

# **Retesting for HIV on antiretroviral therapy (ART) against policy recommendations: investigating the impact on sensitivity of self-testing, Blantyre, Malawi.**

## **Authors (11)**

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## **298 words**

### **Aim**

Patients established on antiretroviral therapy (ART) sometimes retest for HIV, potentially unaware that prolonged viral load (VL) suppression and associated low antibody levels can reduce test sensitivity leading to incorrect results. We investigated OraQuick HIV Self-Test (oral-fluid) and INSTI HIV Self-Test (finger-prick) HIV self-testing (HIVST) kit performance in ART patients.

### **Methods**

Consenting adults  $\geq 16$  years taking ART for  $\geq 4$  years in Malawi completed a standardised questionnaire before randomisation to either INSTI HIVST or OraQuick HIVST from April-October 2018. Following pre-test demonstrations, participants self-tested privately, with video-recording. HIVST kits were re-read by health-workers who collected blood for further testing using the national algorithm (Determine HIV-1/2, Uni-Gold), and VL testing (Xpert HIV-1). Sensitivity used standard methods, omitting invalids and assuming participants were HIV-positive, with sample size of 250 patients per arm to give lower 95%CI of  $\geq 95\%$  assuming self-read sensitivity  $\geq 98\%$ .

### **Results**

Of 609 ART patients approached, 502 were recruited (38 declined, 66 ineligible), with equal numbers (251) allocated to INSTI and OraQuick.

On self-read (Table), sensitivity of INSTI (1 invalid excluded) was 98.8% (95%CI: 96.6-99.9%), with 3 false-negatives. Self-read sensitivity of OraQuick was 98.0% (95%CI: 95.4-99.4%) with 5 false-negatives and no invalid results.

Health-workers read the same result as self-reads for all INSTI kits (Table) but reclassified 4 OraQuick kits (three negative to positive, and one positive to negative), increasing sensitivity to 98.8%.

Clients with undetectable VLs were more likely to have negative self-read HIVST results (7/233 [3.0%] sensitivity 97.0%) for undetectable vs 0/163 detectable VL:  $p=0.027$ , and included 4 clients negative on Determine and Unigold. VL testing was not run for the final 95 patients, and 14 had invalid VL results.

### **Conclusions**

Long-term ART affected WHO pre-qualified HIVST kit performance, although sensitivity remained  $\geq 98\%$  for each kit, with combined-kit sensitivity of 97.0% in clients with undetectable VL.

**Table**

| <b>Arm/Kit</b>  | <b>Reader</b> | <b>True Pos</b> | <b>False Neg</b> | <b>Invalid</b> | <b>Sensitivity</b> | <b>95% CI</b> | <b>Comments</b>   |
|-----------------|---------------|-----------------|------------------|----------------|--------------------|---------------|---|
| INSTI/INSTI     | Self          | 247             | 3                | 1              | 98.8%              | 96.5 - 99.8%  | 3/3 VL UD. 2/3-ve on all reads and RDTs   |
| INSTI/INSTI     | HW            | 247             | 3                | 1              | 98.8%              | 96.5 - 99.8%  | Same 3 clients as INSTI -ve self-read above   |
| INSTI/Determine | HW            | 249             | 2                | 0              | 99.2%              | 97.2 - 99.9%  | 2/2 VL UD. 2/2 -ve on all reads and RDTs  |
| INSTI/Unigold   | HW            | 249             | 2                | 0              | 99.2%              | 97.2 - 99.9%  | Same 2 clients as Determine-ve above  |
| OQ/OQ           | Self          | 246             | 5                | 0              | 98.0%              | 95.4 - 99.4%  | 4/5 VL UD. 1/5 VL invalid. 1/5 all reads & RDTs-ve. 3/5 all other reads & RDTs+ve     |
| OQ/OQ           | HW            | 248             | 3                | 0              | 98.8%              | 96.5 - 99.8%  | 3/3 VL UD. 1/3 -ve on OQ only; 1/3 +ve only on OQ self-read; 1/3 all reads & RDTs -ve |
| OQ/Determine    | HW            | 249             | 2                | 0              | 99.2%              | 97.2 - 99.9%  | 2/2 VL UD. 1/2 +ve only OQ self-read; 1/2 all reads & RDTs -ve                        |
| OQ/Unigold      | HW            | 249             | 2                | 0              | 99.2%              | 97.2 - 99.9%  | Same 2 clients as Determine-ve above  |

HW= Health Worker; VL=Viral load; UD= undetectable; RDT= rapid diagnostic test; OQ=OraQuick; UG=Unigold