Caregiver Administered HIV Testing of Children Using Oral Mucosal Transudate (OMT) Test:

Evidence of accuracy, acceptability, feasibility, and safety

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Meeting agenda

- Introductions to our collaborative team and studies

- Ask and answer essential questions:
  - Is OMT **accurate** among children?
  - Who **benefits** from testing?
  - Are caregivers **willing** to test their children at home using OMT?
  - Can caregivers test their children **accurately**?
  - What data exist about **social harms**?

OraQuick test kit

Who we are

- Our **teams**:
  - Chido Dziva Chikwari, leads Zimbabwean team
  - Irene Njuguna & Anjuli Wagner, co-lead Kenyan team

- Our **work**:
  - Pediatric HIV testing for older children prior to symptomatic disease
  - Series of studies about accuracy, acceptability, feasibility, and safety of OMT for children outside of PMTCT settings
    - **STEP-UP**: Kenyan children
    - **B-GAP**: Zimbabwean children

Is OMT **accurate** among children?

Sensitivity: 100% (97.5% CI 94.9-100)
Specificity: 99.9% (95% CI 99.6-100)

		Blood-based national algorithm**		
		Positive	**Negative**	Total
OMT	**Positive**	71	2*	73
	Negative	0	1703	1703
	Total	71	1705	1776

**Subsequently confirmed as HIV-positive using additional tests within 1 week of initial testing.*
***Zimbabwe: A1: Determine (4th gen), A2: First Response; Kenya A1: Determine (3rd gen), A2: First Response*

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

Dziva Chikwari & Njuguna et al, JAIDS 2019

Who **benefits** from testing?

- Caregivers avoid seeking care for untested children
  - **22%** avoided seeking care for child's minor illness due to fear of HIV testing
  - **82%** who avoided care in past **more likely to seek care** after testing

Even with variable yield, testing has benefits for **all children**

Mugo et al, IAS Pediatric Workshop 2019

Are caregivers **willing** to test their children at home using OMT?

Potential Advantages

- Shorter time
- Convenience
- Privacy*
- Control over who knows child status**
- Lower cost*
- Increased child testing
- Reduced provider workload
- Easier administration
- Child comfort of familiar setting
- Caregiver belief of results

*Kenyan and Zimbabwean setting; **Zimbabwean setting alone; remainder is Kenyan setting alone

Neary et al, AIDS 2020
Rainer AIDS Care 2020

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Potential Disadvantages

- Not receiving pre-test counseling
- Not trusting results
- Disagreements with partners or child neglect
- Need for HCW support for HIV positive result**
- Uncertainty in ability to test without assistance or unable to read**

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Generally **acceptable** with concerns that can be mitigated

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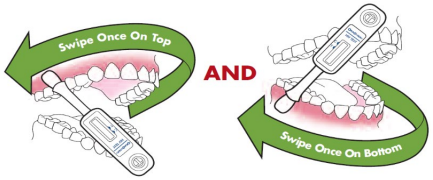
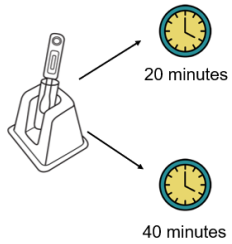
Neary et al, AIDS 2020
Rainer AIDS Care 2020

Can caregivers **accurately** test their children?

- Can caregivers **collect a sample** accurately?



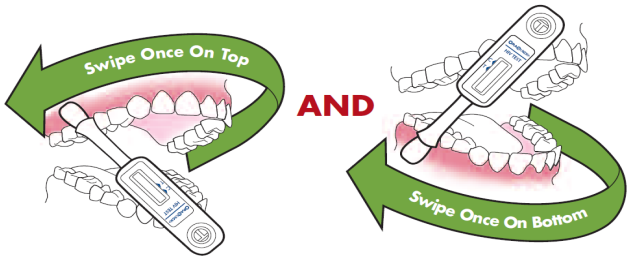
- Can caregivers **manipulate** a test kit correctly?



- Can caregivers accurately **interpret** test results?

Can caregivers **accurately** test their children?

- Can caregivers **collect a sample** accurately?



- **Without** additional provider instruction (N=629):
  - **87%** swabbed both upper and lower gum for fluid
- **With** additional provider instruction (N=157):
  - 87% → **97%** swabbed both upper and lower gum for fluid (p<0.01)

Dziva Chikwari et al, manuscript in preparation

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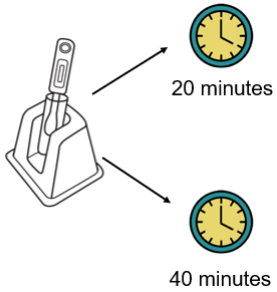
- Can caregivers **manipulate a test kit** accurately?



- **Without** additional provider instruction (N=629):
  - **97%** inserted the flat pad all the way into reaction fluid
  - **90%** used a timer

- **With** additional provider instruction (N=157):
  - 97% → **99%** inserted the flat pad all the way into reaction fluid (p=0.12)
  - 90% → **97%** used a timer (p<0.01)

Dziva Chikwari et al, manuscript in preparation

Can caregivers **accurately** test their children?

- Can caregivers accurately **interpret** test results?

- **Without** additional provider instruction (N=629):
  - **97%** interpreted the test result correctly
- **With** additional provider instruction (N=157):
  - 97 → **98%** interpreted the test result correctly (p=0.91)

Dziva Chikwari et al, manuscript in preparation

Can caregivers **accurately** test their children?

- What was the source of **mis-interpretation**?

		Caregiver interpretation			Total
		Reactive	Non-Reactive	Invalid	
Research Assistant Interpretation	Reactive	4	0	0	**4**
	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**

Dziva Chikwari et al, manuscript in preparation

Can caregivers **accurately** test their children?

- Can caregivers **collect a sample** accurately?

  Yes, gap in swabbing both gums; overcome with instruction

- Can caregivers **manipulate** a test kit correctly?

  Yes, gap in using a timer; overcome with instruction

- Can caregivers accurately **interpret** test results?

  Yes, mostly accurate interpretation even without any instruction

Social harm concerns across different types of testing

Time

		Clinic-based testing	Home-based testing	Self-testing
Adults	Concerns			
	Addressing the Concern			
Children	Concerns			
	Addressing the concern			

Opportunity to prevent and track social harms

- **Mitigation** using available resources
  - Focus counseling messages
    - Most children are negative
    - Positive children can have healthy futures with appropriate care
  - Offer health care worker support for testing and linkage (phone or mHealth)

- **Monitoring** within implementation
  - Routine questions to assess incident social harms

Summary of what's been learned

- OMT highly **sensitive** and **specific** in children 18 months to 18 years
- Even with variable yield, testing has benefits for **all children**
- Caregiver-administered OMT testing of children generally **acceptable** with concerns that can be mitigated
- Caregivers can **accurately** collect samples, manipulate test kits, and interpret test results
- **Concerns** about social harms exist, but existing observational data note **low frequency**
- Opportunities exist to **mitigate** and **monitor** social harms

Questions?

Thanks to the B-GAP and STEP-UP study participants.

STEP-UP team: Grace John-Stewart, Dalton Wamalwa, Jennifer Slyker, Gabrielle O'Malley, David Katz, Laura Oyiengo, Jillian Neary, Michelle Bulterys, Cyrus Mugo, Xinyi Zhai, Yu Wang, Verlinda Anyango, Vincent Omondi, Lukio Agalo, Pamela Agola, Anita Orimba, Anne Auma, Joseph Orondo, and the Kenya Pediatric Studies Staff

B-GAP team: Rashida A Ferrand, Vicky Simms, Helen Weiss, Stefanie Dringus, Sarah Bernays, Tsitsi Bandason, Nicol Redzo, Crissi Rainer, Belinda Chihota, Kearsly Stewart, Collaborating institutions and the B-GAP Research assistants.

Supplementary slides

- Literature review of social harms for adults and children across home and self-testing
- Qualitative evidence of pediatric social harm concerns
- Quantitative evidence of social harm occurrences
- Detailed mitigation strategies

Summary of key studies on social harms

Author	Setting	Design	Age group	Year	Tests distributed	Harm assessment	Number who experienced harms	Description
Reviews								
Brown		Review of evidence of harm from HIV self-tests		2014	300 articles			Although the potential for harm is discussed in the literature on self-tests, there is very little evidence that such harm occurs
Stevens		Review of themes and implications of self-testing		2018	28 articles			Despite concerns stated by study participants regarding self-testers receiving the necessary pre- and post-test HIV counseling, this is not a prominent drawback to the HIV self-testing strategy
Notable studies reporting social harms related to self testing (ST) or home-based testing (HBT)								
Kumwenda	Malawi	Implementation	16+	2011-2017	175,683	Passive and Active	19 (0.011%) overall 4 (1.3% active assessment)	16 marriage break-ups (8 resolved) 1 IPV 1 Suicidal ideation 1 use of test by 12-year-old with untreated HIV
Johnson	Systematic review (5 RCTs – 2 Kenya, 1 USA, China, Australia)	RCTs comparing ST to standard testing	18+	2015-2017	4145 total	Unclear but likely active	One in ST arm 1 in standard testing arm (ONLY in 1 study described as poor quality)	Harm in ST was IPV related to enrollment in study without partner consent rather than the ST
Choko	Malawi	Cluster RCT (14 neighborhoods) comparing home-based HTS with a counselor and self-testing	16+	2012-2014	14004 total	Active of a subset	0 suicides or IPVs 203 reported coercion	0 suicides 0 IPV 203/7006 (2.8%) reported coercion
Doherty	South Africa	Cluster RCT comparing counselor-administered home-based HTS (HBT) and clinic-based HTS (CBT)	14+	2008	4154 total	Passive	IPV – HBT: 22/968 (2%) CBT: 28/709 (4%) Stigma – HBT: 822/2025 (41%) CBT: 1043/2129 (49%)	Smaller proportion of those who received HBT reported IPV compared to CBT (not statistically significant) Any stigmatizing behavior observed in the community in the past year towards people living with HIV (HBT: 41% vs. CBT: 49%; p=0.15)

Qualitative evidence of pediatric social harm concerns

- Caregivers in Zimbabwe did not raise the possibility of suicide risk following a reactive caregiver provided test
  - In the Zimbabwe study and Kenya study, some caregivers felt there may be adverse events such as suicide; this was raised in 1/5 FDGs in Zimbabwe and 2/4 FGDs in Kenya and not among those that took up the test

- HCW and caregivers addressed concerns about stigma due to testing HIV positive or due to misconceptions around saliva-based testing (i.e. misbelief that HIV can be transmitted through saliva)

Image from the STEP-UP study

Quantitative evidence of social harm occurrences

	Caregiver Provided HIV Testing in B-GAP study	Financial Incentives to Increase Pediatric HIV testing (FIT) study
Was there evidence of social harm?	• **No social harms were reported** among the study participants	• Of the 318 children tested, **no social harm was reported** • One social harm event (child left home) was related to abrupt disclosure of caregiver HIV status to the child, prior to testing
Notes about social harm	• Self screening prior to taking the HIVST kit is likely	• To prevent future events, we modified study procedures to include a script that caregivers did not need to disclose their HIV status to children to access HIV testing

Mitigation strategies for social harm

Image from B-GAP study

1) To address stigma, caregivers should be provided with educational materials on HIV transmission with saliva-based test kit

2) Pediatric HIV literacy should be included as part of standard HIV care
   - Caregivers should be equipped with enough information to have the discussion about HIV and HIV testing (disclosure) with their children