Reaching partners of antenatal and index HIV-positive patients in Malawi: a pragmatic cluster randomized trial evaluating uptake, yield, and accuracy of secondary distribution of HIV self-test kits

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RUNNING HEAD: Impact of secondary distribution on testing, yield and secondary accuracy

Abstract (376 words)

Background

Secondary distribution of HIV self-test (HIVST) kits by antenatal care (ANC) and newly diagnosed HIV (Index) patients provides convenient access to sexual partners, and has potential for scale-up in Africa. We evaluated secondary distribution in ANC and among index clients delivered as government services in Malawi.

Methods

A pragmatic cluster-randomised trial of 27 public primary clinics with 3 arms: standard of care (SOC), HIVST-only, and HIVST+ Secondary Accuracy with Financial Incentive (SA/FI). In SOC, personalised letters invited either ANC partners and/or index clients to attend HIV testing services (HTS). In HIVST arms, ANC/Index clients received kits (OraQuick® HIV Self-Test) and were trained (~5-8 min). In the HIVST-only arm, letters advised participants to access HTS at the clinic if HIVST-positive. HIVST+ SA/FI offered partners US$10 to retest at the clinic irrespective of result. Government staff managed kit distribution, patient training, and care.

Outcomes were evaluated at 28-days using patient-interviews, and clinic registers. Follow-up testing of partners in the HIVST+SA/FI arm evaluated HIVST performance. Primary outcomes were: proportion of partners tested within 28-days (ANC clients) and number of new positives (index clients). Cluster-level summaries compared intervention vs SOC using intention-to-treat analyses.

Results

From 12 September 2018 to 30 May 2019, 4248/4298 (98.8% participation) eligible ANC and 708/746 (94.9% participation) eligible index clients accepted HIVST kits, of whom 3577 (84.2%) ANC and 433 (61.2%) index clients were interviewed after 28 days. Baseline characteristics were balanced across arms.

Reported partner testing was higher in HIVST-only (75.6%, RR 1.83, 95% CI: 1.34; 2.43, p<0.001) and HIVST+SA/FI arms (68.1%, RR 1.65, 95% CI: 1.25; 2.18, p<0.001) compared to 43.1% in SOC. From index testing, geometric mean/Index was 1.69 new positives (95% CI: 0.98; 2.92) for SOC, 4.2 (95% CI: 1.77; 10.11, p=0.009) for HIVST+SA/FI, and 1.91 for HIVST-only (1.91, 95% CI: 1.05; 3.51, p=0.750).

Among 863 partners retested in HIVST+SA/FI arm, HIVST sensitivity was 89.7% (95% CI: 78.8; 96.1%) with 99.5% (95% CI: 98.7; 99.9%) specificity. Adverse events included four temporary separations. Cost/partner tested was $4.54, $8.09 and $8.69 for SOC, HIVST-only and HIVST+SA/FI arms, respectively.

Conclusions

Secondary HIVST distribution substantially increased male partner-testing among ANC clients and increased new HIV diagnoses among index clients with incentivised confirmatory testing. HIVST sensitivity was slightly lower than previous reports, highlighting need to further optimise this approach.

Trial registration: NCT03705611

KEYWORDS: HIV self-testing; cluster randomized trial; HIV; secondary distribution; ANC; Malawi; sub-Saharan Africa.