

# Linked Testing Using Rapid HIV Tests for Antenatal Care Sentinel Surveillance in Resource-Limited Settings

Evidence from Angola's Experience in 2009

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## Angola

- ❑ Population 18.5 million
- ❑ Adult HIV prevalence was 2% [1.6%-2.4%] in 2009
- ❑ 68% of pregnant women attended antenatal care (ANC)
- ❑ 26% of pregnant women were tested for HIV through ANC



## HIV Surveillance Among Pregnant Women

- ❑ National HIV estimates are based on periodic surveys among pregnant women attending antenatal care (ANC)
  
- ❑ HIV testing for surveillance was conducted on leftover blood samples collected for syphilis testing
  - ELISA test at the national lab
  - Samples were unlinked
  - HIV test results were not returned
  
- ❑ Alternative methods of surveillance were desired by the National AIDS Council of Angola

## Use of HIV Test Results from ANC Sites

- ❑ Rapid HIV tests are used for routine HIV testing and counseling services at ANC sites
  
- ❑ Angola began using rapid HIV test results from ANC sites as part of a new surveillance protocol in 2009
  - Women consented
  - Results of HIV tests are returned
  
- ❑ HIV test results from ANC sites are not commonly used for surveillance
  - Quality of rapid testing in field conditions
  - Non-consent bias may affect prevalence estimates

## Evaluation Objectives

- ❑ What is the quality of the rapid HIV testing conducted during the surveillance?
- ❑ What is the effect of the non-consent bias on the HIV prevalence estimate?

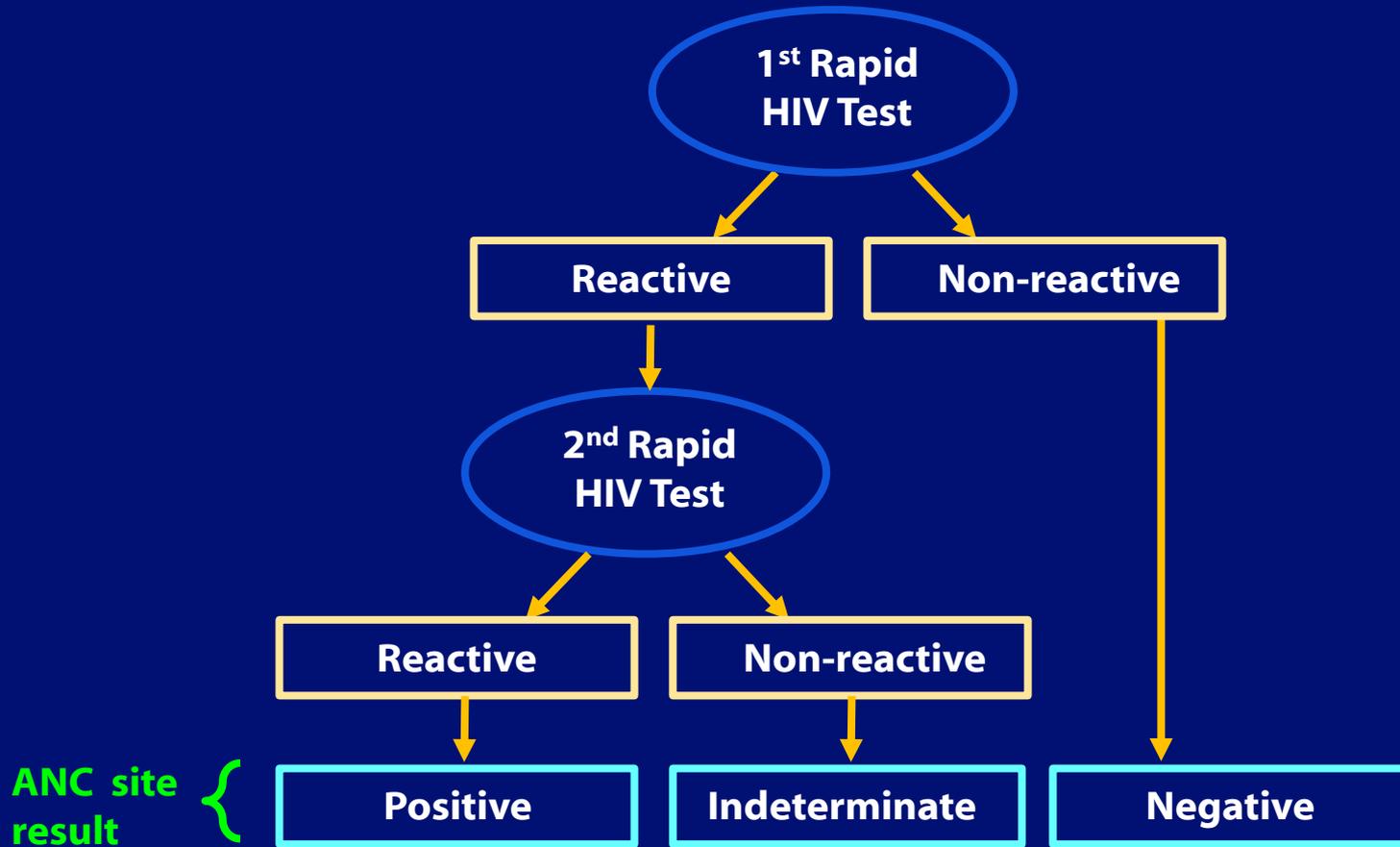
## Evaluation Design

- ❑ Conducted evaluation in Luanda Province, September 12–22, 2011
- ❑ Reviewed surveillance protocols, reports, and data collection instruments
- ❑ Analyzed the 2009 surveillance database
  - Calculate the concordance of results for each ANC site
- ❑ Semi-structured interviews with questions about documentation of non-consenting women

## 2009 ANC Surveillance Round

- ❑ 17,451 women consented and were enrolled at 36 ANC sites
  
- ❑ Consenting women
  - HIV testing
  - Interview to collect demographic information
  
- ❑ Non-consenting women
  - Collection of routine information from ANC record
  - No information on the total number of women approached for enrollment

# Determination of ANC Site Result



# Quality Assurance Process at National Public Health Lab

ANC site result



Positive

Indeterminate

Negative

All Positive + All Indeterminate + 10% Negative

ELISA Test

Reactive

Non-reactive

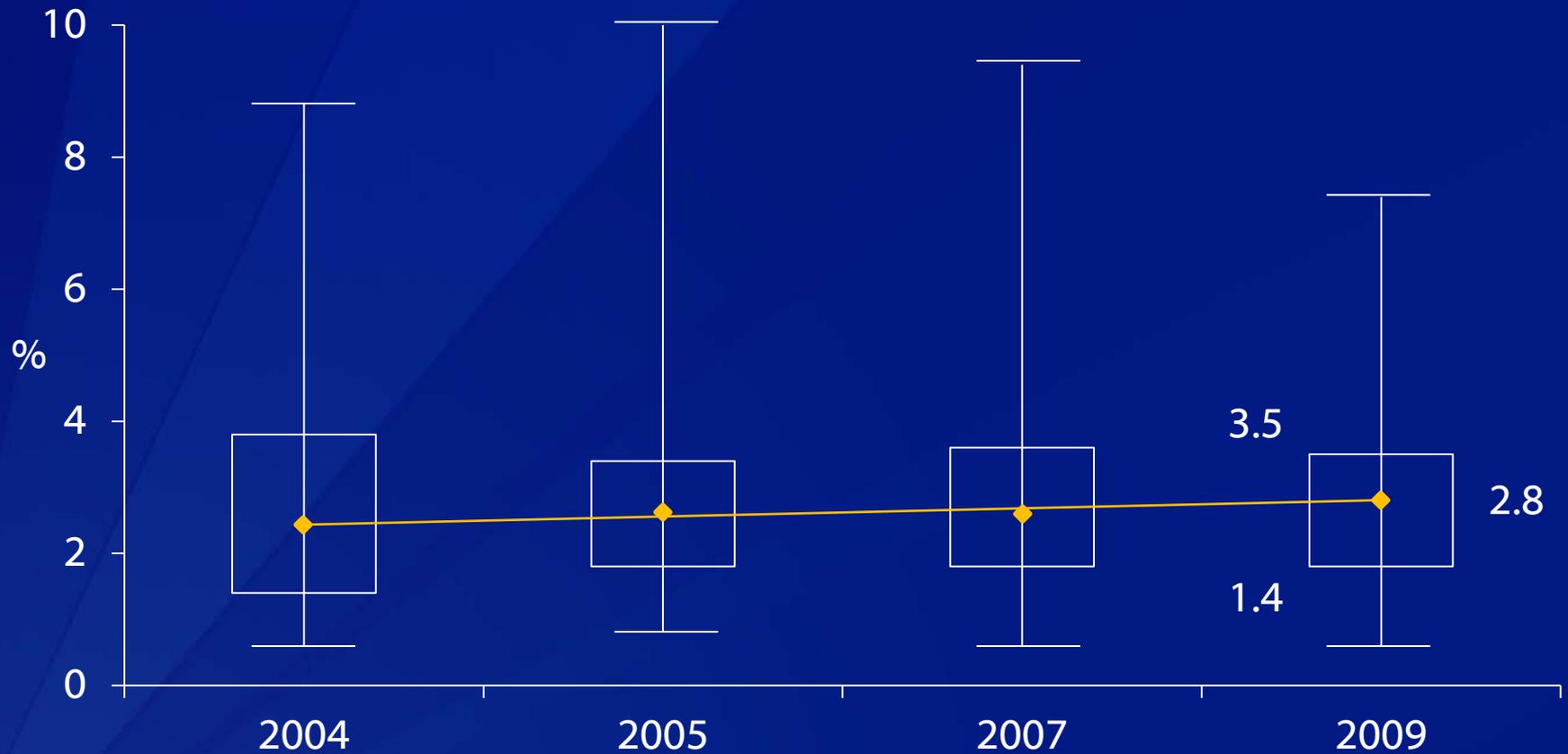
ELISA Result



Positive

Negative

# HIV Prevalence in Pregnant Women in Angola



## Quality Assurance Results

- ❑ 2297 out of 17451 samples were retested with ELISA
- ❑ 3 out of 36 ANC sites had < 95% concordance of ANC site and ELISA results

	<b>Overall Concordance</b>	<b>Positive Concordance</b>	<b>Negative Concordance</b>
<b>ANC Site A</b>	84%	53%	100%
<b>ANC Site B</b>	93%	78%	97%
<b>ANC Site C</b>	88%	36%	100%



## Indeterminate Results

- ❑ 95 indeterminate results across all sites
- ❑ 94% of indeterminate results were negative when retested with ELISA
- ❑ 27 out of 36 ANC sites had at least 1 indeterminate result
- ❑ 4 out of 36 ANC sites had 5 or more indeterminate results
  - Includes ANC Site A and ANC Site B

## Results of the Interviews

- ❑ National surveillance supervisors reported 100% of women consented to testing
- ❑ Clinicians at 3 of 4 sites reported women declining to participate
- ❑ The number and characteristics of non-consenting women were not documented

## Conclusions

- ❑ 33 of 36 ANC sites had adequate quality of their rapid HIV testing for use of ANC site test results for surveillance
- ❑ 3 of 36 ANC sites had quality concerns
- ❑ The majority of indeterminate results at the ANC site were negative when retested
- ❑ Cannot estimate the effect of non-consent bias on prevalence estimates

## Limitations

- ❑ Evaluation occurred two years after surveillance round
  - No direct observation of data collection
  - Recall bias
  
- ❑ Test used for quality assurance differed from test used at ANC site
  
- ❑ One ELISA test is not a gold standard for quality assurance
  - Discordant results from imperfect testing at national lab as well as imperfect testing at the ANC site

## Recommendations

- ❑ Evaluate ANC sites with low positive concordance of ANC site and ELISA test results
- ❑ Change ANC site testing policy to immediately retest indeterminate samples with the same serial rapid testing algorithm
- ❑ Revise National Public Health Lab quality assurance algorithm to include a second ELISA test for confirmation
- ❑ Engage stakeholders to discuss new methods of documentation of non-consenting women

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Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



# Thank You

Center for Global Health

Division of Global HIV/AIDS, Maternal and Child Branch



## Pooled Results

ANC site result	ELISA Result		Totals
	Positive	Negative	
Positive	476	47	523
Negative	2	1677	1679
Indeterminate	6	89	95
Totals	484	1813	2297

## HIV Prevalence for ANC Sites A-C

- 1391 samples were retested with ELISA

	# of Samples	ANC Site Result	ELISA Result	Relative Difference
<b>ANC Site A</b>	487	2.20%	0.80%	-0.64
<b>ANC Site B</b>	404	2.23%	2.23%	0
<b>ANC Site C</b>	500	3.49%	2.87%	-0.18

## HIV Test Performance Characteristics

	Sensitivity (95% CI)	Specificity (95% CI)
<b>Determine Rapid HIV Test</b>	99.3% (98.5 – 99.78)	98.3% (97.1-99.07)
<b>Uni-Gold Rapid HIV Test</b>	100% (95.5-1.00)	99.7% (97.9-1.00)
<b>Serial RT Algorithm</b>	99.3% (94.0 -1.00)	100% (99.9-1.00)
<b>Vironostika II ELISA</b>	100% (97.6-1 – 1.00)	99.5% (97.3-1.00)

- ❑ All tests were compared to Western Blot results as gold standard



## Missing Results

- ❑ Each site had code letter with patients numbered 1-500
- ❑ 46 code numbers missing from database of 17,451
  - May represent missing RT and data forms
- ❑ Of participants with a code numbers assigned
  - 15 RT without an ELISA test
  - 1 ELISA test without a Rapid Test Result
  - 19 participants without either a RT or ELISA result