

# Past, present & future for HIV self-testing

**Cheryl Johnson**  
WHO HIV Dept. Geneva

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*No conflict of interest*

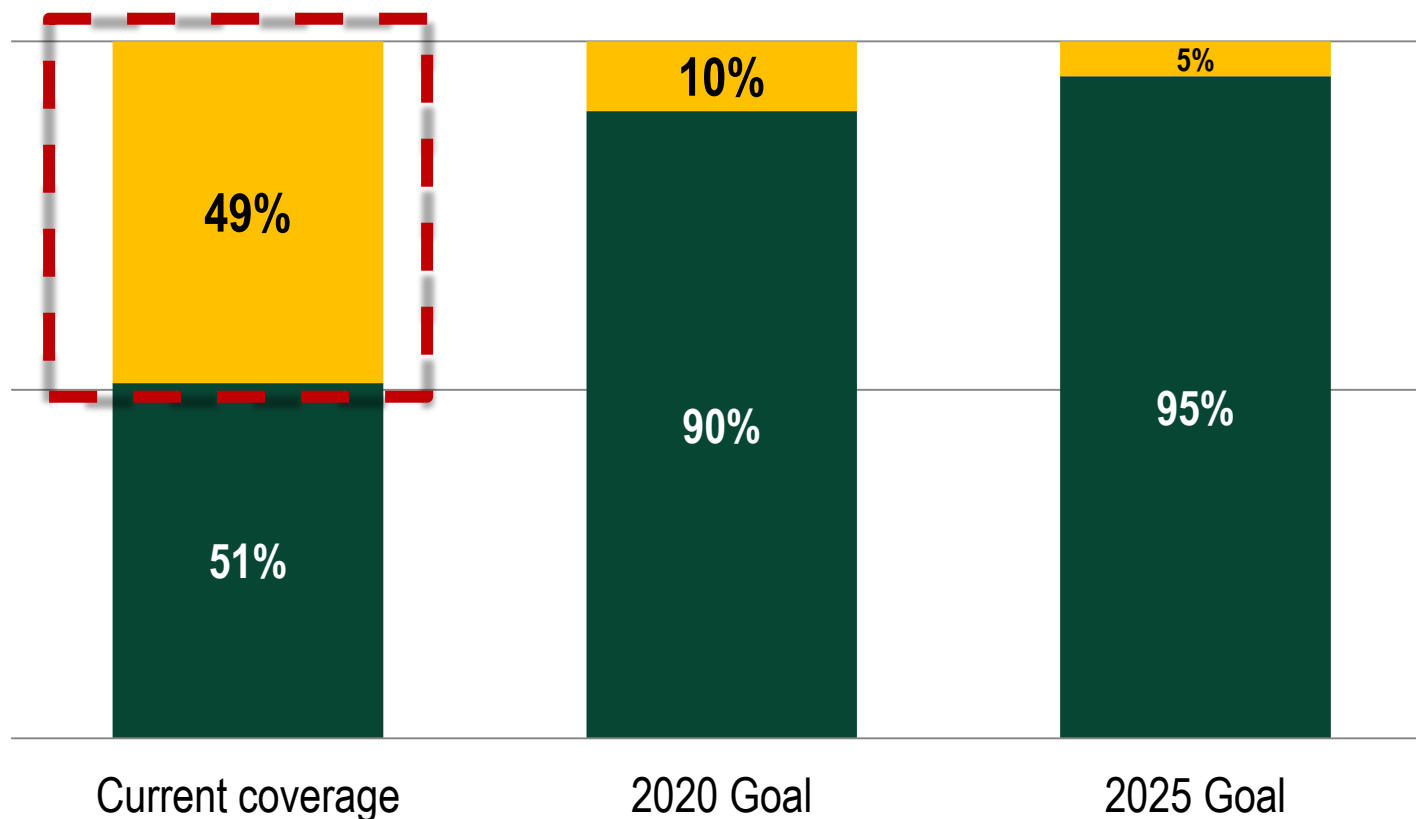


8<sup>th</sup> IAS Conference on HIV Pathogenesis, Treatment & Prevention 18-20 July 2015  
IAS2015.ORG



# Why talk about HIVST?

UNAIDS “90-90-90”



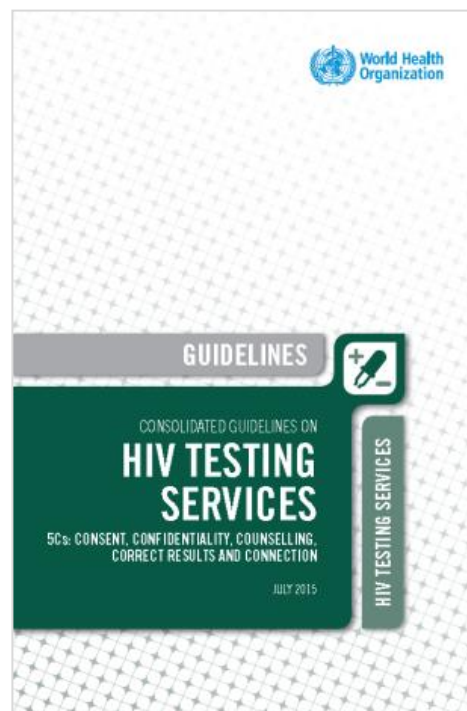
# Current WHO guidance on HIVST

Many models, priorities and policy issues, and evidence gaps

Outlines the issues & technical considerations for HIVST & **encourages countries to conduct demonstration projects**

Normative guidance on HIVST is **planned for 2016**

Most current information available on **HIVST.org**

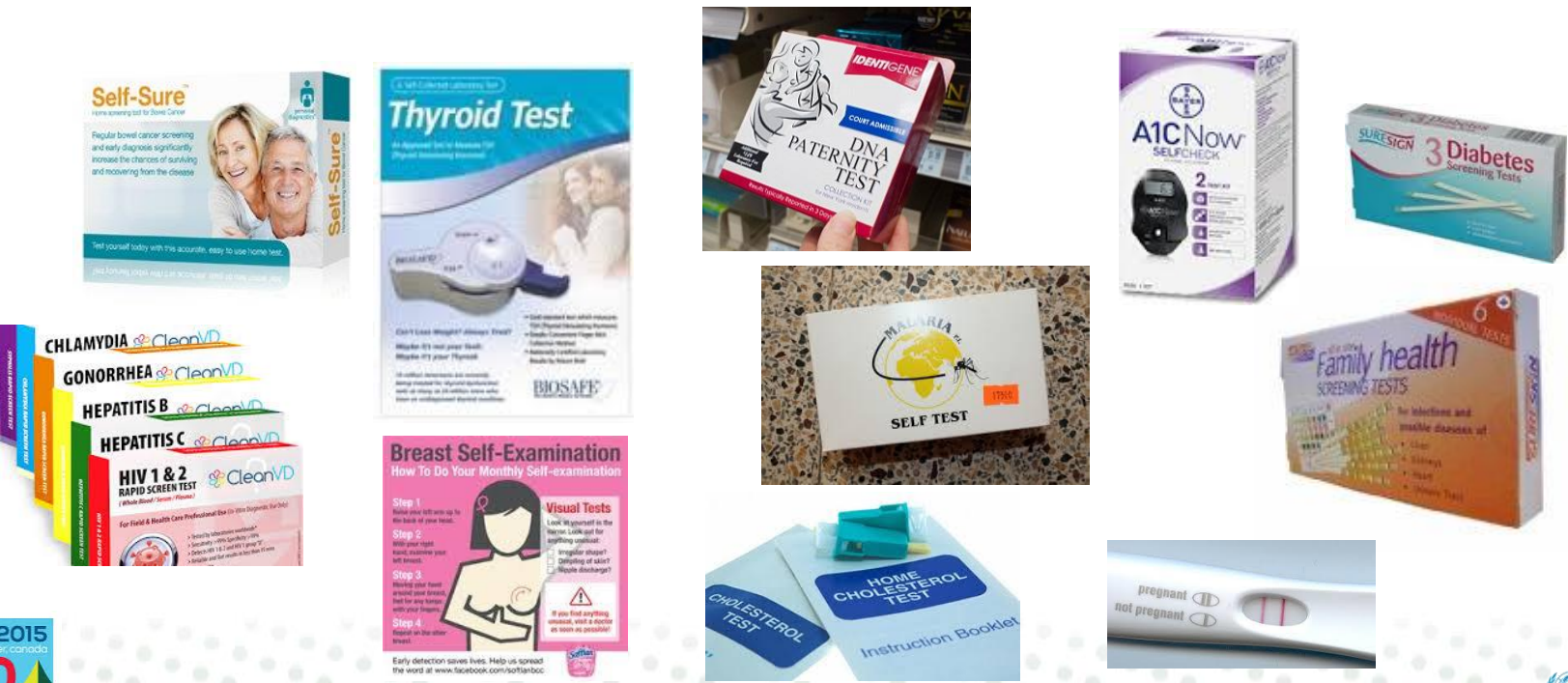


# What is self-testing?

## Collects

## Performs

## Interprets





# What is HIV Self-Testing (HIVST)?

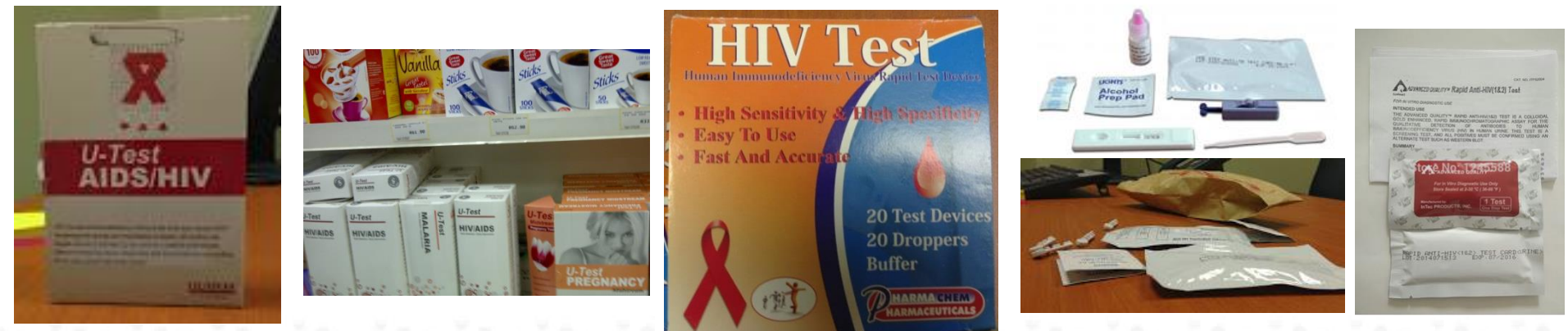


**Reactive results need confirmation by health provider**

# Available *Formally*



# ...& *Informally*



# Current Policy Environment

Policies & Product(s) Licensed & Registered	Policies Explicitly Allowing HIVST	Policies Under Development	HIVST Available Informally+	HIVST Explicitly Illegal
USA 2012	Australia	South Africa*	China	Botswana
UK 2015	Kenya	Zimbabwe	Namibia	Germany
	Hong Kong SAR	Malawi	South Africa	
	South Africa*	Zambia	Russia	
	France <sup>o</sup>	Brazil	Tanzania	
		Peru	Nigeria	
		Thailand		



Slide based on formal and anecdotal reporting, informal sale in different countries may be under-estimated.

\*South Africa allows HIVST kits to be sold through venues, except pharmacies. This policy is currently being reviewed

<sup>o</sup>Policy and product registration is planned for Sept. 2015



# Products with regulatory approvals

Product (supplier)	Specimen	Business Objectives	Regulatory Status	Other RDTs from Manufacturer
<b>Autotest VIH</b> (AAZ, France)+	Whole Blood	Sell in France, other EU countries, & Africa	<b>CE marked</b>	<ul style="list-style-type: none"> <li>• <i>SureCheck HIV-1/2</i></li> </ul>
<b>Biosure HIV Self Test</b> (Biosure, UK)	Whole Blood	Sell in UK, & Europe, international roll out planned	<b>CE marked</b>	<ul style="list-style-type: none"> <li>• <i>SureCheck HIV-1/2</i></li> </ul>
<b>OraQuick In-Home HIV Test</b> (OraSure Technologies, USA)	Oral Fluid	Sell in USA, Europe, Latin America, Africa	<b>FDA, CE marked</b>	<ul style="list-style-type: none"> <li>• <i>OraQuick ADVANCE HIV-1/2</i></li> <li>• <i>OraQuick HIV ½ Rapid test</i></li> <li>• <i>OraQuick HCV Rapid test</i></li> </ul>

As of yet, **no WHO prequalified RDTs for HIVST** —work is underway provide clear guidance on steps to be taken.



# Many Possible Models



Open access

Semi-restricted

Clinically restricted

## SUPERVISED HIV SELF-TESTING

Distribution by community health workers with supervision

Supervised by a health worker in a facility

## UNSUPERVISED HIV SELF-TESTING

Over-the-counter, such as pharmacies, markets or groceries

Kiosks or vending machines

Internet sales

Distribution by community-based organization, NGO or health department through community health workers without supervision

Clinics distribute without supervision

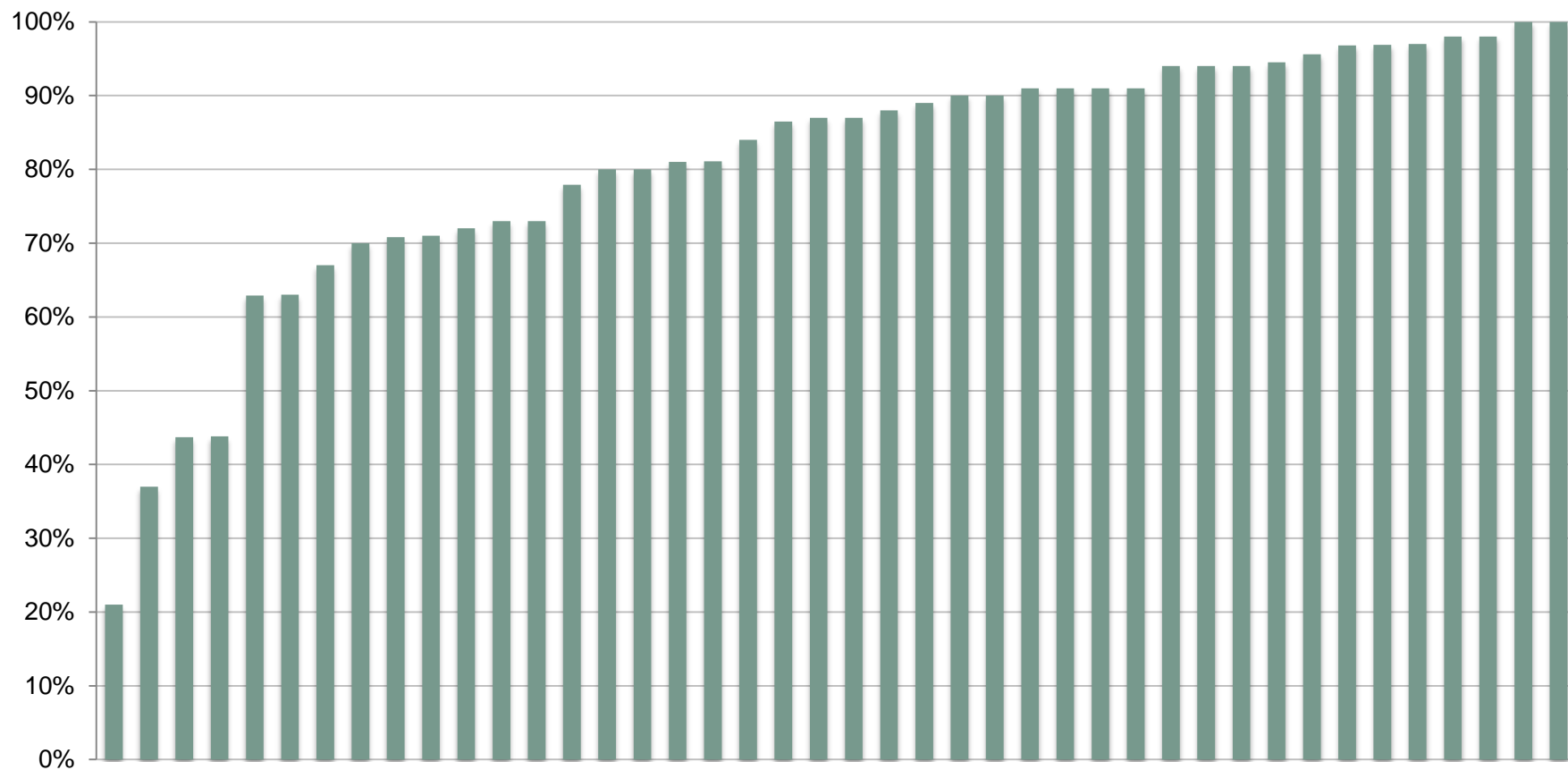


Source: WHO 2015



# What we know?

# Acceptability & Willingness

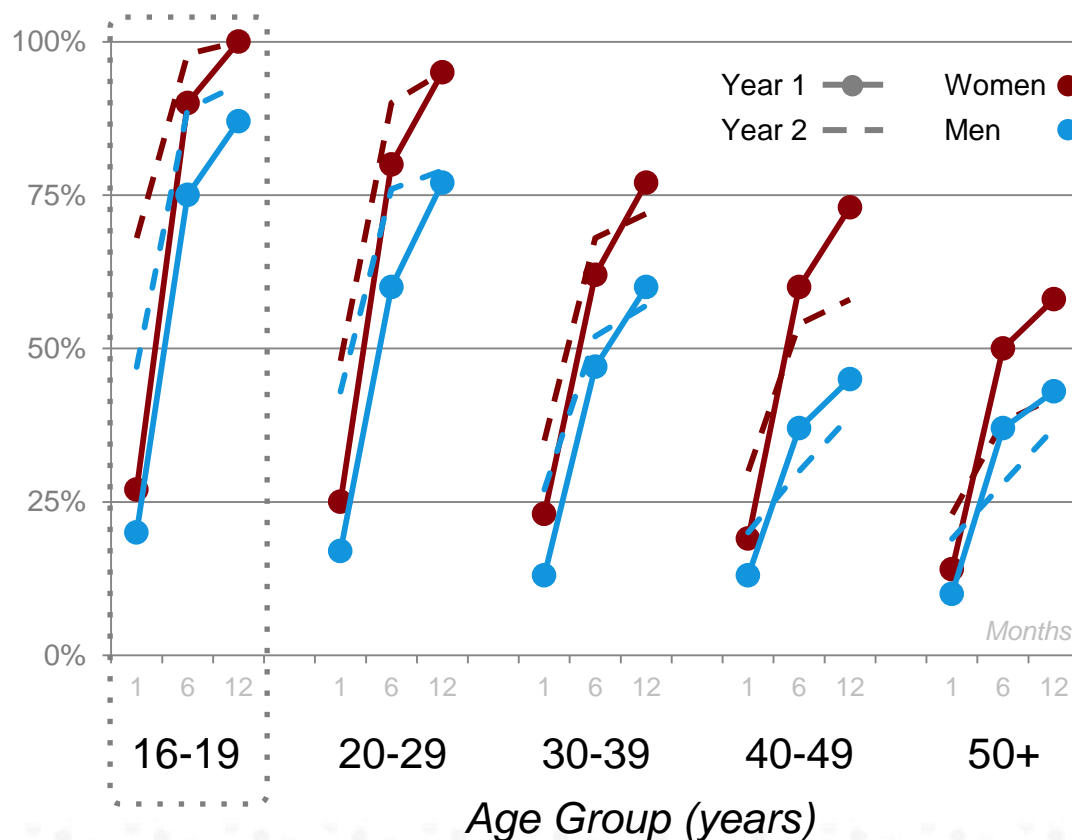


# Uptake Amongst All Residents in Malawi

Since HIVST Made Available

## Highest uptake among adolescents

- 76% in months 1-12
- 74% in months 13-24
- **44% first-time testers**
- ~90% returned kits with self-completed questionnaire

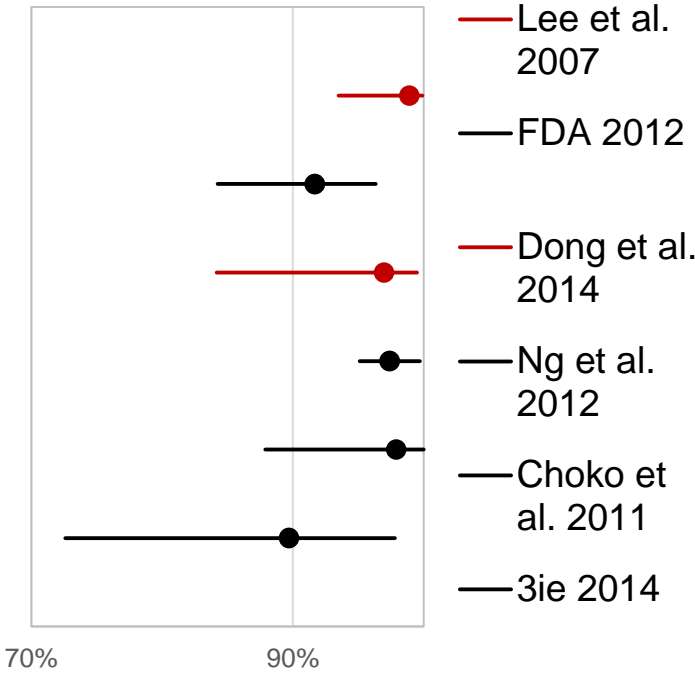




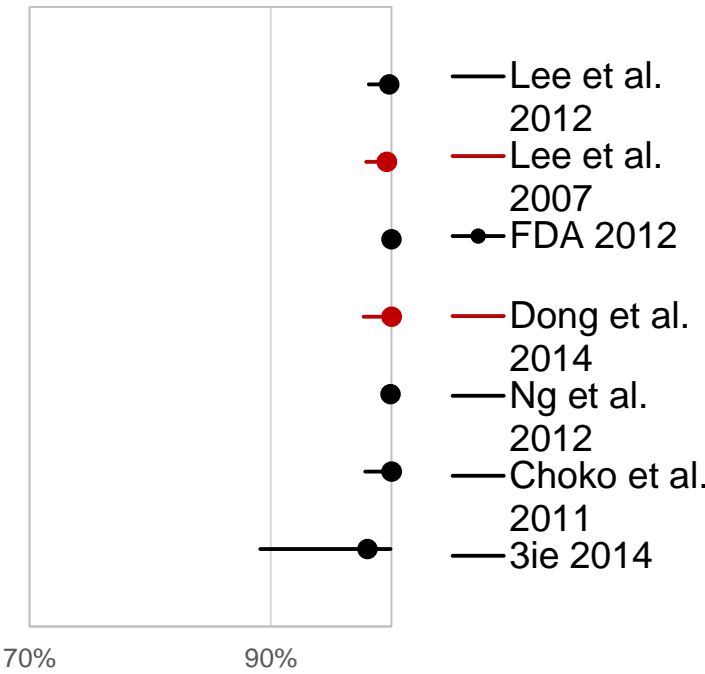
# Accuracy can be good, but not always

*Important to consider within the bigger picture*

## Sensitivity (n=6)



## Specificity (n=7)



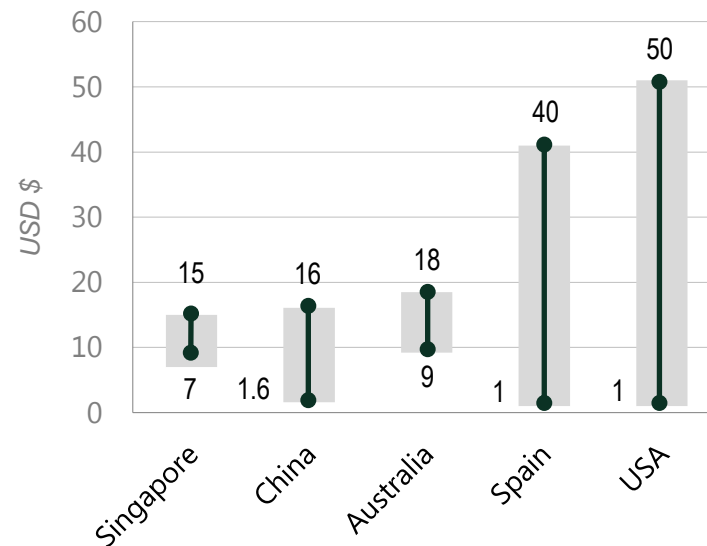
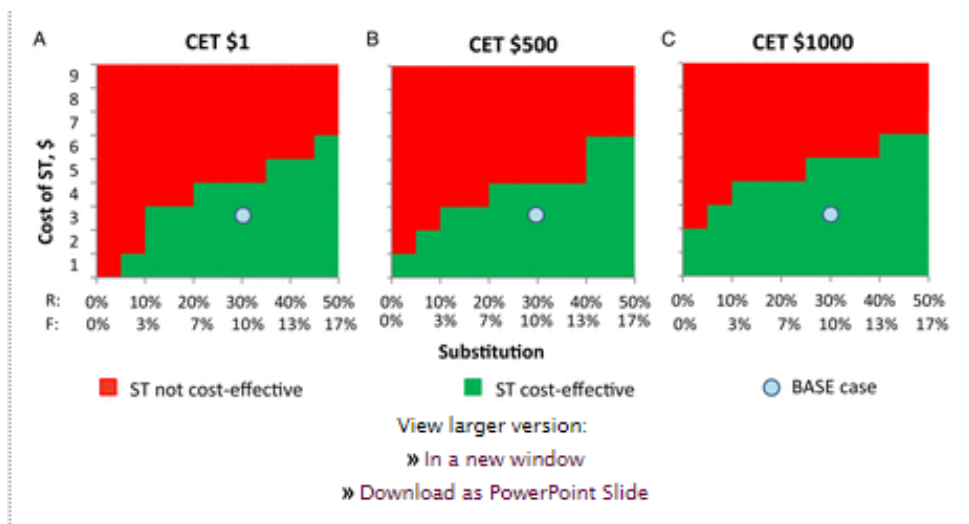
**Red= fingerstick whole blood**  
**Black = oral fluid**

# HIVST may be cost-effective

In Zimbabwe, US \$ 3 HIVST kit would save 75 million & avert ~7000 DALYs over 20 yrs.

Willingness to Pay varies greatly among Key Populations

Studies, n=8



# Linkage

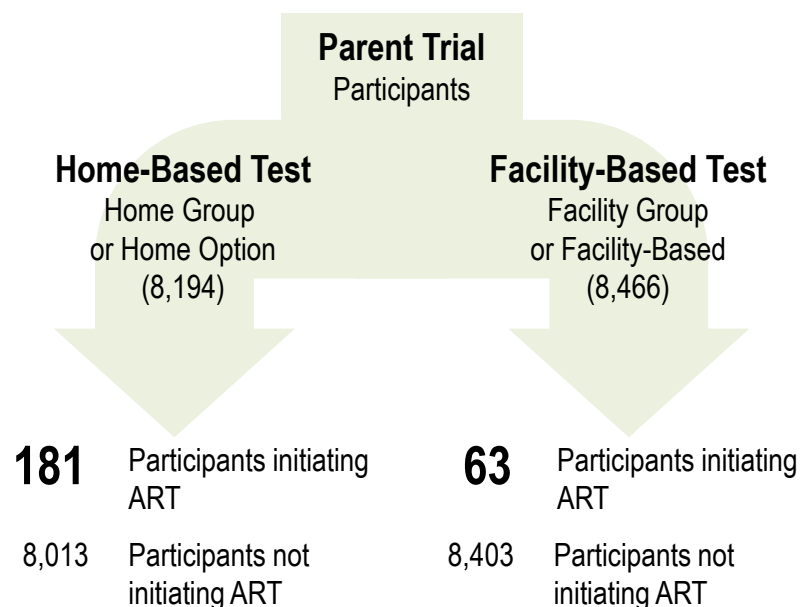
## Evidence is limited, but promising<sup>1,2</sup>

- Especially when coupled with a proactive approach (e.g. home-based ART initiation)
- 80-100% of MSM report they would link to further testing and care, if they had a reactive self-test result<sup>3</sup>



## Higher ART among Home Self-test Clusters than Facility-based

MacPherson 2014 (Malawi)





# Adverse Events

No serious adverse events for self-testing for multiple diseases and conditions, including HIV, reported in published literature<sup>1</sup>.

**Monitoring and reporting systems are few, important to develop and implement such systems.**

Some potential issues identified so far:

- Verbal confrontations<sup>2</sup> or participant's plan to coercively test someone<sup>3</sup> ;
- Couples report that discordant self-test result can be challenging<sup>5,6</sup> and though few emerging reports of IPV—but primarily among couples with a history of IPV<sup>4</sup>.
- In Blantyre, ~3% of people felt coerced/persuaded—however nearly all said they would recommend HIVST to others<sup>4,5,6</sup>.



# PSI/UNITAID STAR Project

## Catalysing HIVST in Southern Africa

### Implementation-research Partnership Tackling Market Barriers by:

- Multiple sites, models, & populations
- Normalizing HIVST in Southern Africa
- Providing evidence for scale-up
- Developing WHO Guidelines
- Encouraging policy change
- Enabling the regulatory environment
- Shaping market to reduce barriers & increase entry of low-cost HIVST products available for purchase & on recommended diagnostic commodities list



### Countries

Malawi

Zambia

Zimbabwe



# So what do people say about (HIVST)?



# Conclusions

**Current HIV testing services are not enough to get to 90.**

Self-testing is **not new**.

Additional tool to **create demand for, not substitute**, HIV testing services.

**Public health response lags behind public demand—and we need to catch up.**

**WHO guidance on the way**

**Get going!**

**Think big.** We need visionaries & champions; we need to stimulate technological advances, better tests & innovations in implementation

# Acknowledgments

**IAS organizers, amazing team at the WHO & all colleagues leading the way in HIV self-testing**

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