ICAP Journal Club

ICAP's Journal Club is designed to inform ICAP staff and colleagues of the latest scientific literature by providing a succinct summary and critical analysis of important studies, and by discussing the implications of the research on clinical work.

Article

Amstutz A, Lejone TI, Khesa L, et al. **Home-based oral self-testing for absent and declining individuals during a door-to-door HIV testing campaign in rural Lesotho (HOSENG): A cluster-randomised trial**. *Lancet HIV*. 2020;7(11):e752-e761.

https://doi.org/10.1016/S2352-3018(20)30233-2

Study Summary

The Home-Based Self-Testing (HOSENG) trial was a cluster-randomized trial that evaluated the impact of secondary distribution of HIV self-test (HIVST) kits for individuals who were absent or declined to test during home-based HIV testing on overall HIV testing coverage.

Study Setting

- Rural villages in the catchment area of 20 health facilities located in two districts of Lesotho.

Methods

- Villages were eligible to participate in the study if they had a consenting village chief and at least one registered village health worker. Eligible villages underwent random sampling, stratified by district, village size (≥30 households vs. <30 households), and access to the nearest health facility (easy to reach vs. hard to reach, defined as needing to cross a mountain or river or travel >10 km to a health facility).
- Clusters were defined as the individual villages, except in cases where several villages shared one village health worker, in which case they were considered one cluster.
- The HOSENG trial provided a recruitment platform for the separate Village-Based Refill of Antiretroviral Therapy (VIBRA) trial, therefore villages were randomly assigned (1:1:1:1) to one of four combinations: VIBRA control and HOSENG control; VIBRA control and HOSENG intervention; VIBRA intervention and HOSENG control; and VIBRA intervention and HOSENG intervention.
- Two teams, consisting of six to ten lay counsellors, one campaign organizer, and one study nurse, visited all households in the enrolled villages during the recruitment period.
- Households were eligible to participate if a head of household or representative aged ≥18 years provided informed consent. A household member was defined as someone considered a member by the household head and who slept in the household at least once every three months.

- In each participating household, the study team offered blood-based HIV testing, HIV prevention services and screening for tuberculosis and alcohol use to all household members who were present at the time of the visit.
- Household members who had tested HIV-negative within the previous 4 weeks, with proof in their health booklet, or who were known to be HIV-positive were not tested.
- In the control group, households were offered the standard of care, which was referral of absent household members and those declining to test to a nearby health facility for HIV testing.
- In the intervention group, the study team asked if they could leave an oral-fluid HIVST kit for every household member ≥12 years who was absent or declined HIV testing on the day of the visit.
    - The HIVST kits were prepacked with pictoral and written instructions in the local language, and a written request to consult the village health worker within two weeks after use, irrespective of the result.
    - The team labeled the kit with the name of the absent household member and trained a present household member to use the HIVST kit.
    - The village health workers received a list of all household members for whom a HIVST kit was dispensed, including the date that household member was expected to return according to their family.
    - The village health worker revisited all households two to four weeks after the reported date of the absent family member's return to collect the HIVST kit if it had not been returned previously. The follow-up period lasted for 120 days after the home visit.
    - The village health workers reread the result of the oral-fluid HIVST strip and in the case of a reactive test, coordinated further blood-based testing to confirm the outcome.
- At the end of the follow-up period, the study team searched through the testing registers at all health facilities in both study districts to collect testing outcomes for participants who decided to attend the clinic for testing.
- The primary endpoint was HIV testing coverage among household members aged ≥12 years within 120 days after the home visit, defined as the proportion of household members living in the surveyed area with a confirmed HIV test result.
- A confirmed HIV test result was defined as being known HIV-positive (tested HIV-positive with documentation before the study); being known HIV-negative (tested HIV-negative within 4 weeks before the start of the study with documentation); or having a confirmed HIV test result during the study period per national guidelines. A reactive HIVST was only considered valid if confirmed by a follow-up blood-based test. HIVST kits that were not returned to the village health worker, or that were not found in the household during the health worker's follow-up, were documented as unused.
- Secondary endpoints included HIV testing coverage irrespective of age, blood-based HIV testing uptake irrespective of age (proportion of all eligible household members who consented to blood-based point-of-care HIV testing) and HIVST uptake (proportion of household members for whom a HIVST kit was left behind with a documented self-testing result within 120 days).
- Village clusters were the unit of randomization whereas individuals were the unit of analysis, and analyses followed an intention-to-treat approach.

Study Population and Follow-up

- Between July and December 2018, 744 villages were assessed for eligibility, of which 648 were eligible for random sampling. Of these, 49 village clusters with 1,573 occupied households were included in the control group, and 57 village clusters with 1,777 occupied households were included in the intervention group.
- There was a median of 78 (interquartile range [IQR] 50-123) households per village cluster in the control group, and a median of 80 (IQR 49–109) households per village cluster in the intervention group.
- In the control group, 94% (n=1,471/1,573) of households consented and 91% (n=1,620/1,777) consented in the intervention group, with a median of 4 (IQR 3–6) household members in both groups.
- A total of 7,816 household members aged ≥12 years were enumerated in consenting households, 3,642 (2,059 present, 1,583 absent) in the control group and 4,174 (2,400 present, 1,774 absent) in the intervention group.
- Among the present household members aged ≥12 years, 70% were female, median age was 41 years (IQR 27-62), median years of schooling was 6 (IQR 3-7), and 44% had no regular income.
- Among absent household members aged ≥12 years, 64% were male, median age was 24 years (IQR 16-38), and the main reasons for being absent at the time of the visit were being outside the village (31%) and at school (29%).
- Baseline characteristics were similar across the intervention and control groups among present and absent household members.

Primary Outcomes

- At the time of the home-based visit, 59% (n=2,163/3,642) of eligible individuals in the control group and 61% (n=2,545/4,174) of eligible individuals in the intervention group had a known HIV status or were tested for HIV as part of the study.
- Within 120 days, 3% (n=38/1455) initially absent or declining household members in the control group had been tested at a health facility, whereas 53% (n=841/1601) of initially absent or declining household members had a confirmed HIV status within 120 days in the intervention group. Of these, 1% (n=12/841) were tested at the clinic and 99% (n=829/841) used their HIVST kit.
- Overall testing coverage for household members aged ≥12 years after 120 days was significantly higher in the intervention group vs. the control (81% vs. 60%; adjusted odds ratio [aOR] 3.00; 95% confidence interval [CI] 2.52-3.59; p<0.0001).
- In subgroup analyses, the intervention effect was greater in male participants than in female participants (aOR 4.82 vs. 2.42; p for interaction <0.0001), greater in adolescents (12-19 years) than in young adults (20-24 years) and adults >24 years old (aOR 22.15 in adolescents, vs. 3.15 in young adults and 2.23 in adults; p for interaction <0.0001) and greater for those who had received only a primary education compared to secondary or tertiary education (aOR 3.30 vs. 2.62; p for interaction <0.0033).
- By employment status, the intervention had the greatest effect on students (aOR 31.42; 95% CI 14.40-68.54; p<0.0001) and those working in South Africa (aOR 14.99; 95% CI 3.06-73.31; p=0.0001).

Secondary Outcomes

- HIV testing coverage 120 days after the testing campaign irrespective of age was significantly greater in the intervention group than in the control group (71% vs. 56%, aOR 1.93, 95% CI 1.63-2.28, p<0.0001).
- Across both groups, 90% (n=3,500/3,903) of eligible present household members of any age consented to blood-based testing during the home visit and uptake of blood-based HIV testing was similar between the groups.
- In the intervention group, an HIVST kit was left for 84% (n=1,438/1,704) of household members aged ≥12 who were absent on the day of the visit (n=1402) or declined blood-based testing (n=36). Of these, 829 (58%) used and returned the kit within 120 days, with an uptake of 58% (n=814/1402) in people who were absent and 42% (n=15/36) in those who declined initial blood-based testing.
- A reason was noted for 106 people who did not use and return the HIVST kit, with the most common reasons being mistrust of the test (34%), followed by not being ready to test (25%), the absent person had not returned home yet (18%), lost the test (16%), and reported other HIV testing recently (8%).

Other Outcomes

- During the home visits, 3% (n=73/2,977) of tests across both groups were positive.
- Among 829 household members who used the HIVST, seven (1%) had reactive tests, three of which were confirmed HIV-positive, two were confirmed negative, and two did not have confirmatory testing.
- Of the 38 household members in the control group and 19 in the intervention group who sought testing at the health facility, three tested HIV-positive, with two in the intervention group and one in the control group.

Critical Analysis

The cluster-randomized HOSENG trial found that providing HIVST kits for secondary distribution to individuals who were absent or who declined to test during a rural home-based HIV testing campaign improved overall HIV testing coverage, especially among men, migrant workers and adolescents. While this method of improving coverage through home-based testing programs appears feasible, the yield of new confirmed people living with HIV was relatively low.

The following points should be considered when interpreting the study findings:

- Linkage to care and treatment outcomes after testing were not reported, as they will be reported in the interlinked VIBRA trial. However, investigators did not find evidence of an interaction between the VIBRA study groups and the HOSENG primary endpoint.
- There were no systematic safety endpoints collected or reported, which makes any social adverse events associated with this method of distribution harder to assess.
- Among participants for whom a reason for not using the kit was reported, almost one in five reported the household member had not returned yet. Therefore, the 120-day follow-up period may have resulted in an underestimation of HIVST uptake.

- The study could not account for HIV testing done at locations outside of the study districts, and therefore HIV testing coverage may have been higher than reported, especially among those who were absent from the village.
- The study design did not allow for blinding, but slightly different consent forms were used so that participants were not aware of the services villages in the other study arm were receiving.

Implications

The HOSENG trial found that integrating secondary distribution of HIVST kits into a home-based HIV testing program in rural Lesotho improved testing coverage among those who were absent from the home or declined HIV testing at the time of the visit. This improvement in testing coverage was most notable in men and adolescents, especially among students and migrant workers. While testing coverage improved, overall yield was relatively low, suggesting that a more targeted approach may be warranted. Taken together, these results suggest this method could be considered as a person-centered, differentiated approach to providing HIV testing services for those who are not routinely found at home during the day in similar high-burden, rural settings.

This article synopsis was written by Cassia Wells. Share your thoughts on this article or suggest an article for Journal Club by emailing her at caw2208@columbia.edu.