


UNITAID ◆ PSI

HIV SELF-TESTING AFRICA

Zambart: Interim Results of Clinical Performance Study

Alwyn Mwinga

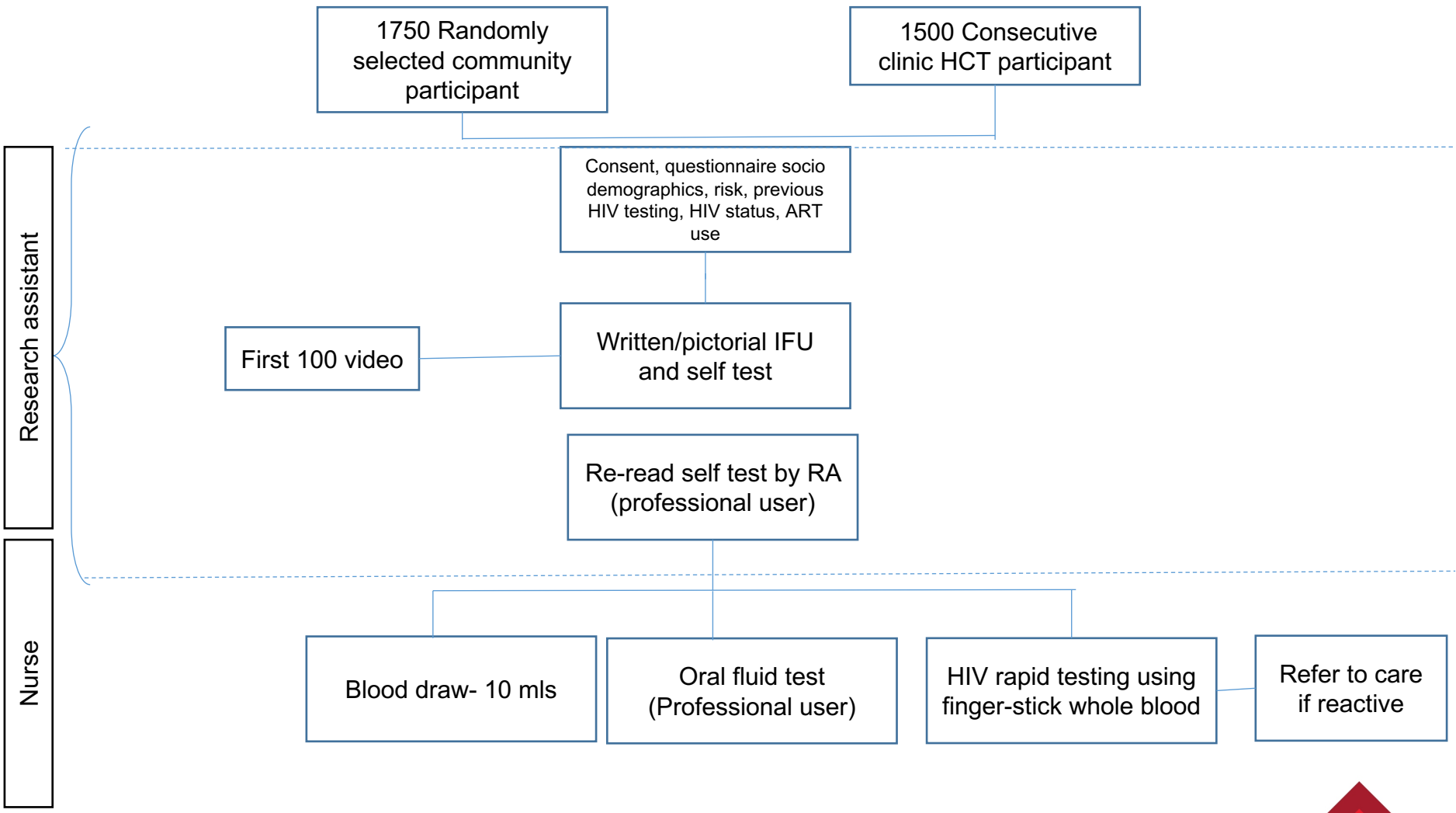
Overview of Presentation

- Study Objectives
  - Clinical Performance study
  - Visual stability study
- Progress to date
- Interim results
- Challenges

UNITAID·PSI
HIV SELF-TESTING AFRICA

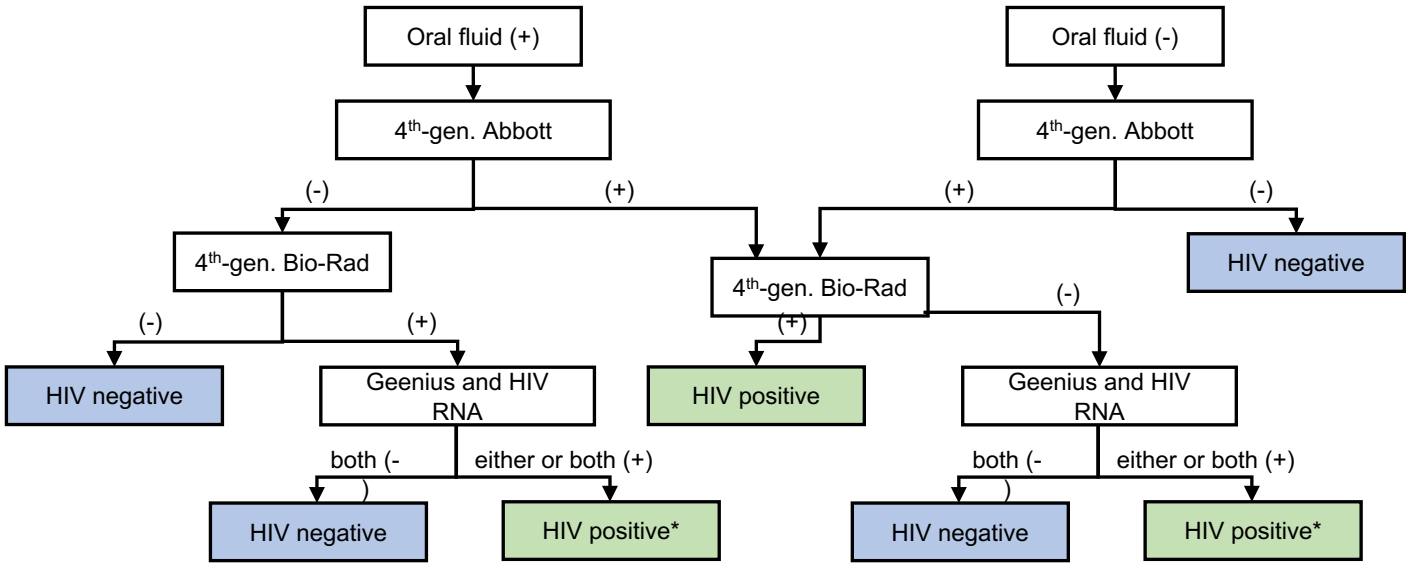
Objectives

- Determine sensitivity and specificity of the OraQuick® HIV Self Test
  - as carried out by the intended user using manufacturer's IFUs, compared to a laboratory-based testing algorithm for HIV diagnosis.
  - as carried out by the intended user compared to the Zambian national HIV testing algorithm of fingerprick rapid testing by a health worker.
  - as carried out by intended user, followed by confirmatory fingerprick rapid testing, compared to a laboratory-based testing algorithm for HIV diagnosis.
- To assess user competency in performing the test using written and pictorial instructions only.
- To estimate levels of user competency in interpretation of the OraQuick® HIV Self Test result when compared to a professional user interpretation of the OraQuick® HIV Self Test.
- To determine the stability of OraQuick® HIV Self Test results with delayed visual re-reading for up to 12 months.



UNITAID·PSI
HIV SELF-TESTING AFRICA

Reference testing algorithm



Assays: Oral fluid: OraQuick HIV test; 4th-gen. Abbott: Architect HIV Ag/Ab Combo assay; 4th-gen. Bio-Rad: GS HIV Combo Ag/Ab EIA assay; Geenius: Geenius HIV 1/2 Supplemental Assay; HIV RNA: Abbott Real Time HIV assay.
(+) indicates reactive/positive; (-) indicates non-reactive/negative.
*If HIV RNA is undetectable, samples may be tested for the presence of antiretroviral drugs.

Clinical Performance study

- Study sites
  - Rural site – Kanakantapa community
  - Urban Site – Mtendere health facility and community
- Target
  - 3,250 – Rural site 1,250, Urban site 2,000
- Methods
  - Study team – 2 research assistants, 1 research nurse
  - Community
    - Visit all homes in zone
    - Enumerate household, offer self-testing to eligible household members

Progress

- Recruitment since May 2016
- All sites active by August 2016
- Initial procedure
  - HIVST provided with instructions to read/follow IFU

UNITAID·PSI
HIV SELF-TESTING AFRICA

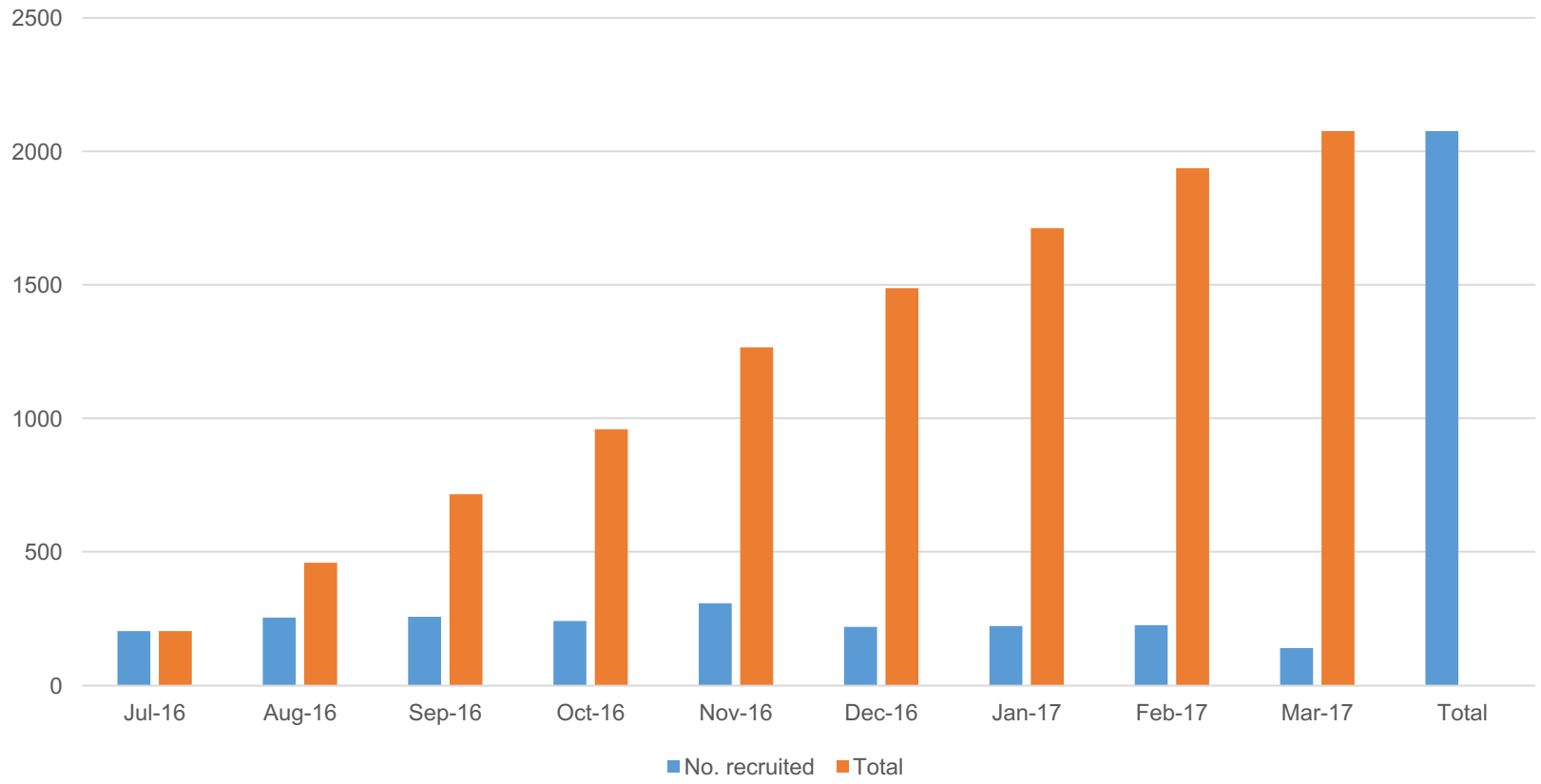
Interim Anlyses

- First 58
- Qualitative from video analysis:
  - Inability to open pouch
  - Inability to understand swabbing of gums
  - Swabbed with developer fluid
  - No timing of measurement period
- Qualitative from cognitive interviewing similar issues- swabbing, illiteracy
- Quantitative analysis:

	Sensitivity	Specificity
With invalids	29%	88%
Without invalids	40%	98%

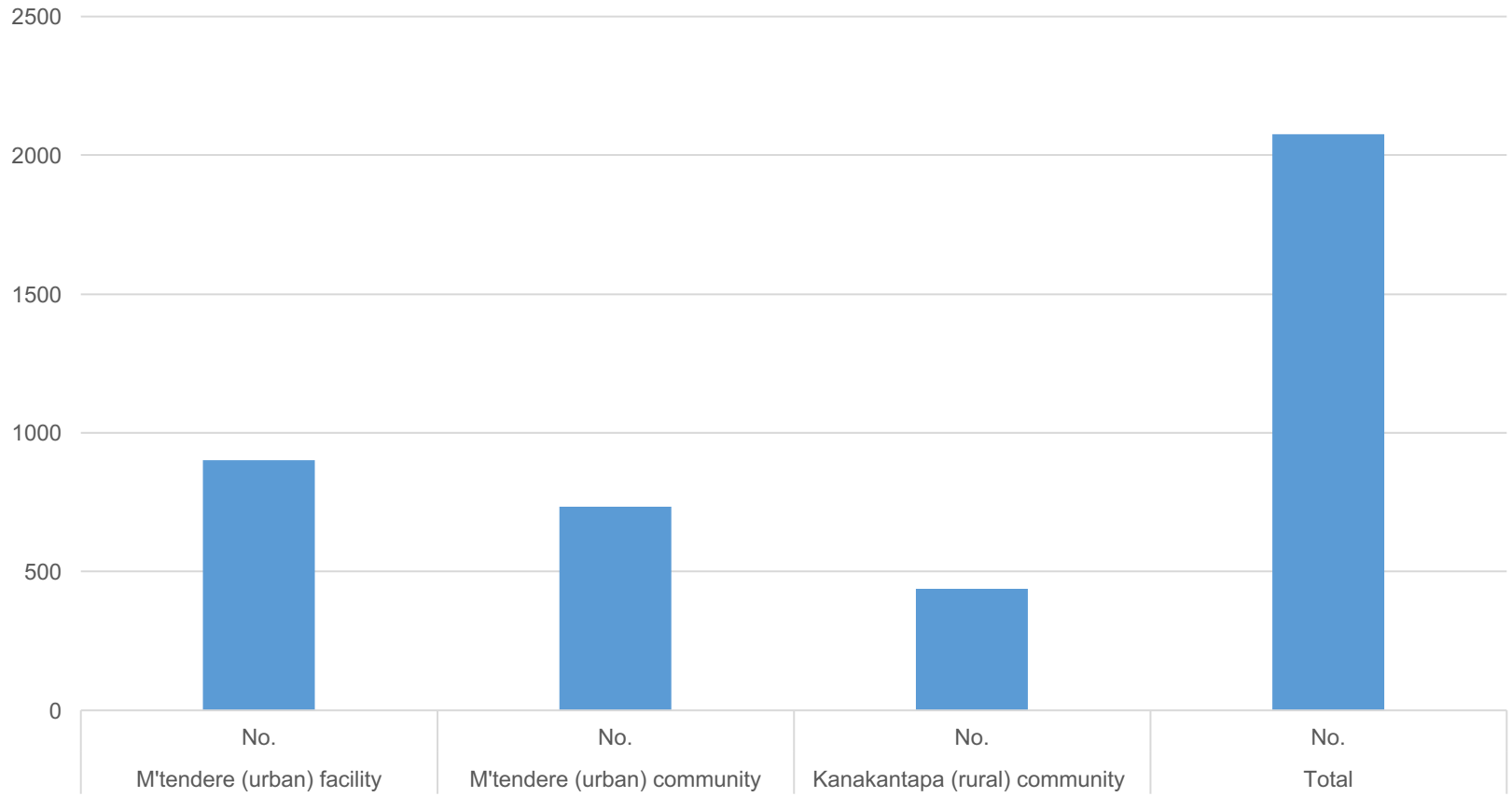
- Revised procedure introduced with research assistant providing an overview of the steps to follow in carrying out the test.

Recruitment July 2017 – March 2017

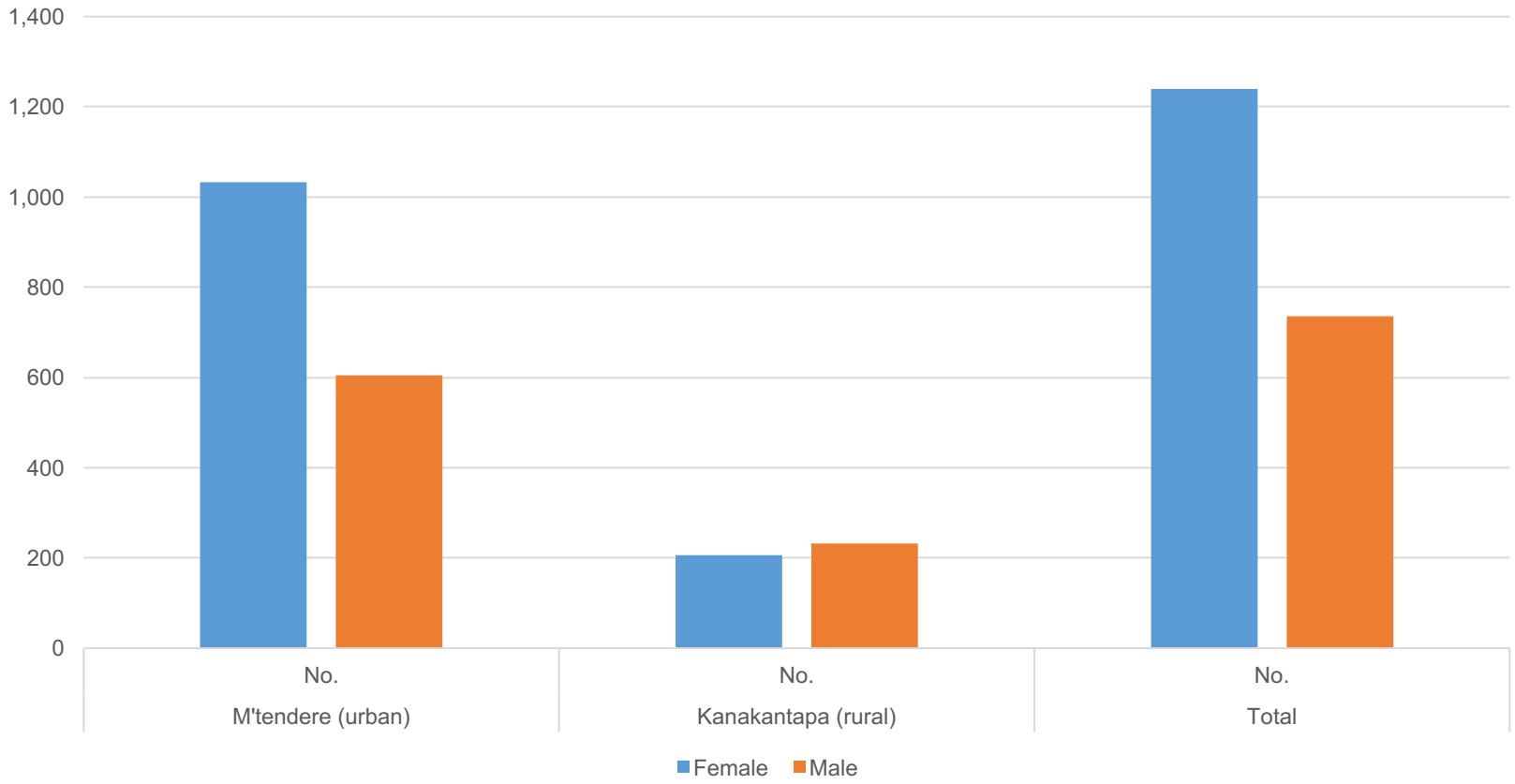


UNITAID·PSI
HIV SELF-TESTING AFRICA

Distribution of participants by site



Gender distribution by site



CPS Progress

- Video-taping of procedure
  - Clients reluctant to consent for video of procedure
  - A total of 91 videos are available

	Males	Females	Total
Kanakantapa	19	9	28
Mtendere	39	24	63
Total	58	33	91

Results of 2052 participants HIVST Vs RDT

Agreement between Client administered and read OFT and Nurse administered RDT			
	RDT positive	RDT negative	Sub-total
Client read reactive	185	8	193
Client read nonreactive	12	1,847	1,859
Sub-total	197	1,855	2,052
Agreement (%)	99		
Sensitivity (%, 95% CI)	93.9	89.6-98.6	
Specificity (%, 95% CI)	99.6	99.2-99.8	

Results of 1080 participants HIVST (with instructions) Vs laboratory algorithm

Agreement between client-administered and read OFT result and laboratory test algorithm

	Laboratory positive	Laboratory negative	Sub-total*
Client-read reactive	105	7	112
Client-read non-reactive	15	953	968
Sub-total	120	960	1080
Agreement (%)	97.96		
Cohen's kappa	0.8938	p<0.001	
Sensitivity (%, 95% CI)	87.5	80.2-92.8	
Specificity (%, 95% CI)	99.3	98.5-99.7	

* Excludes 5 OFT read as invalid by client and 4 clients missing OFT, and 15 clients with OFT but no laboratory results (24 total)

UNITAID·PSI
HIV SELF-TESTING AFRICA

Visual stability study

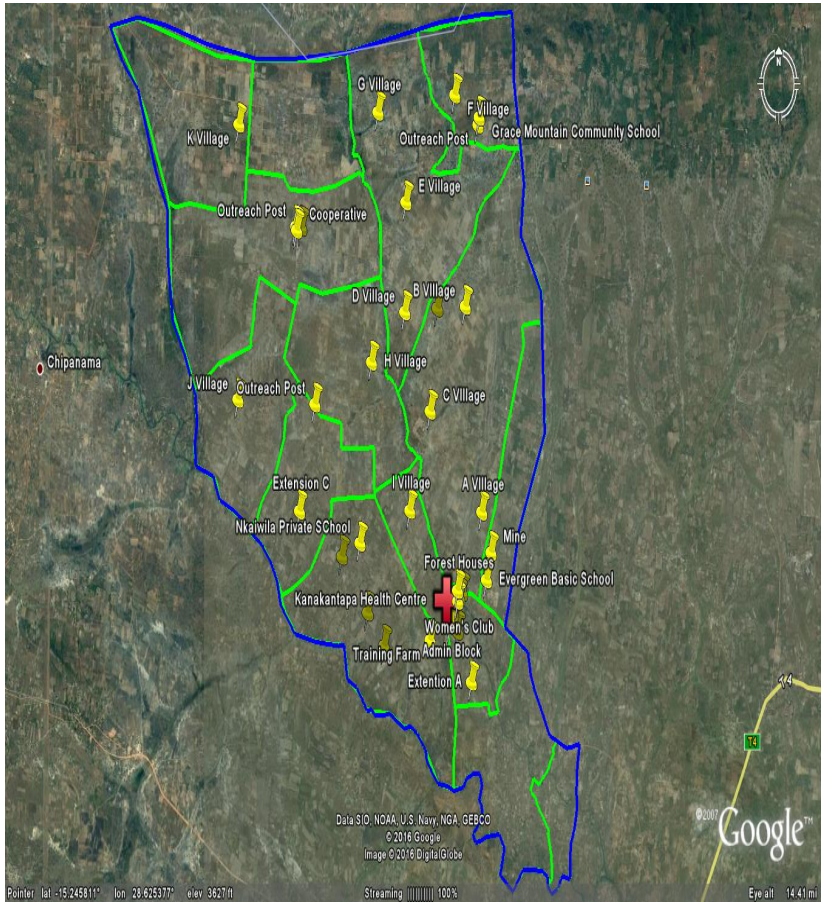
- Objective
  - Determine the stability of OraQuick® HIV Self-Test results with delayed visual re-reading for up to 12 months in Zambia under normal conditions.
- Study Site
  - Mtendere community
- Timeline
  - April – June 2017

Visual stability study

- Methods
  - Used testing device stored in clinic at ambient temperature
  - Results re-read by 3 individuals at the following times;
    - Daily from day 1 for 7 days
    - Monthly
  - Results entered into EDC
- Progress
  - Study began on 14 March

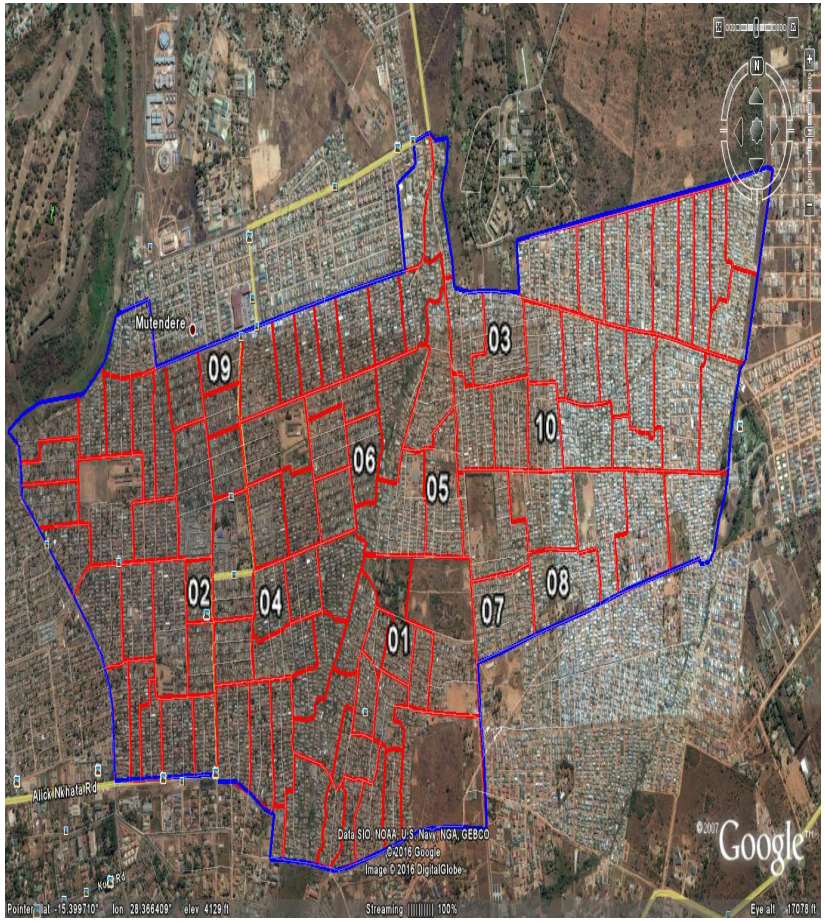
Challenges

- Kanakantapa
  - Vast area, large distances between households
  - Farming area – most households empty as occupants preparing fields



Challenges - Mtendere

- Field work interrupted during the election period.
- Recruitment from health centre delayed due to need to renovate a structure to provide space for study



Next steps