Positive control wells (PCW) for malaria RDT: Training effectiveness, Impact of RDT Use and Health worker Perceptions in Lao and Uganda

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Introduction

- Malaria RDTs are widely used in endemic setting
- Quality control (QC) and quality assurance (QA) is critical to maintain confidence in mRDTs
- Prototype PCWs containing dried recombinant antigens (HRP2, pLDH, aldolase) have been developed
- PCWs designed for health workers to test RDT stocks at their health facilities, to ensure RDT validity and accuracy

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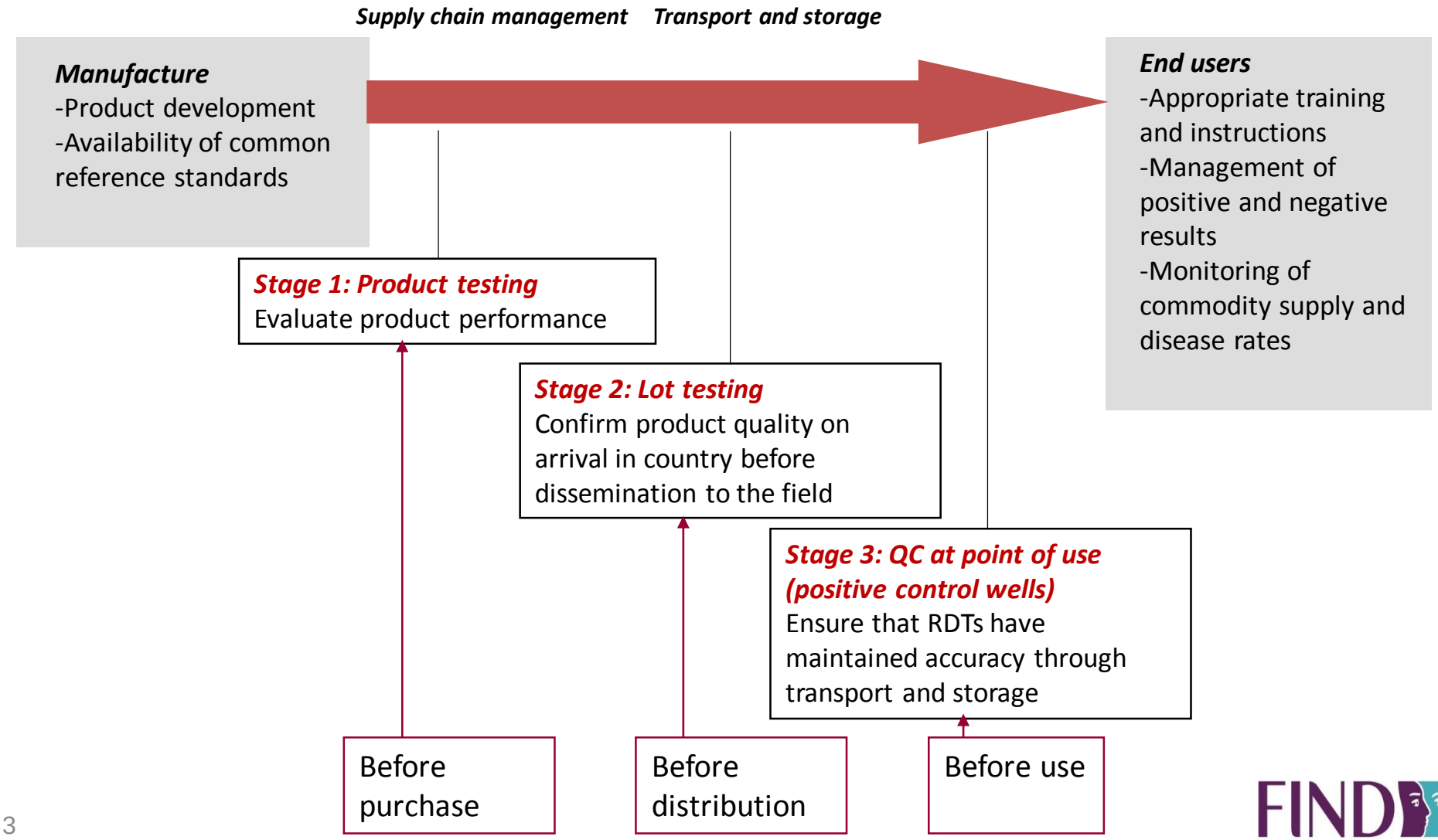
WHO and FIND strategy for QA of RDT-based diagnosis

Delivering a quality product and effectively using results



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Objectives

- **The study was designed**
  - to determine whether health workers in various settings can use prototype PCWs correctly to detect RDTs with inadequate sensitivity;
  - to assess the impact of PCW availability on RDT use;
  - and to gather information on health workers' perceptions of PCWs and preferred strategies for routine use in public health care sectors

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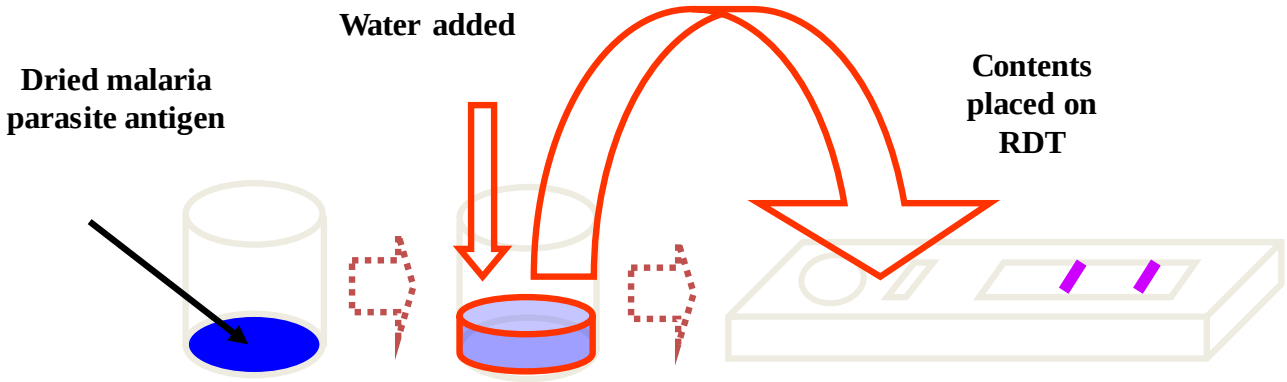
Using Positive Control Wells (PCWs)



- Small polypropylene tubes coated with dried recombinant proteins (HRP2, pLDH and aldolase)
- Concentrations <u>equivalent to 200 parasites per microlitre of blood</u>
- Re-constituted with water and transferred to a malaria RDT using a dropstir

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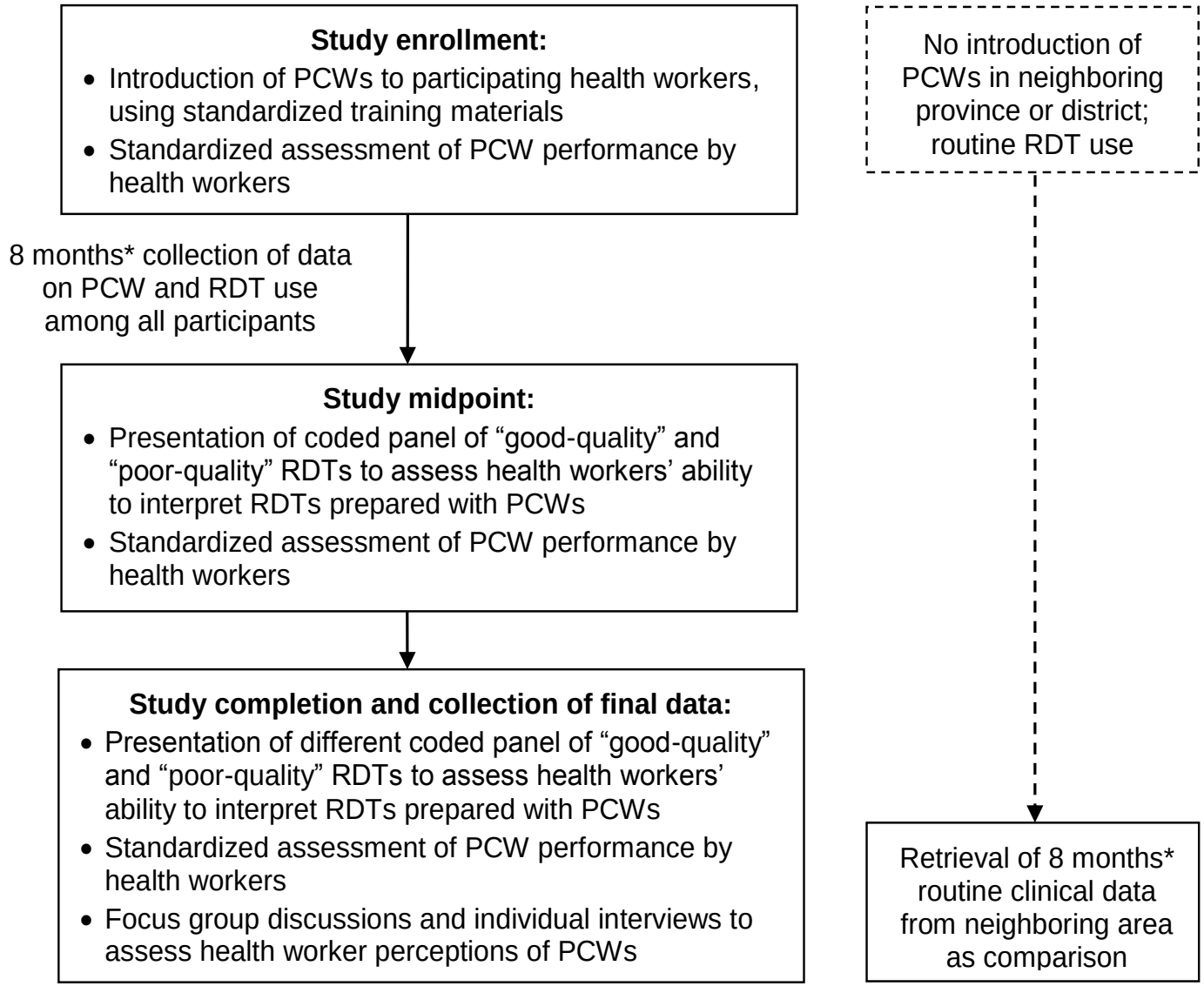
Study design

Quasi-experimental design
Jan-Oct 2013
Uganda and Lao
-Prospective collection of data
-Pre and Post intervention data analysis with Control arm



* Data retrieved for a period of 2 months before study start, plus 6 months during study activities.

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Methods

- **Study site selection criteria:**
  - WHO procurement criteria met
  - varied malaria endemicities,
  - geographical regions and cultures
- **Study sites:**
  - Salavan Province, southern Lao PDR;
  - Kiboga District, west-central Uganda.
- **HWK trained to use PCWs**
  - Not told when or how frequently to use PCWs;
  - RDTs provided through the routine mechanisms in the study areas
  - Did not provide training on RDT use or fever case management
  - KII and FGDs conducted at the end of study period

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Training job aids to perform PCW

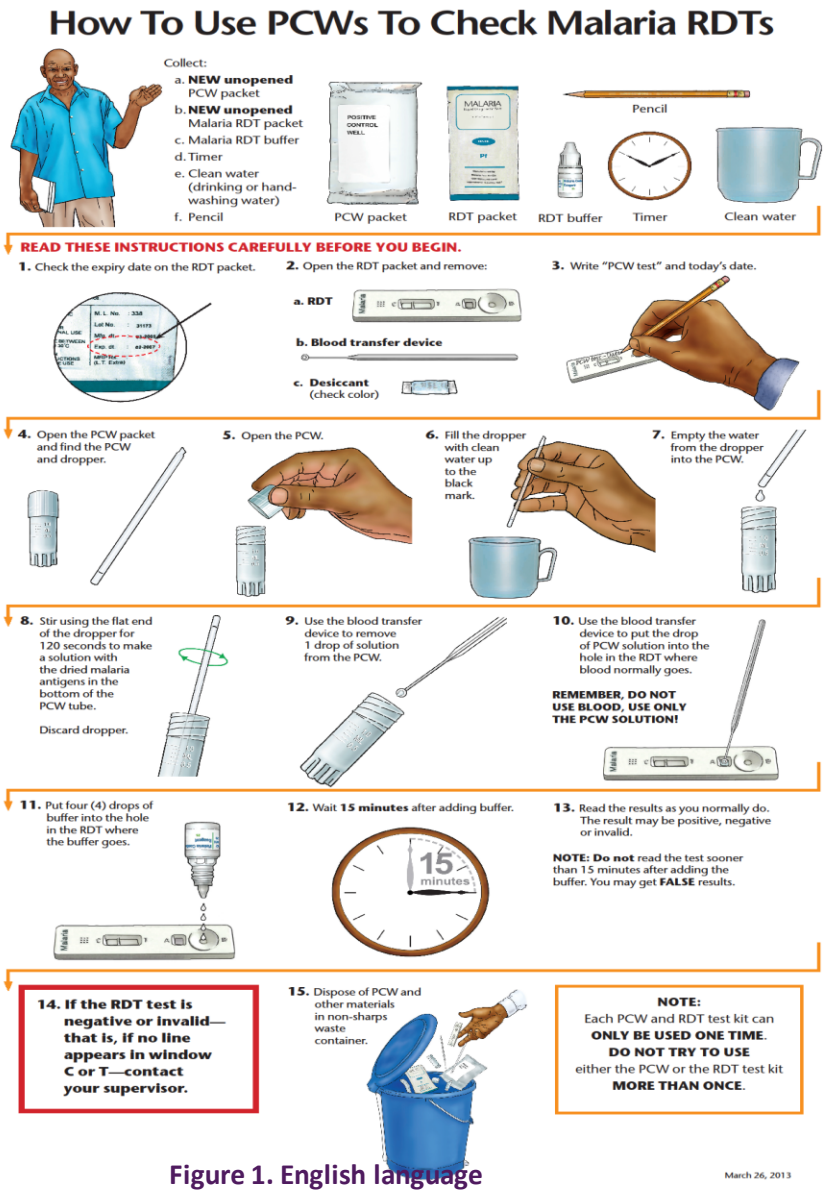
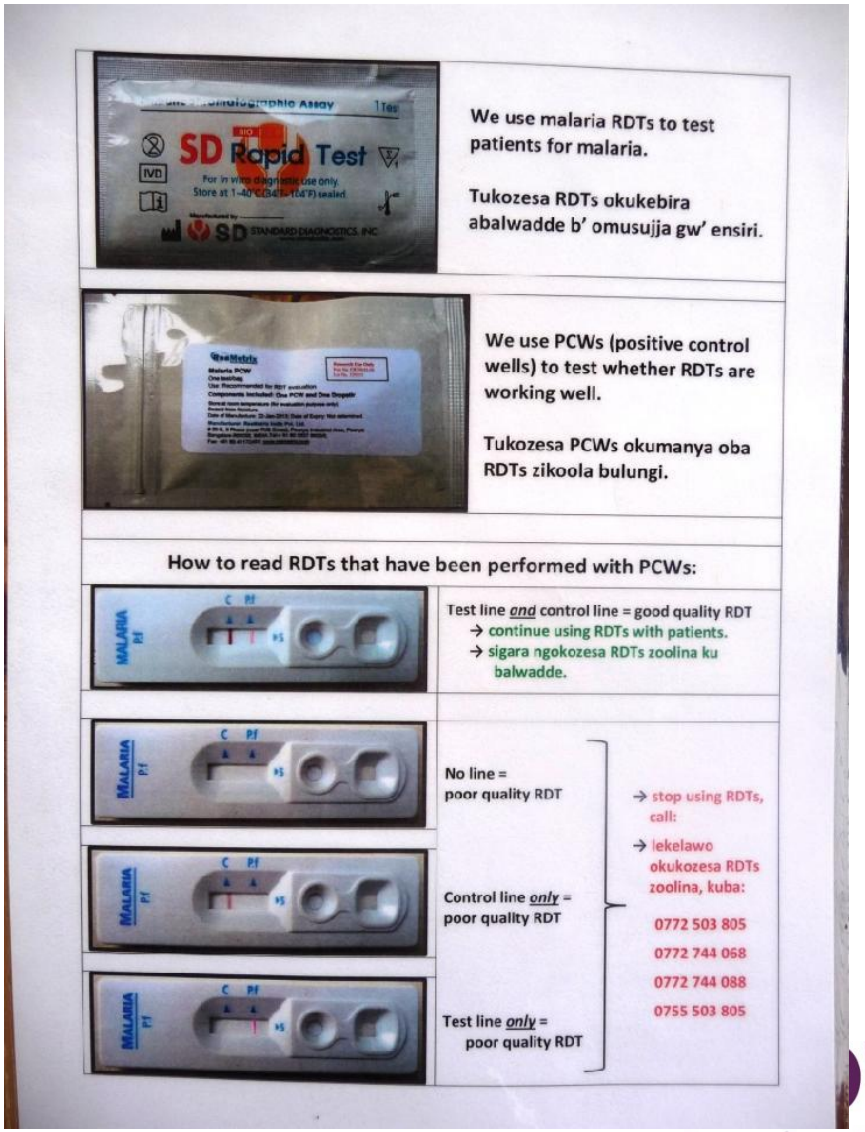


Figure 1. English language version of PCW job aid



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Training session in Laos PDR

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Training session in Uganda

Results

Feature	Lao PDR	Uganda
Participating HWKs	269	290
Participants (Village health volunteers)	194 (72%)	239 (83%)
Health workers who performed key individual PCW steps correctly under observation after initial training, and 6 months later	≥ 92%	≥ 88%
Health workers who reported the correct action to take for a panel of "good-quality" and "poor-quality" RDTs at study mid-point and study end	≥ 89%	≥ 95%
Number of PCWs used and recorded over 6-month study period	793	1685
Reason recorded* for performing a PCW: "I received a new stock of RDTs"	485 / 752 (64%)	485 / 1647 (29%)
Reason recorded* for performing a PCW: "I wanted to check the quality of my RDTs"	240 / 752 (32%)	1054 / 1647 (64%)

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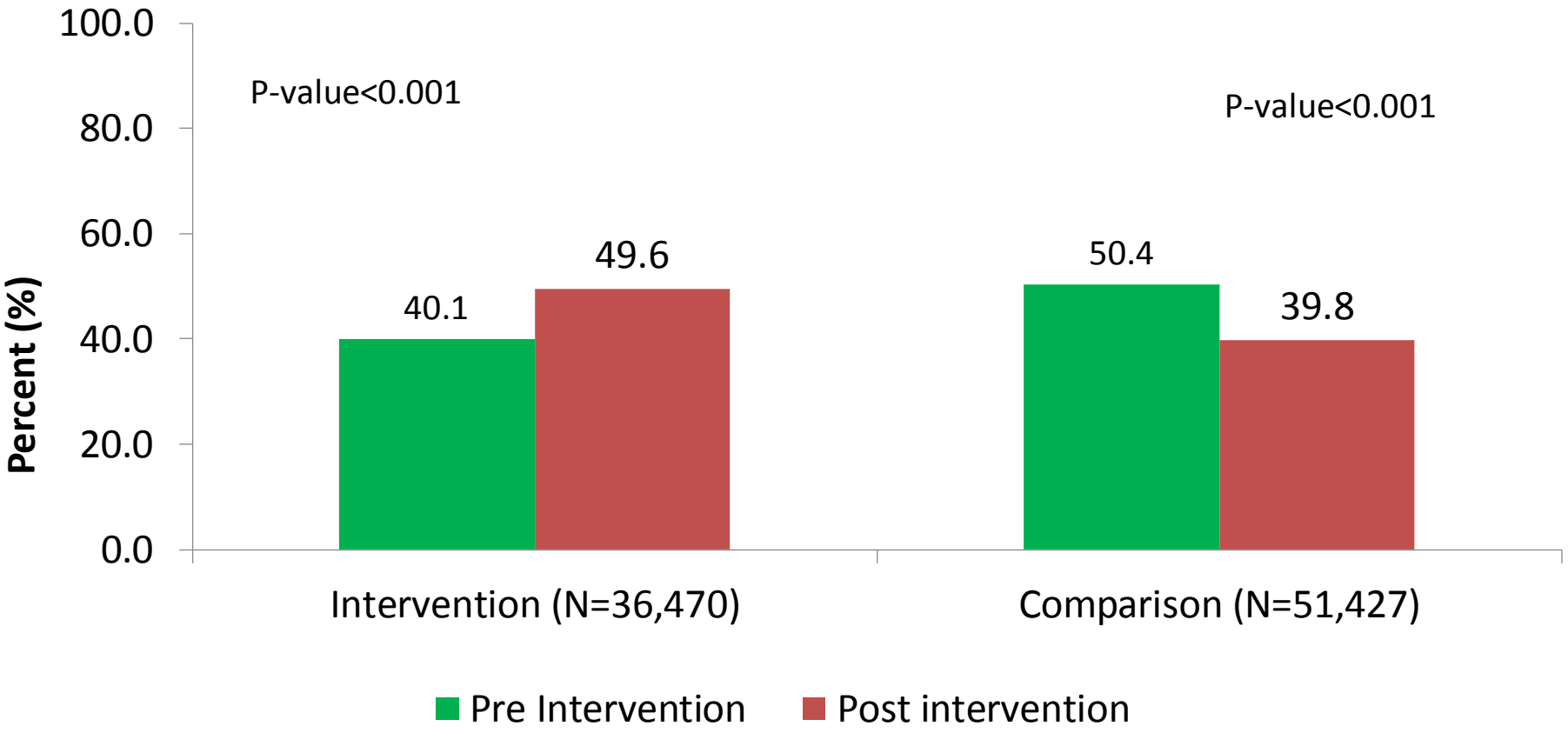
Percent of fever OPD patients that were tested with RDTs in Uganda



Other factors in play:

- Stock outs of RDTs and ACTs
- Malaria Consortium tried replenishing esp. in Kiboga
- Trainings during study period

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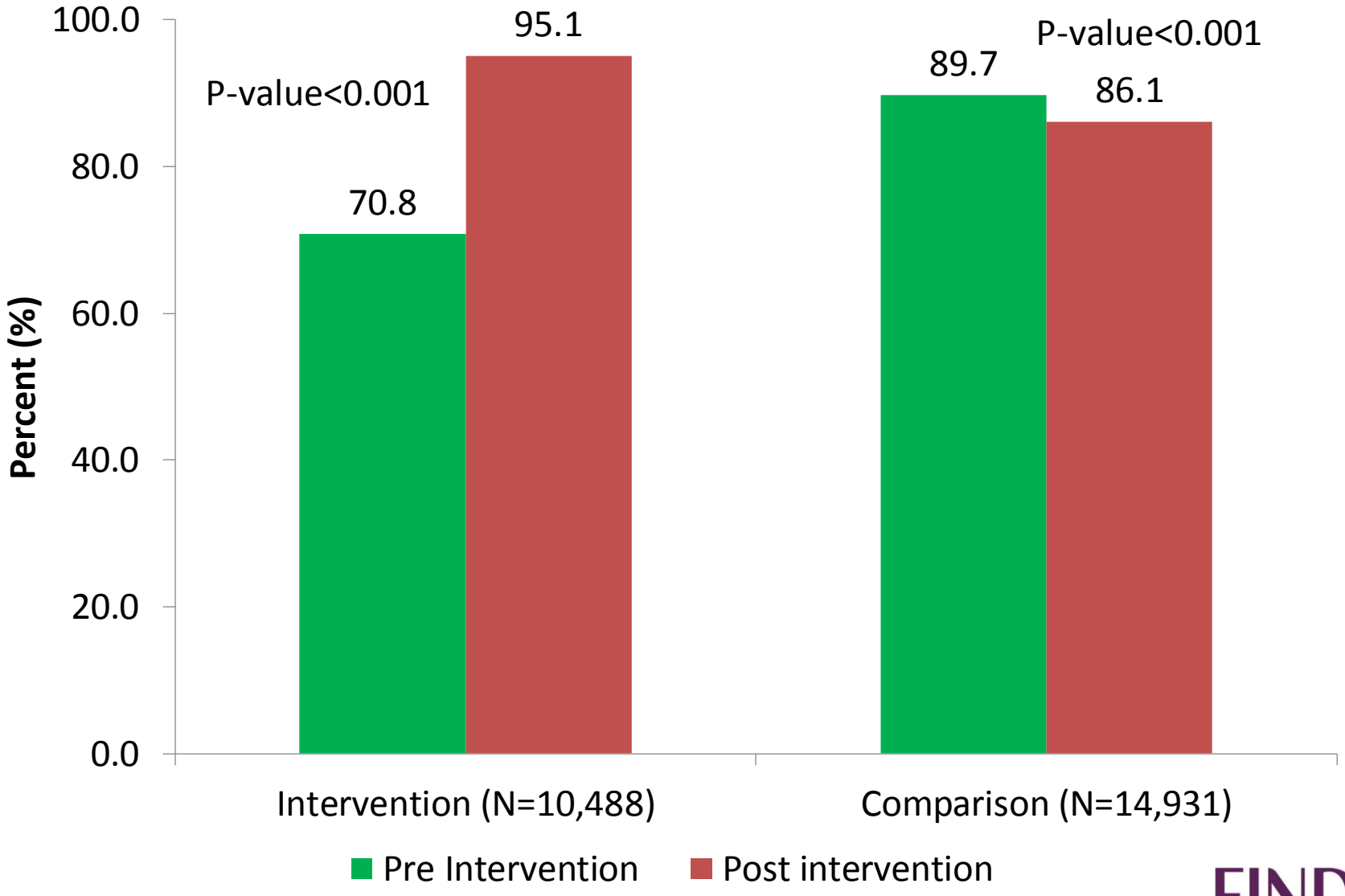
Percent of RDT positive OPD patients that were given ACTs in Uganda



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Qualitative results summary - 1

Two types of understanding quality of RDTs:

- Performance-based understanding of quality of RDTs
- Technically mediated understanding of quality of RDTs

- **Consecutive negative RDT results (quotes from users)**

  -they don't trust RDT quality when RDTs are expired, when there are too many negative and positive (they re-test, if still negative, then they understand that this is not malaria) `

  For some health workers, PCWs use is a waste of RDTs

- **Value of use**

  -PCW use removes doubts HWs may have, especially when patients come with Malaria symptoms and RDT turns out negative.

  Use of the PCW gave them confidence about the reliability of the results

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Qualitative results summary-2

- **Positive & negative PCW-RDT reaction and quality of PCWs /Formalization of bad RDTs before and after PCWs**

  -Quotes saying that when HWs get positive PCW-RDT reaction, they rely on this result but when they get a negative result, they repeat the test (sometimes 3 times and if 2 out of 3 are positive they consider a positive results)

  -The practice of repeating PCW-RDTs after a negative reaction wasn't mentioned during the training but has to be seen as local way of coping with different expectations

  -Data shows there is a strong bias towards positive PCW-RDT reactions

  -Some HWs would even doubt the quality of the PCWs when they received a negative reaction

conclusion

- **Health workers, including village health volunteers,**
  - correctly perform and interpret PCW after a half-day training,
  - maintain this standard over 6 months of routine use
- **PCW appear to improve health workers' confidence in RDT validity**
- Further analysis will provide recommendations for future PCW operational research and implementation

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Thank you !!

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