TITLE

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

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Background: 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 HIVST distribution on recent HIV testing and antiretroviral therapy (ART) uptake in rural Malawi.

Methods: Government clinics (n=22) and their defined rural catchment areas were allocated using restricted 1:1 randomisation to either (i) door-to-door distribution of HIVST kits by resident community-based distributors (CBD) or (ii) the standard of care (SOC). Distributors provided continuous HIVST access and option of post-test support and assisted referral to routine confirmatory testing and ART services. Social harm monitoring was also established.

The primary outcome compared recent HIV testing (previous 12 months) across arms, ascertained through population-based surveys conducted 12 months after the cluster start date in pre-defined evaluation villages. Analysis used logistic regression with adjustment for imbalance between arms. For the secondary outcome, we used generalized estimating equations to analyse cluster-level ART initiations that were recorded in clinic registers in the 12 months after cluster enrolment, adjusting for ART initiations in the preceding 12 months.

Results: A total of 83 CBDs delivered 79,349 HIVST kits over a 12 to 15-month period, with three reported social harms. Of 5,504 adults in the post-intervention survey, 42.6% were men and 15.4% were adolescents aged 16-19 years. Coverage was significantly higher in the HIVST than SOC clusters for both recent testing (64.1% versus 45.6%, adjusted risk ratio [aRR] 1.38, 95%CI 1.14-1.68) and lifetime testing (87.3% versus 78.7%, aRR 1.12, 95%CI 1.05-1.16). Differences between arms were more pronounced for adolescents (aRR 1.99, 95%CI 1.35-2.92) and men (aRR 1.55, 95%CI 1.19-2.01). Among 93,640 adults living in the defined study area, the proportion of ART initiations per 1000 adult clinic population increased in the HIVST versus SOC arm in the intervention period, adjusting for pre-intervention ART uptake (adjusted initiation risk ratio 1.36, 95%CI 0.95-1.94, p=0.09).

Conclusions: CBD-delivered HIVST increased HIV testing coverage in rural populations, especially among men and adolescents, and population-level demand for ART. This approach can rapidly improve knowledge of HIV status in underserved populations and have a measurable impact on ART uptake.