

# HIV self-testing (HIVST) to be offered as an additional testing option in health facilities?: A systematic review and meta-analysis

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## BACKGROUND

- HIV self-testing (HIVST) is a process in which a person collects their own specimen (oral fluid or blood) using a rapid HIV test, performs the test, and interprets their result, when and where they want.
- World Health Organization (WHO) has recommended HIV self-testing (HIVST) since 2016. HIVST is now routinely implemented globally across different service delivery models, supporting both HIV case-finding and prevention.
- To optimise limited resources, some programmes have used risk-screening tools to limit HIV testing services to at-risk populations. However, evidence suggests that risk-screening tools may have contributed to declining HIV diagnosis and ART initiations. To date, WHO does not recommend the use of "screen-out" risk-screening tools.
- Facility-based HIVST (FB-HIVST) has been used in high HIV burden settings or sites with limited staff to increase testing coverage.
- This review aimed to evaluate the risks and benefits of FB-HIVST and explore whether FB-HIVST may be an effective method to increase diagnosis in high-burden settings.

## METHODS

- Searched 9 electronic databases using key terms: "HIV" AND "self-test"
- To be included, studies needed to directly compare people receiving FB-HIVST to people receiving standard HIV testing services or no intervention.
- Risk of Bias was assessed according to guidance by Cochrane Handbook.
- Meta-analyses of studies reporting on comparable outcomes was conducted on REVMAN 5.4.1 using random-effects model for relative risk (RR), with 95% confidence intervals
- Certainty of evidence was rated using GRADEPro

## RESULTS

Figure 1. Prisma flow chart of study selection

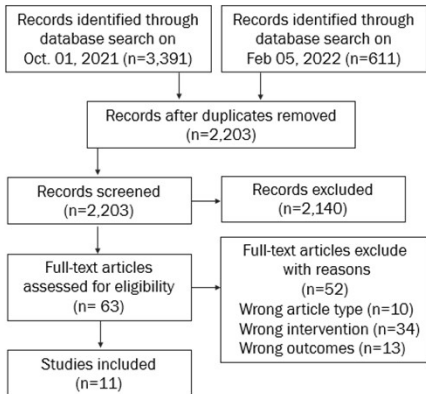


Table 1. Study Characteristics

| Study ID               | Study Type   | Characteristics                             |
|------------------------|--------------|---|
| Dovel et al, 2020      | RCT, cluster | Malawi; OPD                                 |
| Nichols et al, 2020    | Cost         | Adolescent & adult outpatients              |
| Nichols et al, 2021    | CEA          |   |
| Mphande et al, 2018    | Qual         |   |
| Kelvin et al, 2018     | RCT, indiv.  | Kenya; Clinics<br>Truck drivers             |
| Kelvin et al, 2019 (a) | RCT, indiv.  | Kenya; Clinics<br>Truck drivers             |
| Kelvin et al, 2019 (b) | RCT, indiv.  | Kenya; Clinics<br>Female sex workers        |
| Gaydos et al, 2013     | Cohort       | USA; ED<br>Adult outpatients                |
| Hector et al, 2018     | Cohort       | Mozambique; YF<br>Hospital<br>Adolescents   |
| Sande et al, 2021      | Cost         | Zambia, Zimbabwe<br>Clients ANC and OPD     |
| Hubbard et al, 2022    | Qual         | Malawi, Adolescent & adult positive testers |

RCT: Randomized controlled trial, Indiv.: Individual, OPD: Out-patient department, ED: Emergency department, YF: Youth Friendly, ANC: Ante-natal clinic, NS: Not specified, FS: Female sex workers

## SUMMARY OF EVIDENCE

### HIV Testing Uptake

| Study or Subgroup   | FB-HIVST |             | SOC    |             | Weight        | Risk Ratio          |                     |
|---|----------|-------------|--------|-------------|---------------|---------------------|---------------------|
|   | Events   | Total       | Events | Total       |               | M-H, Random, 95% CI | Risk Ratio          |
| Dovel, 2020 (1)   | 406      | 802         | 95     | 746         | 25.8%         | 3.98                | [3.26, 4.85]        |
| Kelvin, 2018  | 131      | 150         | 113    | 155         | 26.0%         | 1.20                | [1.07, 1.34]        |
| Kelvin, 2019 (A)  | 31       | 750         | 10     | 762         | 22.8%         | 3.15                | [1.56, 6.38]        |
| Kelvin, 2019 (B)  | 119      | 750         | 43     | 696         | 25.3%         | 2.57                | [1.84, 3.58]        |
| <b>Total (95% CI)</b>   |          | <b>2452</b> |        | <b>2359</b> | <b>100.0%</b> | <b>2.47</b>         | <b>[0.96, 6.33]</b> |
| Total events  | 687      |             | 261    |             |               |                     |                     |
| Heterogeneity: Tau <sup>2</sup> = 0.88; Chi <sup>2</sup> = 187.21, df = 3 (P < 0.00001); I <sup>2</sup> = 98% |          |             |        |             |               |                     |                     |
| Test for overall effect: Z = 1.88 (P = 0.06)  |          |             |        |             |               |                     |                     |

#### Footnotes

(1) Adjusted for cluster effect using reported ICC. Dovel, 2020 additionally reports an Adjusted OR(95% CI) for site: 8.89(4.17-18.94);...

### HIV Positivity

| Study or Subgroup  | FB-HIVST |             | SOC    |             | Weight        | Risk Ratio          |                      |
|--|----------|-------------|--------|-------------|---------------|---------------------|----------------------|
|  | Events   | Total       | Events | Total       |               | M-H, Random, 95% CI | Risk Ratio           |
| Dovel, 2020 (1)  | 11       | 802         | 2      | 746         | 41.5%         | 5.12                | [1.14, 23.00]        |
| Kelvin, 2018   | 0        | 150         | 2      | 155         | 18.7%         | 0.21                | [0.01, 4.27]         |
| Kelvin, 2019 (A)   | 5        | 750         | 0      | 762         | 19.9%         | 11.18               | [0.62, 201.75]       |
| Kelvin, 2019 (B)   | 5        | 750         | 0      | 696         | 19.9%         | 10.21               | [0.57, 184.29]       |
| <b>Total (95% CI)</b>  |          | <b>2452</b> |        | <b>2359</b> | <b>100.0%</b> | <b>3.77</b>         | <b>[0.81, 17.44]</b> |
| Total events   | 21       |             | 4      |             |               |                     |                      |
| Heterogeneity: Tau <sup>2</sup> = 0.88; Chi <sup>2</sup> = 4.67, df = 3 (P = 0.20); I <sup>2</sup> = 36% |          |             |        |             |               |                     |                      |
| Test for overall effect: Z = 1.70 (P = 0.09)   |          |             |        |             |               |                     |                      |

#### Footnotes

(1) Adjusted for cluster effect using reported ICC. Dovel, 2020 additionally reports an Adjusted OR(95% CI) for site: 1.10(0.45-2.69);...

| Outcome                                   | # Studies & Type | Result   | Interpretation   | Certainty of Evidence |
|---|------------------|--|--|-----------------------|
| <b>HIV Testing Uptake</b>                 | 4 RCTs           | RR= 2.47; 95% CI: 0.96, 6.33; Chi <sup>2</sup> = 187.21; df = 3; p<0.00001; I <sup>2</sup> = 98%   | FB-HIVST may improve HIV testing uptake.   | Low                   |
| <b>HIV Positivity</b>                     | 4 RCTs           | RR= 3.77; 95% CI: 0.81, 17.44; Chi <sup>2</sup> = 4.67; df = 3; p<0.20; I <sup>2</sup> = 36%   | FB-HIVST may lead to greater likelihood of HIV diagnosis compared to standard of care.   | Low                   |
| <b>Acceptability (would test again)</b>   | 1 RCT            | RR= 1.21; 95% CI: 1.10, 1.33   | FB-HIVST is likely acceptable to populations   | Low                   |
| <b>Acceptability (would recommend)</b>    | 1 RCT            | RR=1.12; 95% CI: 1.04, 1.21  |  | Low                   |
| <b>Acceptability (choice of HIV test)</b> | 3 RCTs           | Among participants offered a choice between 3 testing options, 16.78% (n=151/900) chose FB-HIVST vs. 10.33% (n=93/900) chose SOC   |  | Moderate              |
| <b>Diagnostic Accuracy</b>                | 1 Cohort         | Out of 299 tests, and excluding invalid results, specificity was measured at 1.00 [95% CI: 0.48, 1.00] and specificity at 1.00 [95% CI: 0.99, 1.00].                           | High specificity and sensitivity, but there may be cases of diagnostic discrepancies related to inconclusive results.                | Very Low              |
| <b>Usability</b>                          | 2 Cohorts        | 75.33% (n=577/766) reported HIVST was easy to use vs. 2.87% (n=22/766) reported HIVST was not easy to use.   | Majority of populations may find FB-HIVST easy to use, but certain populations, such as adolescents, may require additional support. | Very Low              |
| <b>Linkage to HIV Care</b>                | 1 RCT            | RR= 3.77; 95% CI: 0.68, 15.62  | Linkage to care may be comparable between FB-HIVST and SOC.  | Low                   |
| <b>Social Harm</b>                        | 1 RCT            | No participants in FB-HIVST reported coercion to test or disclose test results compared to 10 participants in SOC reporting coercion to test, 1 in 1 to disclose test results. | FB-HIVST may engender minimal risk of social harm  | Low                   |

## VALUES & PREFERENCES

- 5 studies reported on values & preferences
- Values & Preferences for FB-HIVST were generally positive.
- FB-HIVST was commonly associated to ease of use, immediate access to counseling and support, greater autonomy, and improved privacy - particularly for adolescents.
- Some participants reported lack of confidence in correctly self-administering the test, lack of trust in oral fluid HIV tests compared to blood-based tests and concerns with linkage to care. Not everyone preferred HIVST when offered as an option.

## RESOURCE USE

- Sande 2021, found the average incremental cost per FB-HIVST kit distributed comparable to home-based HIVST
- Assuming threshold analysis of \$200 USD per new diagnosis, Nichols 2020 found FB-HIVST may be cost-effective
- In Nichols 2021 CEA, FB-HIVST remained cost-effective across scenarios, and even became cost-saving when kit price was reduced to \$1.00
- Time and Motion Studies found that FB-HIVST has a potential of reducing staff time in HIV testing services.

## CONCLUSIONS

- FB-HIVST may encourage higher HIV testing uptake and contribute to finding more HIV positive diagnoses. Linkage may be comparable between FB-HIVST and SOC, but further operational research to improve rapid linkage to prevention and care is still desirable.
- FB-HIVST may be an efficient method to increase testing coverage, particularly in high-burden settings, sites with limited staff and reach people in need of HIV prevention and care. Based on the findings of this review, and additional evidence, WHO now recommends FB-HIVST.