HOSENG ("HOme-based SElf-testiNG") trial: Oral self-testing for individuals absent or declining testing during home-based HIV testing: A cluster randomized trial in Lesotho

Alain Amstutz^{1,2,3} Thabo Ishmael Lejone⁴ Lefu Khesa⁴ Josephine Muhairwe⁴ Bienvenu Lengo Nsakala⁴ Moniek Bresser^{1,2} Mathebe Kopo⁴ Mpho Kao⁴ Fiona Vanobberghen^{1,2} Thomas Klimkait^{2,5} Manuel Battegay^{2,3} Niklaus

¹Swiss Tropical and Public Health Institute ²University of Basel ³University Hospital Basel ⁴SolidarMed Lesotho ⁵Department of Biomedicine UniBasel *presenting author

INTRODUCTION

In sub-Saharan Africa, HIV testing coverage remains below the targeted 90% despite efforts and resources invested. Home-based HIV testing is a key approach endorsed by the World Health Organization, especially to reach individuals who might not seek testing otherwise. Although acceptance of testing during such campaigns is high, coverage remains low due to absent household members. This cluster-randomized trial aims to assess the impact on testing coverage of oral HIV self-test (HIVST) distribution for household members (HM) who are absent or decline home-based HIV testing.

METHODS

- **Design:** cluster-randomized, controlled parallel group, superiority trial in two districts of Lesotho, Southern Africa.
- *Intervention*: Oral HIVST left for HM who are absent or decline testing during home-based testing, and training of one present HM on HIVST

RESULTS

- Enrolled 3106 consenting households with 7,846 HM aged \geq 12 (intervention: 57 clusters, 1628 households, 4192 HM; control: 49, 1478, 3654)
- 2413 (58%) intervention and 2070 (57%) control HM were present.
- Absent HM were mostly male (64%) and the majority were outside the village ullet(31%) or at school (29%).
- Uptake of blood-based HIV testing was high at 92% and did not differ between study arms.
- In the intervention arm:
 - 1889 HM were absent (94%) or present and declined testing (6%).
 - 1447 (77%) were left an HIVST
 - 826 (57%) HIVST were used and returned within 120 days.
 - 7 HIVST were positive; 3 of which were confirmed positive
- In the control arm:
 - 1695 HM were absent (93%) or declined testing (7%)

usage. Distributed HIVST followed up by village health workers.

- **Control**: HM who are absent or decline testing are left information inviting them to the clinic for testing (standard of care).
- *Primary endpoint:* HIV testing coverage among HM aged ≥12 years within 120 days after the home visit defined as a confirmed HIV test result, known HIV+, or HIV- result within last 4 weeks.
- Secondary endpoints: blood-based and oral-based testing uptake
- *Eligibility:* Villages must be in catchment area of a study facility, have consent of village chief, and have a registered, capable, trained village health worker. Household heads and HM have to consent to HIV testing.
- **Randomization:** cluster is defined as a village or group of villages serviced by one village health worker. Randomization is stratified by district, village size (<30 vs \geq 30 households), and access to the nearest health facility (easy vs hard to reach).
- **Sample size:** Testing coverage 63% in control, Δ =15%, variance inflation factor 8.3, Power>90%, α =0.05 => 100 clusters; min. of 3200 individuals.
- Analysis: Individuals are the unit of analysis, ITT, multi-level logistic regression models, adjusted for stratification factors and clustering (village and household). Planned subgroup analyses include age and gender. *Trial Registration*: NCT03598686

12 (0.7%) were tested at the facility within 120 days.



Figure: Testing coverage

- HIV testing coverage was 3372/4188 (81%) in the intervention versus 2187/3654 (60%) in the control arm (odds ratio 2.9 [95% confidence interval 2.5-3.5]; p<0.001).

Pictures: training of present HM on the usage of HIVST



The intervention effect was: greater in males (74% vs 44%; 4.2 [3.3-5.2]) than females (86% vs 73%; 2.4 [1.9-3.0], p interaction<0.001) and in adolescents (75% vs 38%; 5.6 [4.4-7.1]) than adults (84% vs 71%; 2.2 [1.8-2.7], p interaction<0.001).

CONCLUSIONS

- Acceptance and uptake of blood-based testing and HIVST was high.
- Secondary distribution of HIVST achieved HIV testing coverage of 81%, an increase of 21% over the control arm.
- The intervention was particularly successful among males and adolescents, an especially vulnerable group.
- Cost-effectiveness analysis will offer important cost considerations for the implementation of secondary HIVST distribution as an addon during home-based HIV testing.



Correspondence: tracy.glass@swisstph.ch **Funding**: Swiss National Science Foundation (IZ07Z0_160876/1; PCEFP3_181355; 323530_177576)

Departement Biomedizin

Universitätsspital Basel



SOLID/IR MED **SWISS NATIONAL SCIENCE FOUNDATION**

PRESENTED AT THE 10TH IAS CONFERENCE ON HIV SCIENCE (IAS 2019) | MEXICO CITY, MEXICO | 21-24 JULY 2019

#IAS2019 01AS_CONFERENCE WWW.IAS2019.0RG