3·09–19·39)	10·88 (4·62–25·63)	9·75 (3·84–24·74)
Adolescent (15–24 years)	86/742 (12%)	95/582 (16%)	381/766 (50%)	9·35 (4·01–21·82)	9·42 (4·15–21·38)	5·42 (2·36–12·46)	5·33 (2·38–11·92)
Subset analysis by testing history							
Never tested HIV-positive and tested >3 months ago	148/849 (17%)	175/930 (19%)	797/1382 (58%)	10·01 (3·83–26·18)	9·29 (3·42–25·19)	6·97 (2·70–17·99)	6·77 (2·53–18·12)
Never tested for HIV	40/317 (13%)	38/237 (16%)	145/275 (53%)	11·05 (3·87–31·55)	10·91 (3·78–31·50)	7·17 (2·52–20·39)	5·41 (1·91–15·33)
Tested >12 months ago	124/910 (14%)	134/866 (15%)	550/1053 (52%)	10·00 (3·73–26·79)	9·27 (3·45–24·92)	6·66 (2·52–17·60)	5·90 (2·23–15·62)
Previously tested HIV-positive	0/174	2/185 (1%)	11/127 (9%)	..	..	8·68 (1·89–39·85)	8·51 (1·57–46·24)
Subset analysis by sexual risk behaviour							
More than two sexual partners in past 12 months	23/102 (23%)	26/137 (19%)	96/179 (54%)	4·30 (1·90–9·71)	5·36 (2·45–11·74)	5·25 (2·43–11·36)	5·45 (2·63–11·32)
Condomless sex with a non-stable partner in past 12 months	26/112 (23%)	27/145 (19%)	85/145 (59%)	5·26 (2·29–12·06)	4·99 (2·25–11·07)	6·78 (3·14–14·64)	6·41 (3·02–13·60)

Data are n/N (%) unless otherwise indicated. OR=odds ratio. *Models with site as a random effect. †Models adjusted for facility, sex, age, age squared, currently married, and number of years of school completed, with site as a random effect.

Table 2: **Uptake of HIV testing on the day of enrolment**

depending on the number of clients seen in a given day. A similar number of outpatients per site completed the exit survey.

3633 (62%) exit survey respondents were female, representing the gendered composition of outpatients in Malawi (table 1). The median respondent age was 33 years (IQR 22–41). 5056 (86%) outpatients had been tested for HIV before, with 3056 (52%) tested within the past 12 months. 127 (6%) respondents in the HIV self-testing group reported previously testing HIV-positive before the study, compared with 174 (9%) in the standard provider-initiated testing and counselling group and 185 (10%) in the optimised provider-initiated testing and counselling group.

1063 (51%) of 2097 patients in the HIV self-testing group had HIV testing on the same day as enrolment, compared with 248 (13%) of 1951 in the standard provider-initiated testing and counselling group and 261 (14%) of 1837 in the optimised provider-initiated testing and counselling group (table 2). The odds of same-day HIV testing were significantly higher in the facility-based HIV self-testing group compared with either standard provider-initiated testing and counselling (adjusted odds ratio [OR] 8·52, 95% CI 3·98–18·24) or optimised provider-initiated testing and counselling (6·29, 2·96–13·38). Findings were similar across age and sex categories (figure 3), with adolescents showing the greatest benefit from facility-based HIV self-testing compared with standard provider-initiated testing and counselling (table 2).

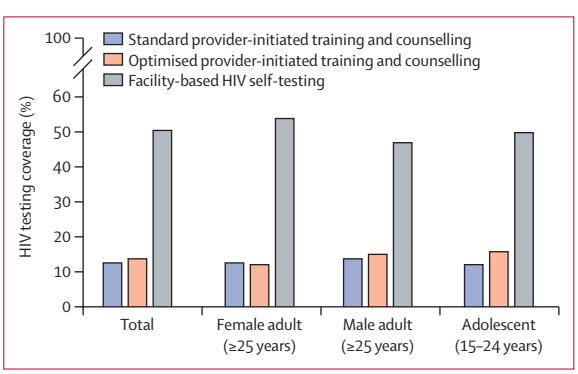

Figure 3: **HIV testing coverage by sex and age across trial groups (n=5885)**

Across all study groups, HIV testing was highest among those who reported risky sexual behaviour in the past 12 months (more than two sexual partners or condomless sex with a non-stable partner; table 2). Among those with risky sexual behaviour, 181 (56%) of 324 participants were tested in the HIV self-testing group, 49 (23%) of 214 participants were tested in the standard provider-initiated testing and counselling group, and 53 (19%) of 282 participants were tested in the optimised provider-initiated testing and counselling group. 145 (53%) of 275 patients who had never been tested for HIV before were tested in the HIV self-testing group, compared with 40 (13%) of 317 in the standard provider-initiated testing and counselling group and

	Standard provider-initiated testing and counselling (n=248)	Optimised provider-initiated testing and counselling (n=259)	Facility-based HIV self-testing (n=1052)	Facility-based HIV self-testing *vs* standard provider-initiated testing and counselling		Facility-based HIV self-testing *vs* optimised provider-initiated testing and counselling	
				Adjusted OR (95% CI)*	Adjusted OR (95% CI)†	Adjusted OR (95% CI)*	Adjusted OR (95% CI)†
Test result							
Positive	6 (2%)	8 (3%)	28 (3%)	1·10 (0·45–2·69)	0·85 (0·31–2·33)	0·86 (0·39–1·91)	0·91 (0·34–2·45)
Negative	239 (96%)	251 (97%)	1010 (96%)	..	..	..	..
Unknown‡	2 (1%)	0	14 (1%)	..	..	..	..
Subset analysis by demographics							
Male adult (≥25 years)	3/57 (5%)	5/87 (6%)	9/221 (4%)	0·76 (0·20–2·92)	0·86 (0·21–3·55)	0·70 (0·23–2·14)	0·67 (0·19–2·36)
Female adult (≥25 years)	2/105 (2%)	2/78 (3%)	11/450 (2%)	1·29 (0·28–5·91)	0·46 (0·08–2·70)	0·95 (0·21–4·38)	0·85 (0·09–8·28)
Adolescent (15–24 years)	1/86 (1%)	1/94 (1%)	8/381 (2%)	1·83 (0·18–8·77)	1·99 (0·24–16·74)	1·89 (0·19–8·43)	1·98 (0·23–16·89)
Of those with a new HIV-positive diagnosis							
Initiated ART <3 months after diagnosis	5/6 (83%)	8/8 (100%)	19/28 (68%)	..	..	..	..
Subset analysis by demographics							
Male adult (≥25 years)	3/3 (100%)	5/5 (100%)	7/9 (78%)	..	..	..	..
Female adult (≥25 years)	1/2 (50%)	2/2 (100%)	9/11 (82%)	..	..	..	..
Adolescent (15–24 years)	1/1 (100%)	1/1 (100%)	3/8 (38%)	..	..	..	..

Data are n (%) or n/N (%), unless otherwise indicated. OR=odds ratio. ART=antiretroviral therapy. *Models with site as a random effect. †Models adjusted for facility, sex, age, age squared, currently married, and number of years of school completed, with site as a random effect. ‡Unknown refers to clients who did not receive test results from the provider (standard and optimised provider-initiated training and counselling) and clients who could not interpret the kit or had invalid results (HIV self-testing).

Table 3: **Prevalence of HIV positivity and ART initiation among outpatients who had never tested HIV-positive before study enrolment and were tested on the day of recruitment**

38 (16%) of 237 in the optimised provider-initiated testing and counselling group.

Repeat testing among those already known to be HIV-positive was highest in the HIV self-testing group compared with the standard and optimised provider-initiated training and counselling groups (table 2). All repeat testers in the HIV self-testing group received a positive HIV self-test result and six (55%) of 11 were currently receiving ART.

Excluding those with previously known HIV-positive status, 27 (3%) of 1052 participants in the HIV self-testing group (using HIV self-test results), six (2%) of 248 participants in the standard provider-initiated testing and counselling group, and eight (3%) of 259 participants in the optimised provider-initiated testing and counselling group were HIV-positive, with no difference between the groups (table 3). HIV self-testing resulted in more than three times the absolute number of newly diagnosed HIV-positive individuals compared with the other trial groups because of high uptake of testing. Reports of either unknown (ie, did not receive test result or, for HIV self-testing, unable to interpret test result) or invalid test results (for HIV self-testing only) were rare across all study groups (data not shown).

Across all study groups, the prevalence of HIV positivity varied by sex and age. Adult men (≥25 years) had almost double the prevalence of HIV positivity compared with adult women, representing the unmet need for testing in this population (table 3). HIV-positivity among adolescents (aged 15–24 years) was highest in the HIV self-testing group, although there was no significant difference between the study groups.

In the HIV self-testing group at 3 months, 19 (68%) of 28 newly diagnosed individuals initiated ART (79% same-day initiation), compared with five (83%) of six participants in the standard provider-initiated training and counselling group (all same-day initiation) and eight (100%) of eight participants in the optimised provider-initiated training and counselling group (50% same-day initiation; table 3; same-day initiation data not shown). Adolescents in the HIV self-testing group had the lowest prevalence of ART initiation, with only three (38%) of eight participants initiating ART within 3 months. We observed no differences across groups in terms of ART initiation but were restricted by small sample sizes. 2 (7%) of 28 newly diagnosed individuals in the HIV self-testing group discussed their HIV self-test status with the outpatient provider on the same day as testing (data not shown). Nonetheless, most of these individuals received same-day confirmatory testing and initiated ART.

Acceptability was highest in the HIV self-testing group, with 1043 (99%) of 1052 individuals stating that they would use the same testing strategy again, compared with 204 (82%) of 248 in the standard provider-initiated testing and counselling group and 222 (86%) of 259 in the optimised provider-initiated testing and counselling group (table 4). Acceptability

	Standard provider-initiated testing and counselling (n=248)	Optimised provider-initiated testing and counselling (n=259)	Facility-based HIV self-testing (n=1052)	Facility-based HIV self-testing *vs* standard provider-initiated testing and counselling		Facility-based HIV self-testing *vs* optimised provider-initiated testing and counselling	
				Adjusted OR (95% CI)*	Adjusted OR (95% CI)†	Adjusted OR (95% CI)*	Adjusted OR (95% CI)†
Acceptability							
Would test again using the same method	204 (82%)	222 (85%)	1043 (98%)	5·57 (1·44–21·55)	6·17 (1·70–22·47)	5·61 (1·55–20·35)	7·32 (2·10–25·46)
Would recommend the testing method to friends	219 (88%)	224 (86%)	1054 (99%)	11·35 (3·19–40·34)	8·70 (2·41–31·32)	14·86 (4·37–50·51)	16·25 (4·86–54·26)
Desire additional counselling	172/248 (69%)	183/261 (70%)	800/1063 (75%)	1·21 (0·47–3·11)	1·03 (0·36–2·99)	1·13 (0·44–2·85)	1·11 (0·40–3·14)
Presence of coercion							
Coerced to test	10 (4%)	10 (4%)	0	..	..	..	..
Coerced to disclose test results	1 (<1%)	3 (1%)	0	..	..	..	..

Data are n (%) or n/N (%), unless otherwise indicated. OR=odds ratio. *Models with site as a random effect. †Models adjusted for facility, sex, age, age squared, currently married, and number of years of school completed, with site as a random effect.

Table 4: **Acceptability and adverse events among outpatients exposed to the intervention**

was similar across sex and age (data not shown). Across all study groups, most outpatients who tested for HIV desired additional post-test counselling, with 95% of those newly diagnosed with HIV desiring additional counselling (data not shown). Desire for additional counseling did not differ by group (adjusted OR 1·03, 0·36–2·99; table 4). Around 4% of those tested in both the standard and optimised provider-initiated testing and counselling groups felt coerced to test, and around 1% felt coerced to share test results. No coercion was reported in the HIV self-testing group.

The mean cost per person who received an HIV test in the HIV self-testing group was US$4·99 (table 5). The main components of this cost were consumables and meetings with local leaders for community sensitisation. The mean cost per person who received an HIV test in the optimised provider-initiated testing and counselling group was $4·79, of which the main components were staff training and consumables. The mean cost per person who received an HIV test in the standard provider-initiated testing and counselling group was $2·44, comprised primarily of consumables, followed by staff time. The cost per newly identified positive case was $189 in the HIV self-testing group, $101 in the standard provider-initiated testing and counselling group, and $156 in the optimised provider-initiated training and counselling group. The cost per person initiated on ART was $279 in the HIV self-testing group, $121 in the standard provider-initiated training and counselling group, and $156 in the optimised provider-initiated training and counselling group (table 5).

Discussion

In this cluster-randomised controlled trial, we found that facility-based HIV self-testing increased the proportion of outpatients tested for HIV compared with standard and optimised provider-initiated testing and counselling, with more adult outpatients in the HIV self-testing group tested for HIV compared with the other study groups. Facility-based HIV self-testing performed better than other documented strategies for testing outpatients.[20,21] Testing hard-to-reach populations, such as men and adolescents, is a major barrier to achievement of high testing coverage and reaching UNAIDS 90-90-90 targets.[1] Our data suggest that facility-based HIV self-testing in outpatient waiting spaces can drastically improve testing coverage for both of these important groups, and can more than double the absolute number of individuals newly diagnosed with HIV. Importantly, uptake of HIV self-testing was high among outpatients who reported high-risk sexual behaviour in the past 12 months and those who had never been tested for HIV before, suggesting that facility-based HIV self-testing might be effective at engaging high-risk and hard-to-reach groups.

Our study design included an optimised provider-initiated testing and counselling group, which comprised intensive staff training, job aids, expanded testing hours, and integration within outpatient departments during morning hours, without providing additional staff. Despite these optimised conditions, facility-based HIV self-testing outperformed traditional provider-initiated testing and counselling strategies, and optimised provider-initiated testing and counselling was not better than standard provider-initiated testing and counselling in terms of the number of participants tested. This is probably because of the insufficient number of personnel available for testing and the lack of private space and time required to complete one-on-one testing (a health-care provider must spend at least 20 min per HIV test, resulting in a maximum of three tests in 1 h). These conditions contrast with facility-based HIV self-testing, whereby over half of all outpatients could be tested in

	Standard provider-initiated testing and counselling (n=248)	Optimised provider-initiated testing and counselling (n=261)	Facility-based HIV self-testing (n=1063)
Staff*	0·95	0·95	1·22
Equipment†	0·08	0·08	0·26
Consumables‡	1·37	1·37	2·07
Facility overheads§	0·03	0·03	0·00
Training	0·01	2·36	0·31
Community sensitisation	0·00	0·00	1·14
Total cost	2·44	4·79	4·99
Cost per newly identified positive case	100·85	156·27	189·44
Cost per person initiated on ART	121·02	156·27	279·18

All costs in 2017 US$. Does not include cost of ART. ART=antiretroviral therapy. *Depending on group, costs include HIV counsellors, outpatient department providers, and study staff who conducted the HIV self-testing intervention. †Includes all facility-based equipment for standard and optimised provider-initiated testing and counselling, including testing booths for those in the HIV self-test group and facility-based equipment for those who were screened positive and went through the testing algorithm at the facility. ‡Depending on group, costs include HIV self-testing kits and standard-of-care testing supplies. §Includes building maintenance and utilities.

Table 5: **Cost analysis—cost per test provided, by cost category, total cost, and cost per outcome**

several hours with the assistance of one dedicated staff member. Only one or two HIV testing counsellors were needed to demonstrate and administer HIV self-testing kits to an entire outpatient clinic. These HIV testing counsellors were readily available to assist individuals struggling with the HIV self-testing process. Private booths were placed throughout outpatient department waiting spaces for patients to interpret test results, addressing infrastructure limitations common for traditional provider-initiated testing and counselling strategies. Given the simplicity and low staffing requirements of facility-based HIV self-testing, along with high client acceptability and low risk for adverse events, this strategy has tremendous promise for scale-up across similar settings in sub-Saharan Africa. HIV self-testing might be particularly beneficial in other settings with high HIV prevalence, where facility-based HIV testing coverage is low.

Outpatients in all study groups desired additional post-test counselling, regardless of their HIV test result. Those who tested HIV-negative wanted information on how to remain uninfected, and those who tested positive desired more information about HIV. These findings suggest that improved counselling after HIV testing might be needed for all facility-based testing strategies. Post-test counselling could be particularly challenging for HIV self-test users since disclosure is voluntary. Options to improve post-test counselling in facility-based HIV self-testing could include generic group post-test counselling for HIV self-test users (providing simultaneous counselling for both negative and positive results) or offering opt-out one-on-one counselling after HIV testing to outpatients exiting private booths for HIV self-test interpretation. The latter strategy would increase cost but might also improve linkage to care for those who test positive, increase HIV prevention benefits of testing for those who are negative, and improve post-test counselling satisfaction for all testers.

ART initiation in the HIV self-testing group was lower than in both provider-initiated training and counselling groups, although HIV self-testing resulted in more than double the absolute number of new initiators compared with the other study groups. Adolescents in the HIV self-testing group had a particularly low prevalence of ART initiation and warrant further study. Nonetheless, HIV self-testing linkage rates in our study were substantially higher than those reported in previous community-based HIV self-testing studies, where rates have been reported to be 29–45%.[10,22–24] Higher prevalence of ART initiation with facility-based HIV self-testing compared with community-based strategies might be due to reduced barriers to ART initiation—individuals were already at health facilities, removing the time and financial costs usually required to access HIV services. Outpatients might also represent individuals who are ready and able to use facility-based health services.

Most newly diagnosed HIV-positive individuals in the HIV self-testing group initiated ART without discussing their HIV self-test result with the outpatient department provider. HIV-positive individuals either sought out ART initiation through their own initiative or disclosed to the study staff distributing HIV self-test kits in the outpatient department waiting space, but not to the outpatient department provider. When developing the trial design, we hypothesised that providing HIV self-testing before an outpatient consultation would better facilitate integration of outpatient department and HIV services by giving outpatients and their providers the opportunity to have a one-on-one discussion about the HIV self-test result, post-test counselling, and referrals to additional HIV services. Our study findings show that under the strained conditions of busy health facilities and overworked providers, integration in routine outpatient consultations remains a challenge. Other studies showed that outpatient services are rushed, with little time for holistic care.[16,25] Clients rarely feel comfortable asking unprompted questions to a health-care provider and often believe their concerns are not heard.[26,27] As the strained environment of outpatient department clinics is unlikely to change, future interventions should focus on making HIV counsellors and strategies for linkage to additional services readily available in outpatient department waiting spaces before clients reach the providers.

Our costing analysis showed that the cost of providing one HIV self-test under study conditions is slightly more than the cost of providing one test through optimised provider-initiated testing and counselling and more than $2 more than the cost of one test with standard provider-initiated testing and counselling. The cost of HIV self-testing increased substantially between the cost per newly diagnosed positive case and cost per ART initiated because of a lower linkage rate with HIV self-testing

compared with both standard and optimised provider-initiated testing and counselling. Reducing the cost of the HIV self-test kit, use of government HIV testing and counselling staff (compared with research staff used in our study), and improved ART initiation could reduce the cost per ART initiation using facility-based HIV self-testing. Our costs of facility-based HIV testing are lower than those previously reported in community-based studies ($4·92 in Malawi[28] compared to our mean of $2·44). This difference was driven by differences in personnel costs, which could stem from differences in assumed compensation or duration of time staff spend on different activities. If our provider-initiated testing and counselling costing had yielded high costs similar to other studies, the relative difference between standard provider-initiated testing and counselling and HIV self-testing would decrease markedly, also making facility-based HIV self-testing more economically attractive. Further research is needed to assess whether facility-based HIV self-testing could have efficiency effects for provider time among those responsible for HIV testing and effects on testing efficiency (unit costs).

This trial has several limitations. First, it was not possible to survey all outpatients in high-burden sites because of infrastructure constraints; our study therefore relied on a sample of outpatients obtained by recruiting every tenth patient exiting the clinic. Although efforts were taken to ensure systematic selection of survey participants, our sampling method was approximate and we might have missed clients who left from a separate entrance. Although a small number of clients declined to participate or were ineligible (allowing for strict adherence to the sampling strategy), there could be unmeasured biases resulting from our sampling methods. Second, HIV testing and test results were based on self-reports and might result in under-reporting of newly diagnosed HIV-positive individuals if outpatients felt uncomfortable sharing their test result. However, we do not anticipate differences in social desirability bias across study groups and reported HIV-positivity prevalence was similar to national averages within outpatient settings. Third, we were unable to mask the interventions from research assistants who did the exit surveys. Although these research assistants did not implement the interventions, they could have biased surveys toward a positive response. We attempted to minimise this risk by emphasising the importance of all study groups during the training of research assistants. Finally, ART initiation was assessed at 3 months after HIV testing, and some individuals might have initiated ART after the 3-month period. Underestimations of ART initiation would probably affect the HIV self-testing group and might have resulted in underestimation of the effects of facility-based HIV self-testing on ART initiation. The study was not powered to evaluate ART linkage, which is a critical step in the HIV test and treatment cascade.

In conclusion, facility-based HIV self-testing in outpatient department waiting spaces increased HIV testing and the identification of HIV-infected individuals compared with standard and optimised provider-initiated testing and counselling, with no evidence of adverse events. HIV self-testing was easily integrated into routine outpatient services and drastically reduced provider workload related to HIV testing while increasing testing coverage, including coverage among high-risk and hard-to-reach individuals. Facility-based HIV self-testing provided privacy and autonomy for HIV testing and improved the efficiency of testing by overcoming bottlenecks created by limitations in trained personnel and facility space. Additionally, facility-based HIV self-testing addressed several challenges faced during HIV self-testing scale-up, including decreased barriers to ART initiation and improved opportunities for quality assurance and monitoring and evaluation. More research is needed into ART linkage within facility-based HIV self-testing, particularly for adolescents, who had a low prevalence of ART initiation in this study. Further research is also needed into which high-risk populations might be missed through facility-based HIV self-testing and the best strategies to reach these individuals to achieve epidemic control.

Contributors

KD and RMH conceived the study. KD, FS, KB, KP, VW, BEN, MN, TM, and RMH contributed to study design. KD, FS, OAO, KB, KP, and EL developed the guideline and training. KB and EL prepared and cleaned the data. KD and C-HT analysed the data. FS, OAO, RC, and BEN collected the cost data. RC and BEN analysed the cost data. SKG, VW, TJC, and RMH provided substantial scientific input into the statistical methods and interpretation of the results. KD, FS, and OAO did the literature reviews. FS, OAO, KB, KP, MN, and EL implemented the study. KD took the lead in drafting the report. FS, OAO, SKG, VW, BEN, RC, and RMH provided substantial comments to improve the draft. All authors contributed to the collection or interpretation of data, provided critical revisions to the report, and approved the final draft. KD and RMH are the guarantors of the study.

Declaration of interests

We declare no competing interests.

Data sharing

All primary outcome data files are available upon request. Those interested in the dataset can contact Kathryn Dovel (kdovel@mednet.ucla.edu). Access will be granted after a signed data access agreement is attained. Available data include job aids, consent forms, data dictionary, and deidentified primary outcome data. The study protocol and statistical analysis plan have been published elsewhere and are freely available.

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