# Caregiver Provided HIV Testing for Children

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#### Can we use the Oral HIV test for children?



- 1. Is the Oral Mucosal Transudate test (OMT) accurate among children?
- 2. Can caregivers test their children accurately?
- Data combined from two studies conducted: 2017-2018
  - Kenya: 18 Months 12 Years
  - Zimbabwe: 2 Years 18 Years
- Procedures
  - OMT performed by provider
  - Blood based test performed by provider (according to National Algorithms)



# How well does the OMT perform in children?



**Sensitivity:** 100% (97.5% CI 94.9-100)

**Specificity:** 99.9% (95% CI 99.6-100)

	Bloc	od-based n	1/27		
ОМТ		Positive	Negative	Total	
	Positive	71	2*	73	
	Negative	0	1703	1703	
	Total	71	1705	1776	

<sup>\*</sup>Subsequently confirmed as HIV-positive using additional tests within 1 week of initial testing.

(3<sup>rd</sup> gen), A2: First Response

OMT highly sensitive and specific in children 18 months to 18 years



<sup>\*\*</sup>Zimbabwe: A1: Determine (4th gen), A2: First Response; Kenya A1: Determine

# Implications of Study findings



- OMT <u>highly sensitive and specific</u> in children 18 months to 18 years
- 29 November 2019: WHO Prequalification of OMT for children 2-11

years **by a provider** 



What about caregivers testing their own children for HIV?



# Can caregivers accurately the test their children?



Did the caregiver correctly collect oral fluid?



Did the caregiver insert the flat pad all the way?



Did the caregiver use a timer?



Did the caregiver interpret the test result correctly?

#### **OraQuick Test Results**

- Two lines:
- "C" Control line
- "T" Test line
- Negative result
- Reactive result
- Invalid result





#### Methods



#### **Phase 1 : Jan-Dec 2018**

- 1. Provider demonstration in facility
- 2. Competency Assessment
- 3. Provision of test + manufacturer insert instructions
- 4. Observation by provider

### **Phase 2: Jan - May 2019**

- 1. Provider demonstration in facility
- 2. Competency Assessment
- 3. Provision of test + manufacturer insert instructions
- 4. Observation by provider



# Can caregivers perform the test on their children?



	Did not receive demonstration	Received demonstration	P- value	
	629 (%)	157 (%)		
1. Caregiver correctly collected oral fluid	548 (87.1)	152 (96.8)	0.002	)
2. Caregiver inserted the flat pad all the way	612 (97.3)	156 (99.4)	0.157	
3. Caregiver used a timer	568 (90.3)	152 (96.8)	0.019	>
4. Caregiver correctly interpreted the test result	612 (97.3)	153 (97.5)	0.843	
Caregiver received a score of 4/4	490 (77.9)	145 (92.4)	<0.001	>



# Can caregivers correctly interpret test results?



		Care	Total		
		Reactive	Non-Reactive	Invalid	
Research Assistant	Reactive	4	0	0	4
Interpretation	Non-Reactive	8	567	1	576
	Invalid	1	0	6	7
Total		13	567	7	587

Direction of misinterpretation suggests reactive children would not be missed



#### Conclusions



- Caregivers can accurately collect samples, manipulate test kits, and interpret test results
- Caregiver provided testing is a feasible and accurate HIV testing strategy for children
- PEPFAR Guidance 2020 Caregivers to test children using self test kits during
   COVID19



#### Recommendations



- 1. Further operational research for implementation at scale
- 2. Need for evaluation of cost-effectiveness of caregiver provided testing
- 3. Acceptability should be assessed and may require sensitization efforts
- 4. Additional targeting of user groups should be evaluated e.g. female caregivers receiving antenatal care or newly diagnosed HIV positive individuals



#### References



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CLINICAL SCIENCE **Brief Report: Diagnostic Accuracy of Oral Mucosal Transudate Tests Compared with** Outline **Blood-Based Rapid Tests for HIV Among** Children Aged 18 Months to 18 Years in Kenya and Zimbabwe Dziva Chikwari, Chido MSca,b,\*; Njuguna, Irene N. MBChB, MPH, PhD<sup>c,d,\*</sup>; Neary, Jillian MPHe; Rainer, Crissi MSc<sup>f</sup>; Chihota, Belinda MSc<sup>g</sup>; Slyker, Jennifer A. MSc, PhD<sup>c,e</sup>; Katz, David A. MPH, PhD<sup>h</sup>; Wamalwa, Download Dalton C. MBChB, MMed, MPH<sup>I</sup>; Oyiengo, Laura MBChB, MMed<sup>J</sup>; Bandason, Tsitsi MSc<sup>b</sup>; McHugh, Grace MDb; Dauya, Ethel MPHb; Mujuru, Hilda MBChB, MMedk; Stewart, Kearsley A. PhDf; John-Stewart, Grace C. MD, MPH, PhD<sup>c,e,l</sup>; Ferrand, Rashida A. MB BS, PhD<sup>a,b</sup>; Wagner, Anjuli D. MPH, PhD<sup>e</sup> **Author Information ⊗** JAIDS Journal of Acquired Immune Deficiency Syndromes: December 1, 2019 - Volume 82 - Issue 4 - p <

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