Increasing knowledge of HIV status and demand for ART using community-based HIV self-testing: A cluster randomised trial in rural Malawi

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BACKGROUND

Knowledge of HIV status is the biggest gap in meeting the UNAIDS '90-90-90' targets. In Malawi, 72.7% of people with HIV are aware of their status, 89.6% of whom are on treatment, and 91.2% of whom are virally suppressed [1]. Coverage of HIV testing is relatively low in men, adolescents and rural populations [2]. HIV self-testing (HIVST) has potential to reach populations poorly served by facility-based HIV testing services.

We used a cluster-randomised trial design to investigate the impact of community-based distribution of HIVST kits on HIV testing coverage and antiretroviral therapy (ART) uptake.

METHODS

Public primary health centres and their defined catchment areas (n=22) were allocated using restricted 1:1 randomisation to either (i) **standard of care (SOC)**: facility-based HIV testing, or (ii) **HIVST**: door-to-door distribution of HIVST kits by resident community-based distributors (CBD) in addition to the standard of care. CBDs provided continuous HIVST access and option of post-test support and assisted referral to routine confirmatory testing and ART services.

**Primary outcome**: HIV testing in the last 12 months

Secondary outcomes: Lifetime HIV testing and cluster-level ART initiations for 17 months after cluster enrolment

Data sources:
- Population-based surveys with adults (age ≥ 16 years) of randomly selected households in evaluation villages 12-15 months after the cluster start date.
- ART data from clinic registers; population denominators from village records.
- Social harms monitoring systems established in evaluation villages.

Analysis: Cluster-level analysis. HIV testing analysis adjusts for individual and baseline cluster-level imbalance using a two-step approach. ART adjusts for ART initiations in the 12 months preceding cluster enrolment.

Figure 1. Trial flow diagram
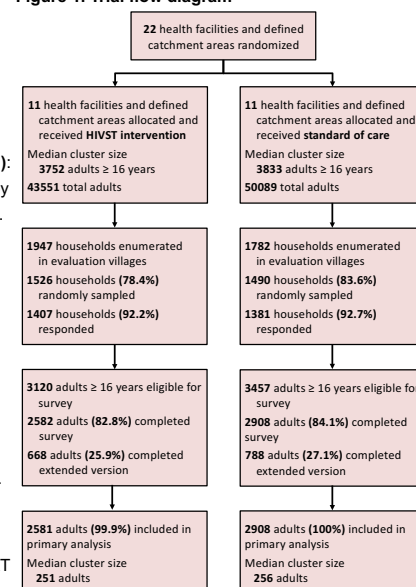
RESULTS

Table 1. Comparison of population characteristics by study arm

		Intervention (N=2800)	Control (N=2663)
Baseline			
Recent testing in the last 12 months		2308 (82.4)	2060 (77.4)
Endline		Intervention (N=2581)	Control (N=2908)
Male		1075 (41.7)	1264 (43.5)
Age group	16-19 years	393 (15.2)	451 (15.5)
	20-49 years	1740 (67.4)	1962 (67.5)
	≥ 50 years	448 (17.4)	495 (17.0)
Assets index [1]	Lowest	746 (29.7)	950 (34.1)
	Middle	801 (31.9)	839 (30.2)
	Highest	964 (38.4)	994 (35.7)

Data are n (%) unless specified otherwise. [1] No data for 122 households.

Table 2. HIV testing coverage and population-level ART initiation rates by study arm

	Intervention % (n/N)	Intervention GM	Control % (n/N)	Control GM	Unadj Risk Difference (95% CI), p-value	Unadj Risk Ratio (95% CI), p-value	Adj Risk Ratio[1] (95% CI), p-value
Primary outcome: tested in the last 12 months							
Overall	68.1% (1758/2581)	67.7%	48.4% (1409/2908)	47.7%	19.2% (10.0-28.5%) <0.001	1.42 (1.20-1.68) <0.001	1.42 (1.20-1.68) <0.001
Stratified by age							
<20 years	69.5% (273/393)	69.6%	42.4% (191/451)	39.4%	27.6% (13.4-41.8%) <0.001	1.77 (1.31-2.39) <0.001	1.76 (1.32-2.34) <0.001
≥ 20 years	67.9% (1485/2188)	67.5%	49.6% (1218/2457)	49.0%	17.5% (9.1-26.9%) <0.001	1.38 (1.16-1.63) <0.001	1.29 (1.08-1.53) 0.007
P-value for interaction					0.10	0.08	0.14
Stratified by sex							
Male	64.8% (697/1075)	63.9%	41.7% (527/1264)	41.1%	22.2% (10.0-34.5%) 0.001	1.55 (1.24-1.94) <0.001	1.50 (1.17-1.92) 0.003
Female	70.4% (1061/1506)	70.3%	53.6% (882/1644)	52.5%	16.9% (8.3-25.6%) <0.001	1.34 (1.14-1.57) 0.001	1.25 (1.05-1.48) 0.01
P-value for interaction					0.13	0.10	0.10
Stratified by assets index							
Low	63.6% (459/722)	59.7%	47.0% (424/902)	45.7%	14.0% (2.20-25.8%) 0.02	1.31 (1.04-1.64) 0.02	1.27 (1.00-1.62) 0.05
Medium	70.9% (588/829)	70.5%	51.5% (447/868)	50.9%	18.6% (9.3-27.9%) <0.001	1.39 (1.18-1.63) <0.001	1.28 (1.09-1.51) 0.005
P-value for interaction (medium vs low)					0.27	0.49	0.61
High	68.3% (656/961)	69.8%	46.8% (474/1013)	46.0%	22.7% (11.2-34.2%) <0.001	1.52 (1.23-1.87) <0.001	1.44 (1.16-1.80) 0.002
P-value for interaction (high vs low)					0.10	0.16	0.19
Secondary outcome: ever tested							
Overall	86.9% (2243/2581)	87.2%	78.5% (2283/2908)	78.6%	8.6% (4.7-12.6%) <0.001	1.11 (1.06-1.16) <0.001	1.08 (1.03-1.13) 0.004

Secondary outcome: ART initiation	Intervention GM	Control GM	Unadj. mean difference (95% CI), p-value	Unadj. GM ratio (95% CI), p-value	Adj. GM ratio (95% CI), p-value
Overall	167	212	55.9 (-74.5-186.4) 0.38	1.27 (0.71-2.26) 0.40	1.14 (0.75-1.75)[2] 0.52

GM, geometric mean (of cluster-level proportions); unadj, unadjusted; adj, adjusted. [1] Adjusted for cluster-level baseline recent testing and individual-level covariates age, sex and marital status. [2] Adjusted for baseline (pre-intervention) ART initiation.

Fidelity

- A total of 157 CBDs delivered 220,314 HIVST kits from September 2016 to January 2018.
- Social harms monitoring detected 1 mild and 2 severe adverse events from 13,083 HIVST episodes in baseline evaluation villages.
- A higher proportion of surveyed adults in the HIVST vs SOC arm (88.9% vs 31.5%) had heard of HIVST and ever self-tested (42.5% vs 8.3%).

CONCLUSION

CBD-delivered HIVST increased recent and lifetime testing coverage in rural populations, especially among men and adolescents. Uptake of HIVST was almost half when kits were easily accessible, and resulted in few social harms. HIVST had no measurable impact on population-level ART uptake. Community-based HIVST is an approach that can rapidly improve knowledge of HIV status in underserved populations.

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