Community-led delivery of HIV self-testing targeting adolescents and men in rural Malawi: a cluster-randomised trial

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Introduction
Community-led interventions using participatory methods can ideally provide better outcomes at lower costs than conventional approaches. We conducted a cluster-randomised trial evaluating community-led HIV self-testing (HIVST).

Methods
Thirty village-head catchment areas in rural Mangochi, Malawi were randomised to community-led HIVST or standard of care (SOC), including periodic community-based testing. Participatory workshops and trainings supported planning and implementation of 7-day HIVST campaigns by village health committees (VHC) and community volunteers. Volunteers receiving standardised gratuity (US$10) distributed HIVST kits, provided HIV prevention information and supported linkage to routine services.

The primary outcome was lifetime testing in adolescents (15-19 years). Secondary outcomes included recent testing (last 3 months) in men and older adults (≥ 40 years), mutual knowledge of status within sexual partners, knowledge of prevention methods, and antiretroviral therapy initiation (ongoing). Analysis compared cluster-level outcomes by arm measured through post-intervention surveys.

Results
From October 2018-January 2019, 15 VHCs oversaw distribution by 188 volunteers of 24,347 kits. Post-intervention surveys showed 74.4% of HIVST arm participants reporting self-testing, with 2.3% testing positive and 0.39% pressured to self-test.

Lifetime testing in adolescents was 84.6% versus 67.1% in HIVST and SOC arm (adjusted risk ratio (aRR) 1.25, 95%CI 1.10-1.43), with differences greatest for younger ages and males (Table). A higher proportion of males reported recent testing in the HIVST than SOC arm (74.5% versus 33.9%, aRR 2.21, 95%CI 1.92-2.55), with similar effects among older adults (74.2% versus 31.6%, aRR 2.37, 95%CI 2.00-2.80). Knowledge of status within couples was higher in the HIVST than SOC arm (71.3% versus 56.9%, aRR 1.24, 95%CI 1.08-1.42), but prevention knowledge did not differ.

Conclusion
Community-led HIVST following participatory workshops and brief didactic training achieved high HIVST uptake, reaching more adolescents, men, older adults and couples and with minimal harm. Testing coverage was greater than recent community-based HIVST models, supporting community-led approaches as highly promising.

Word count: 300/300

Table. HIV testing coverage by study arm

	Community-led HIVST arm % (n/N)	Standard of care arm % (n/N)	Risk difference (95% CI), p-value	Risk ratio (95% CI), p-value	Adjusted risk ratio [1] (95% CI), p-value
Total population surveyed	3974/30371 adults in 15 clusters	3906/25580 adults in 15 clusters			
Primary outcome: Adolescents 15-19 years ever tested	84.6% (773/914)	67.1% (579/863)	16.4% (7.8-25.0%), <0.001	1.26 (1.11-1.43), <0.001	1.25 (1.10-1.43), 0.001
Stratified by age: 15-17 years	79.8% (320/401)	57.2% (219/383)	22.3% (9.6-35.1%), 0.001	1.46 (1.15-1.86), 0.003	1.45 (1.14-1.85), 0.004
18-19 years	88.3% (453/513)	75.0% (360/480)	11.7% (4.5-18.9%), 0.002	1.16 (1.06-1.27), 0.002	1.16 (1.05-1.27), 0.004
Stratified by sex: Males	79.7% (310/389)	57.3% (217/379)	22.6% (12.1-33.1%), <0.001	1.42 (1.19-1.68), <0.001	1.40 (1.18-1.67), <0.001
Females	88.2% (463/525)	74.8% (362/484)	11.9% (2.8-21.0%), 0.01	1.18 (1.04-1.33), 0.01	1.18 (1.03-1.33), 0.01
Secondary outcome: Males tested in last 3 months	74.5% (1180/1584)	33.9% (504/1488)	40.7% (33.1-48.4%), <0.001	2.22 (1.92-2.56), <0.001	2.21 (1.92-2.55), <0.001
Secondary outcome: Adults ≥ 40 years tested in last 3 months	74.2% (871/1174)	31.6% (348/1103)	42.0% (34.5-49.5%), <0.001	2.36 (1.99-2.80), <0.001	2.37 (2.00-2.80), <0.001

[1] Adjusted for sex, age, education level and marital status. P-value for interaction by age group: 0.02. P-value for interaction by sex: 0.01.