

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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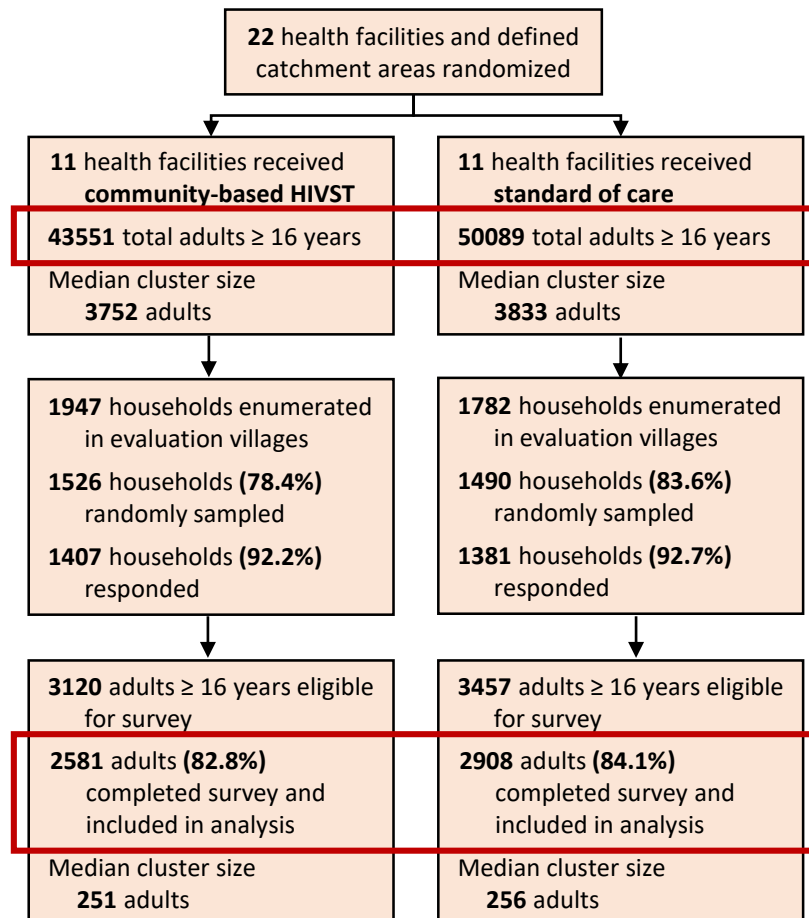
Background

- 72.7% of PLHIV know their status; 89.6% on ART; 91.2% virally suppressed (MPHIA 2015-16).
- HIV testing coverage relatively low in men, adolescents and rural populations

Methods

- Cluster-randomised trial design
- **Primary outcome:** Self-reported HIV testing in the last 12 months
- **Secondary outcome:** Self-reported lifetime HIV testing and ART initiations
- **Data sources:** population-based surveys, clinic registers, routine data, social harms monitoring

Trial flow diagram



ART initiation

HIV testing



Results – primary and secondary outcomes

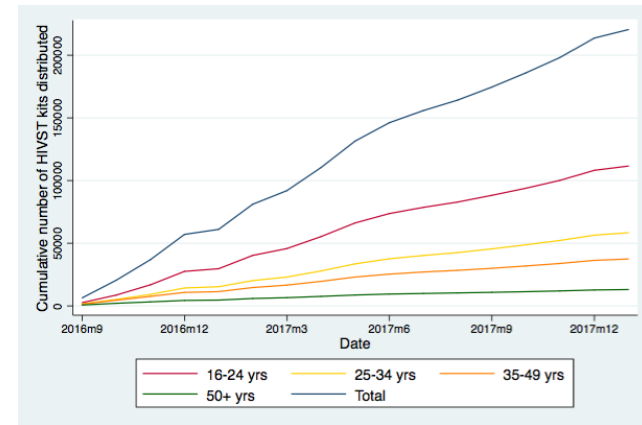
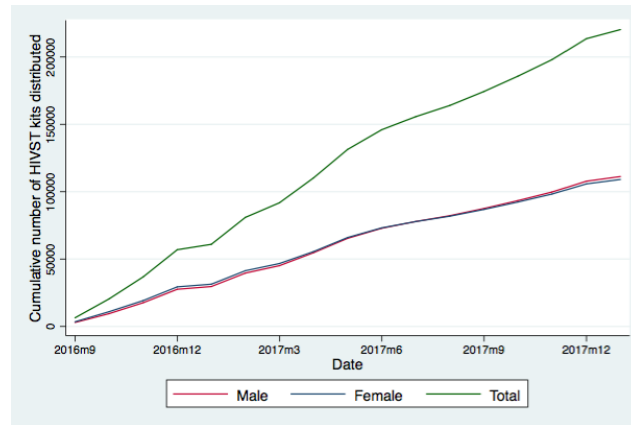
HIV testing coverage and population-level ART initiation rates by study arm

	HIVST % (n/N)	SOC % (n/N)	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)	48.4% (1409/2908)	1.42 (1.20-1.68) <0.001	1.33 (1.12-1.59) 0.003
Stratified by age				
<20 years	69.5% (273/393)	42.4% (191/451)	1.77 (1.31-2.39) <0.001	1.76 (1.32-2.34) <0.001
≥ 20 years	67.9% (1485/2188)	49.6% (1218/2457)	1.38 (1.16-1.63) <0.001	1.29 (1.08-1.53) 0.007
P-value for interaction			0.08	0.14
Stratified by sex				
Male	64.8% (697/1075)	41.7% (527/1264)	1.55 (1.24-1.94) <0.001	1.50 (1.17-1.92) 0.003
Female	70.4% (1061/1506)	53.6% (882/1644)	1.34 (1.14-1.57) 0.001	1.25 (1.05-1.48) 0.01
P-value for interaction			0.10	0.10
Stratified by assets index				
Low	63.6% (459/722)	47.0% (424/902)	1.31 (1.04-1.64) 0.02	1.27 (1.00-1.62) 0.05
Medium	70.9% (588/829)	51.5% (447/868)	1.39 (1.18-1.63) <0.001	1.28 (1.09-1.51) 0.005
P-value for interaction (medium vs low)			0.49	0.61
High	68.3% (656/961)	46.8% (474/1013)	1.52 (1.23-1.87) <0.001	1.44 (1.16-1.80) 0.002
P-value for interaction (high vs low)			0.16	0.19
Secondary outcome: ever tested				
Overall	86.9% (2243/2581)	78.5% (2283/2908)	1.11 (1.06-1.16) <0.001	1.08 (1.03-1.13) 0.004
Secondary outcome: ART initiation				
	HIVST GM	SOC GM	Unadj. GM Ratio (95% CI), p-value	Adj. GM Ratio ² (95% CI), p-value
Overall	167	212	1.27 (0.71-2.26) 0.40	1.14 (0.75-1.75) 0.52

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.

Results – fidelity

- 157 CBDAs delivered 220,314 HIVST kits from 09/16-01/18.
- Ever ST: HIVST, 42.5%; SOC, 8.3%
- 1 mild and 2 severe adverse events from 13,083 HIVST episodes in evaluation villages



Conclusions

- CBDA-delivered HIVST increased recent and lifetime testing coverage in rural populations, including among men and adolescents
- HIVST was acceptable and resulted in few social harms
- HIVST had no measurable impact on population-level ART initiation

Acknowledgments

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Study participants

Unitaid

No conflicts of interest to declare

