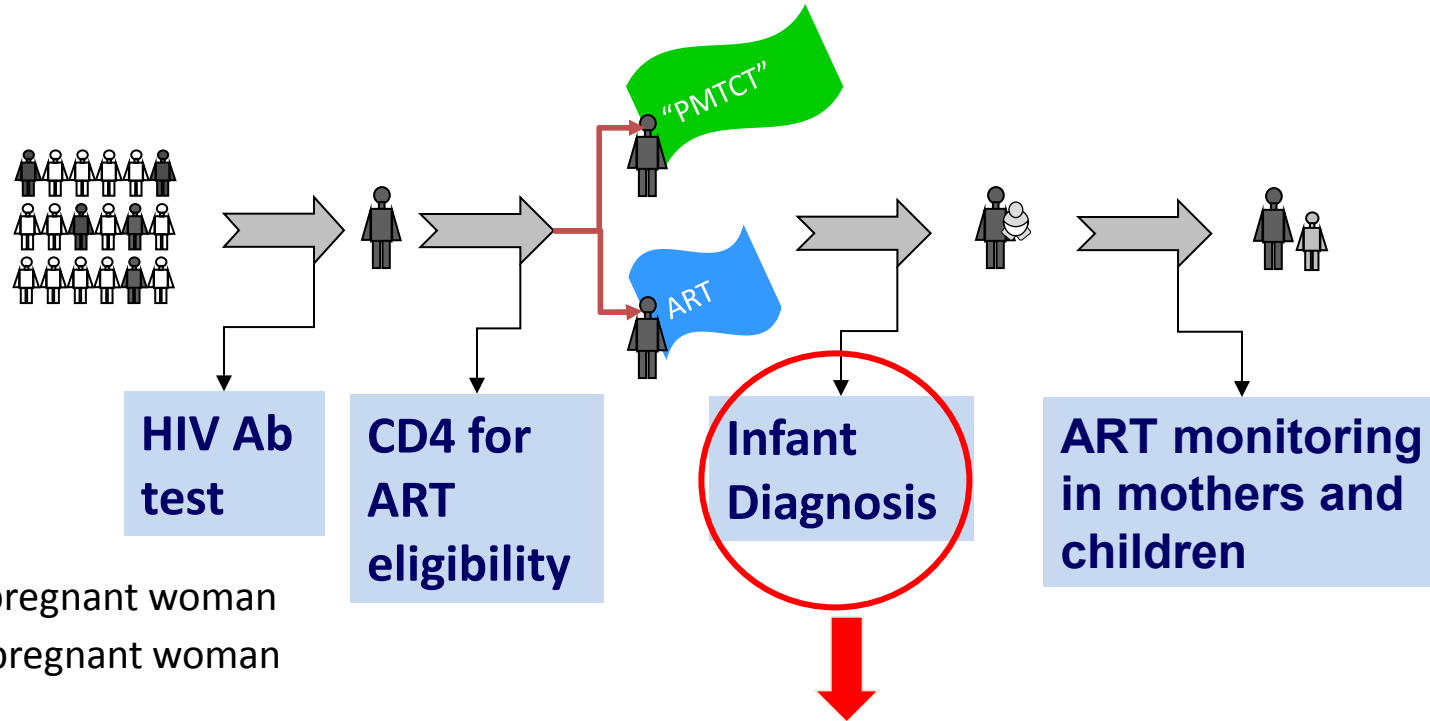


Update on EID testing: Global Progress & Emerging Challenges

Shaffiq Essajee - May, 2013



Lab testing is important all along the pediatric HIV prevention and treatment continuum, but EID is a critical component



Infant diagnosis is important for **PMTCT program monitoring** but *essential* for **identification of infected infants for ART**

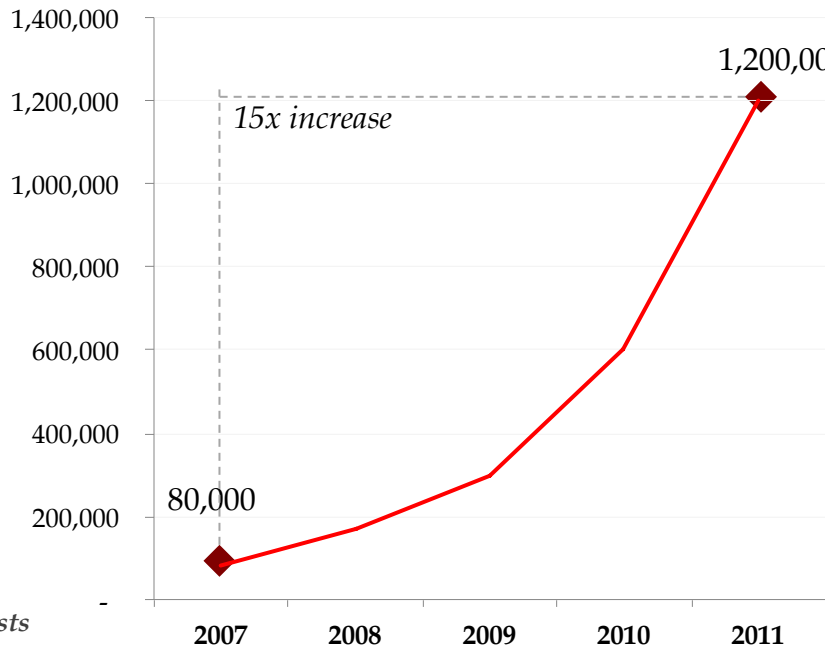
However, there are challenges to **scaling up the service** and **translating that service to better outcomes**

Challenge: Over 75% of exposed infants never even receive an EID test

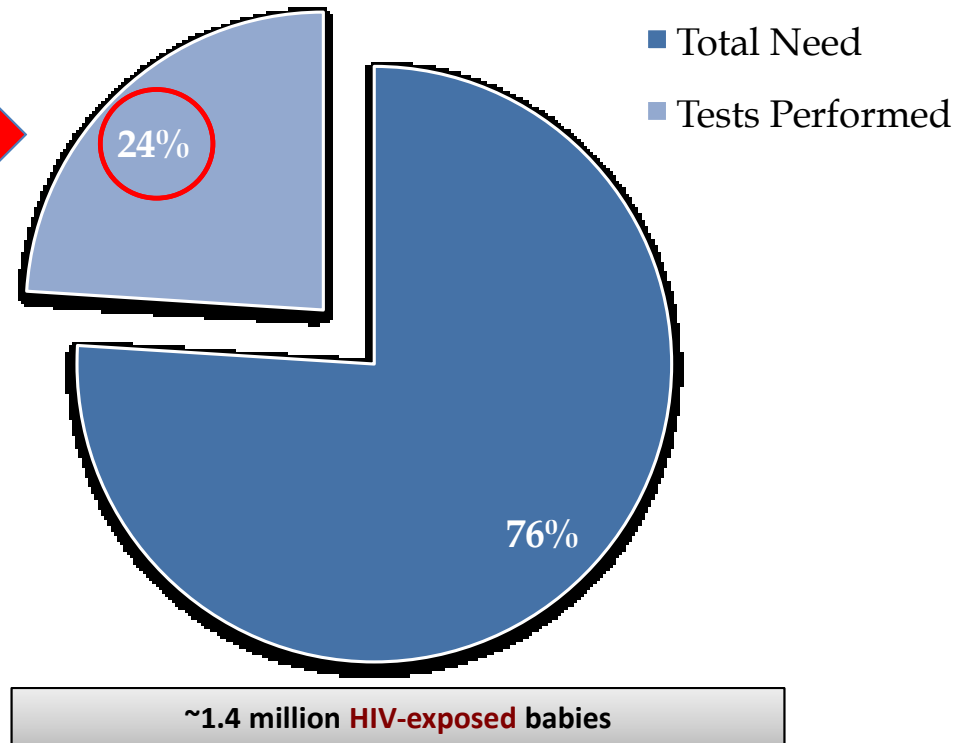
EID has been scaled up from around 80K in 2007 to >1.2m in 2011. **~24% of need**

The remaining 76% represent HIV+ mothers that were never tested, infants known to be HIV exposed but LTFU or incident maternal HIV infection during pregnancy and BF

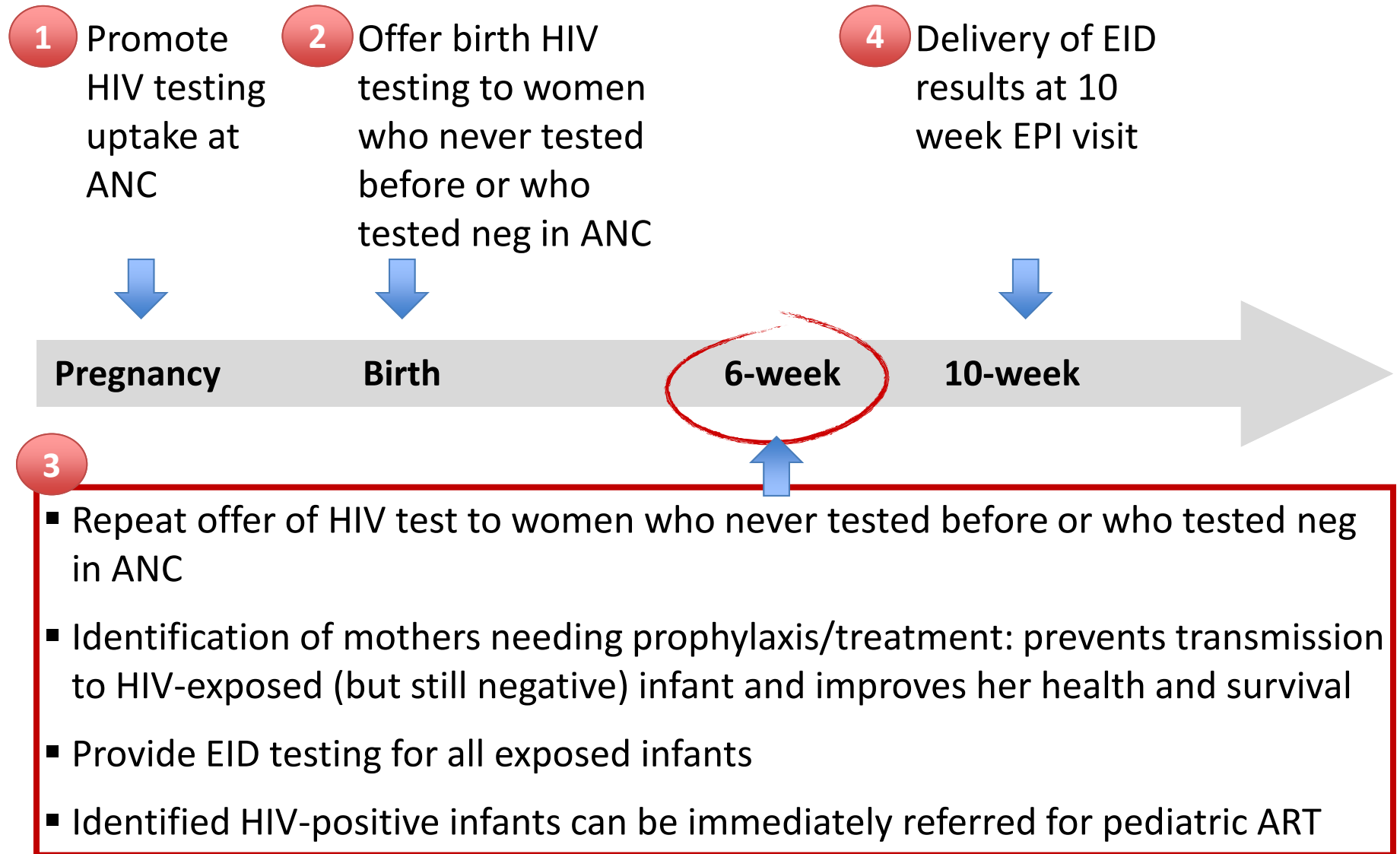
- Number of EID Tests -



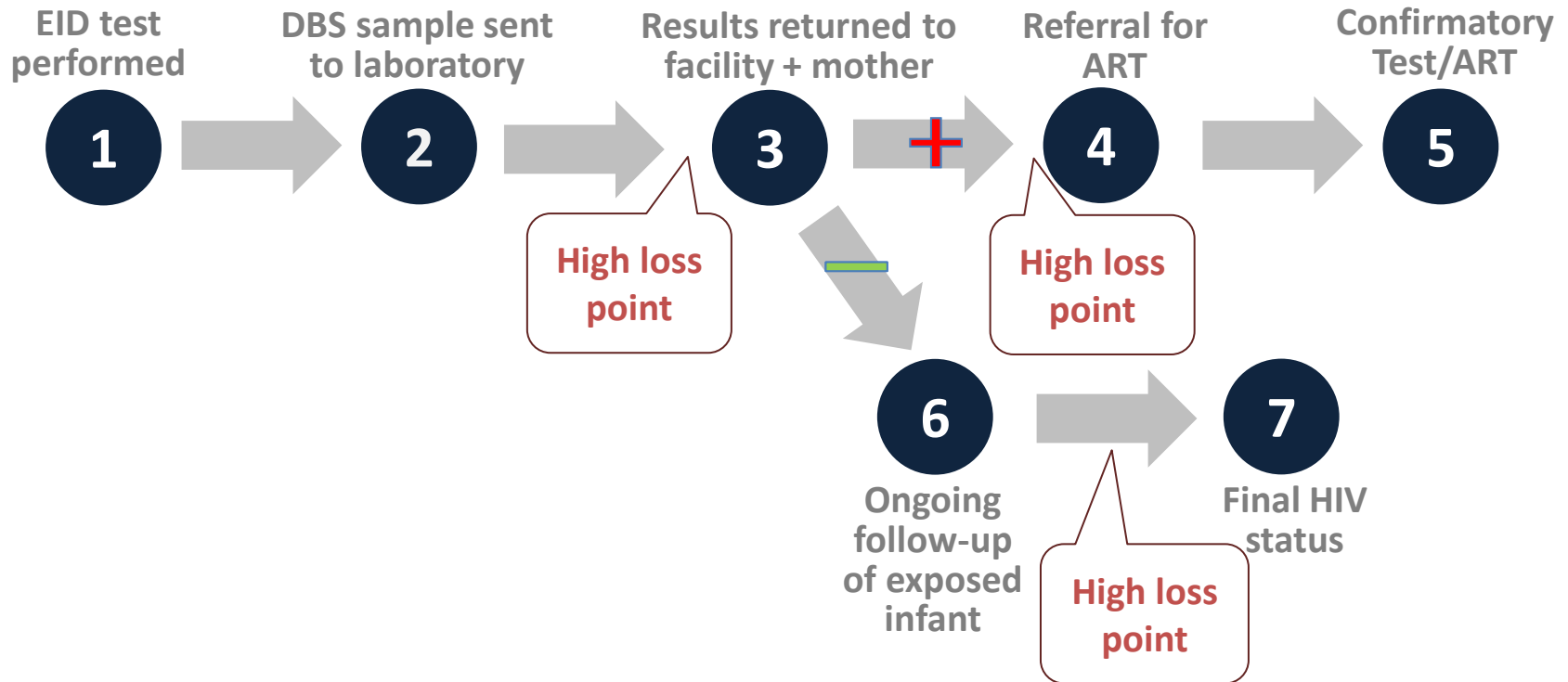
- Global coverage of EID testing -



Solution: Build maternal HIV testing and exposed infant EID testing into the entire care continuum

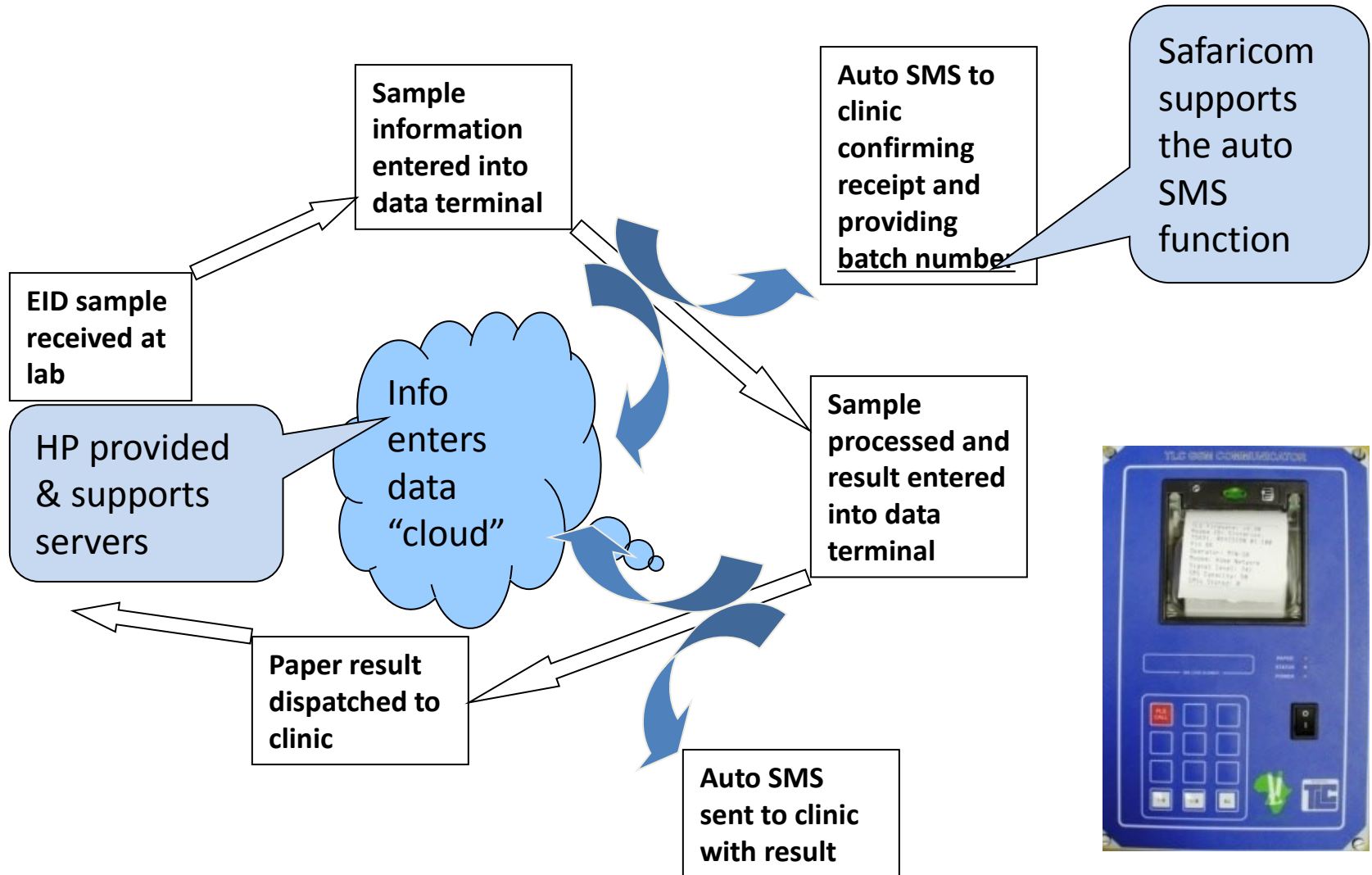


Challenge: For the 24% that DO get a test, a large proportion are lost along the continuum of care



The highest points of loss continue to be in getting positive results returned to mothers [50%], getting infants referred for ART [40%] and following infants for confirmatory testing if initially negative

Solution: In Kenya, a partnership with HP has helped to create a national automated results return system linked to SMS printers



Results are posted in real time into an online database



National AIDS/STD Control Programme (NASCO)
Ministry of Health Government of Kenya

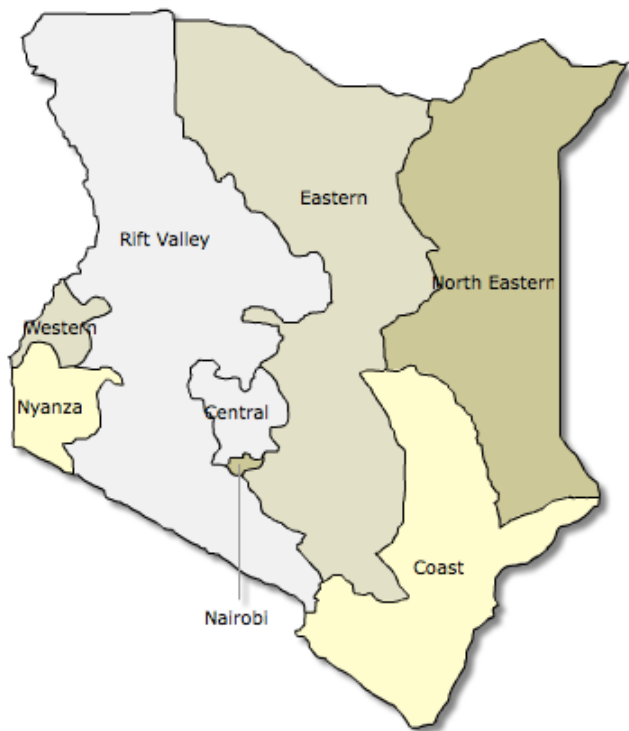
Overall | Regional | PCR Confirmatory | Other Indicators | Testing Trend | Lab Performance | Kits | Reports | Partner LogIn | PASCO LogIn | Facility LogIn

2012 | 2011 | 2010 | 2009 | 2008 | 2007 |

* Refine your view by clicking on Year and/or Month

Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sept | Oct | Nov | Dec

Kenya EID Summary for Dec-2012

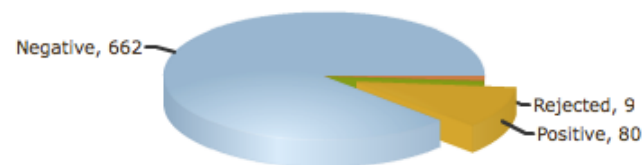


* Hover over the Map to view Provincial Statistics.
* Click on a Province to view Detailed Statistics

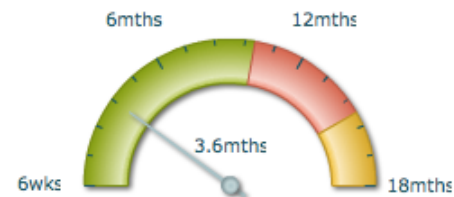
National Statistics

No. of All Infants Tested	744
No. of first DNA PCR test	730
No of Antibody confirmatory tests	13
No. of All Infants Tested (< 2 months)	433
Average Age of Testing	3.6 months
Total Number of Health Facilities	8706
Total Number of PMTCT Facilities	3634
Active EID Sites (Ever Sent a Sample)	2678
EID Sites Sending Samples in (<u>Dec-2012</u>)	111

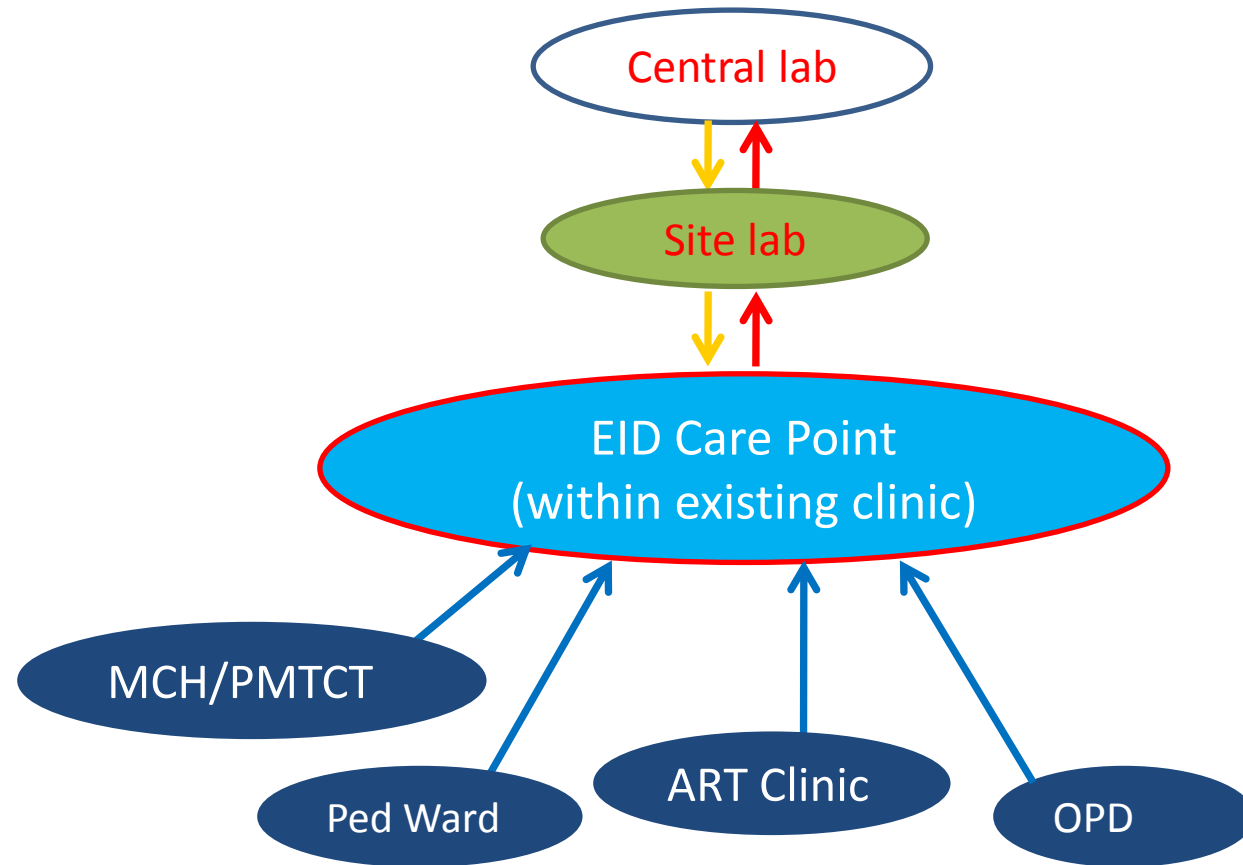
EID Results



Average Age of Testing



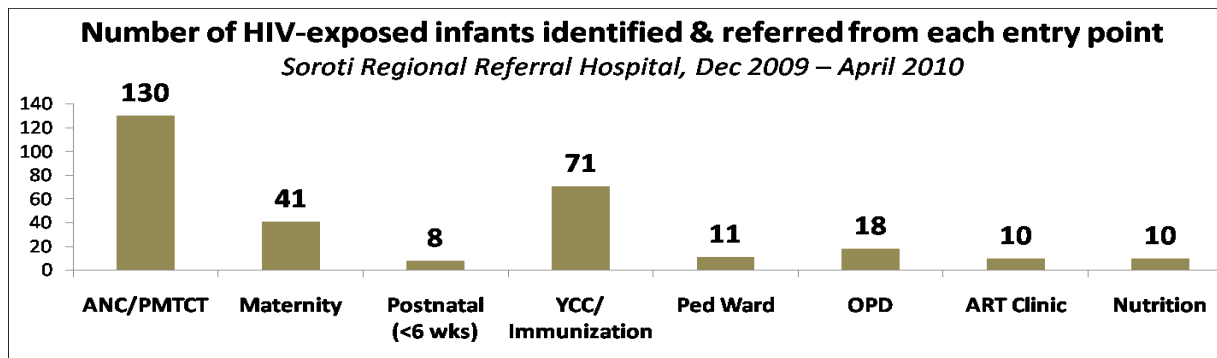
Solution: In Uganda, establishing an EID care point has helped to ensure that exposed infants receive adequate care and follow-up



- Each site chooses the location of EID care point
- The EID care point is equipped with a PERSON, MEDS, TEST EQUIPMENT and TOOLS
- Caregivers return to EID care point for every follow-up visit until no longer exposed

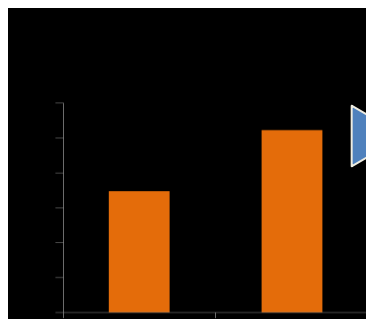
Results of the pilot suggest significant improvement in a number of areas

1



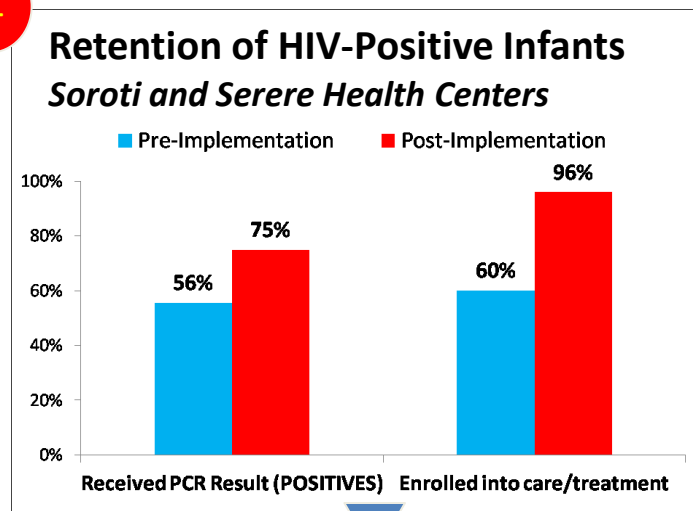
Exposed infants now being picked up earlier and from many health departments, not just PMTCT program

2



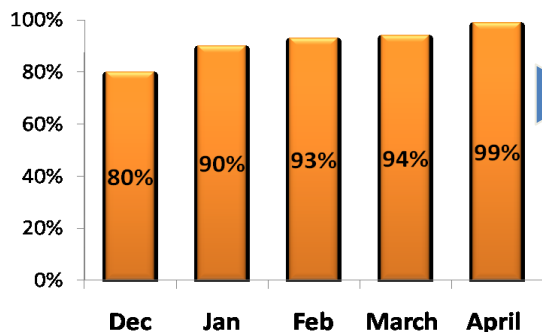
DBS testing volumes have increased by almost 50%

4






75% received results and 96% of positive infants were enrolled at an ART clinic

3



The percentage of exposed infants initiated on CTX increased to 99%

Solution: PoC testing enables same day results and so may reduce LTFU

	Product Name	Test Type	Turnaround Time	Max Throughput
	Northwestern	<ul style="list-style-type: none">• Qualitative EID• Gag p24 antigen detection• Heel-prick blood	<ul style="list-style-type: none">• 40 minutes per test	<ul style="list-style-type: none">• 16 tests per day
	Alere NAT	<ul style="list-style-type: none">• Qualitative EID, Quantitative VL• NAT-based test• Finger-stick or venous blood	<ul style="list-style-type: none">• 60 minutes per test	<ul style="list-style-type: none">• 5-10 tests per day
	SAMBA EID and VL	<ul style="list-style-type: none">• Qualitative EID, Semi-quantitative VL• Isothermal amplification• Blood or plasma	<ul style="list-style-type: none">• 60 minutes per test	<ul style="list-style-type: none">• 25-30 tests per day

In Mozambique CHAI with MoH evaluated Alere NAT PoC against traditional PCR for EID

		All Patients	HIV-Negative	HIV-Positive
		843 (100%)	762 (100%)	65 (100%)
Age groups	1 - 2 months	506 (60.0%)	481 (63.1%)	19 (29.2%)
	2 - 3 months	126 (14.9%)	118 (15.5%)	6 (9.2%)
	3 - 6 months	115 (13.6%)	99 (13.0%)	12 (18.5%)
	6 - 9 months	59 (7.0%)	44 (5.8%)	14 (21.5%)
	> 9 months	37 (4.4%)	20 (2.6%)	14 (21.5%)
	Mothers' regimen	None	15 (1.8%)	10 (1.3%)
	sdNVP	20 (2.4%)	19 (2.5%)	0 (0.0%)
	TARV	287 (34.0%)	273 (35.8%)	10 (15.4%)
	WHO - Complete	61 (7.2%)	61 (8.0%)	0 (0.0%)
	WHO - Incomplete	340 (40.4%)	303 (39.7%)	32 (49.2%)
	Unknown	120 (14.2%)	96 (12.6%)	18 (27.7%)
Infants' regimen	None	11 (1.3%)	5 (0.7%)	6 (9.2%)
	NVP	582 (69.0%)	544 (71.4%)	30 (46.2%)
	AZT	31 (3.7%)	28 (3.7%)	3 (4.6%)
	NVP + AZT	47 (5.6%)	36 (4.7%)	7 (10.8%)
	Unknown	172 (20.4%)	149 (19.6%)	19 (29.2%)
	WHO - Complete: sdNVP + AZT + 3TC			
WHO - Incomplete: AZT, AZT + 3TC, sdNVP + AZT, sdNVP +				

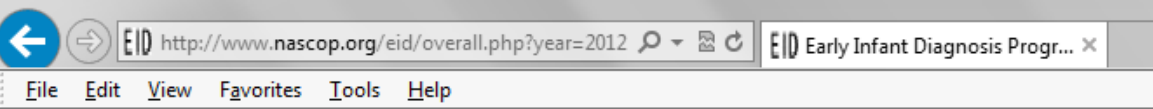
~8% MTCT Transmission

60% were under 2 m

PoC testing performs as well as conventional DNA PCR

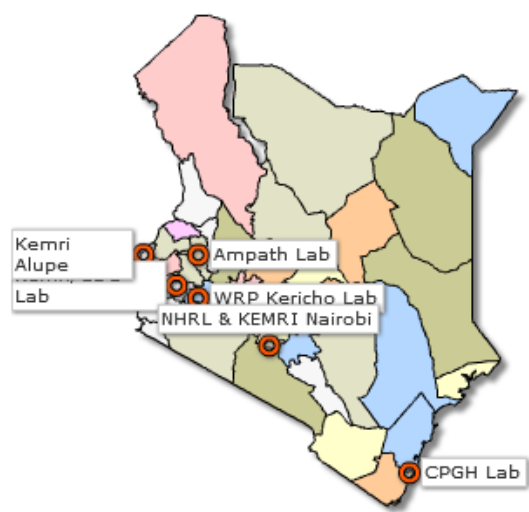
		Conventional Results						
		Positives	Negatives	Overall agreement	95% C.I.	Positive percent agreement	95% C.I.	Negative percent agreement
POC NAT Results	Positives	64	1	99.8%	99.1 - 100%	98.5%	95.5 - 100%	99.9%
	Negatives	1	761					
				Cohen's Kappa	95% C.I.	McNemar's Test	p-value	
				0.981	0.960 - 1.000	0.500	0.480	

Challenge: Infants that get a test are getting it late



National EID Summary :: 2012

Click Here to View Larger Map



* Place Mouse Pointer over the Map to view Provincial Statistics.

EID Results :: 2012



More Charts...

* Click to View Chart

EID Results by PMTCT Intervention

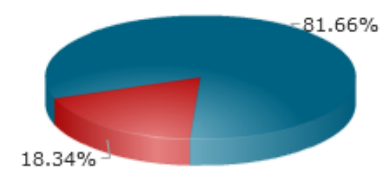
EID Results by Infant Prophylaxis

Load More Charts

National Statistics :: 2012

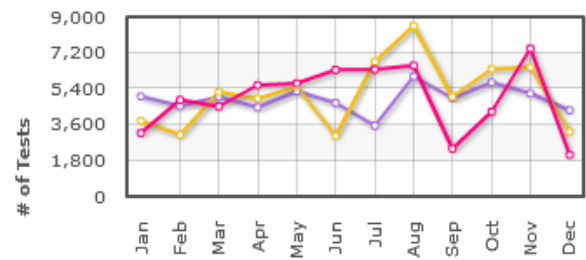
Cumulative No. of All Infants Ever Tested (2007 to Now)	242928
No. of All Infants Tested	59317
No. of first DNA PCR Test	58932
No of Confirmatory PCR Test @9M	278
No. of All Infants Tested (< 2 months)	35125
Average Age of Testing (Months)	3.6
Active EID Sites (Ever Sent a Sample)	2835
EID Sites Sending Samples in (2012)	2315

% Sites Reporting



EID Testing Trend :: 2010 - 2012

* Click on the Year(s) Listed in the Key, to View for Specific Year(s)



EID Results by Age of Testing :: 2012

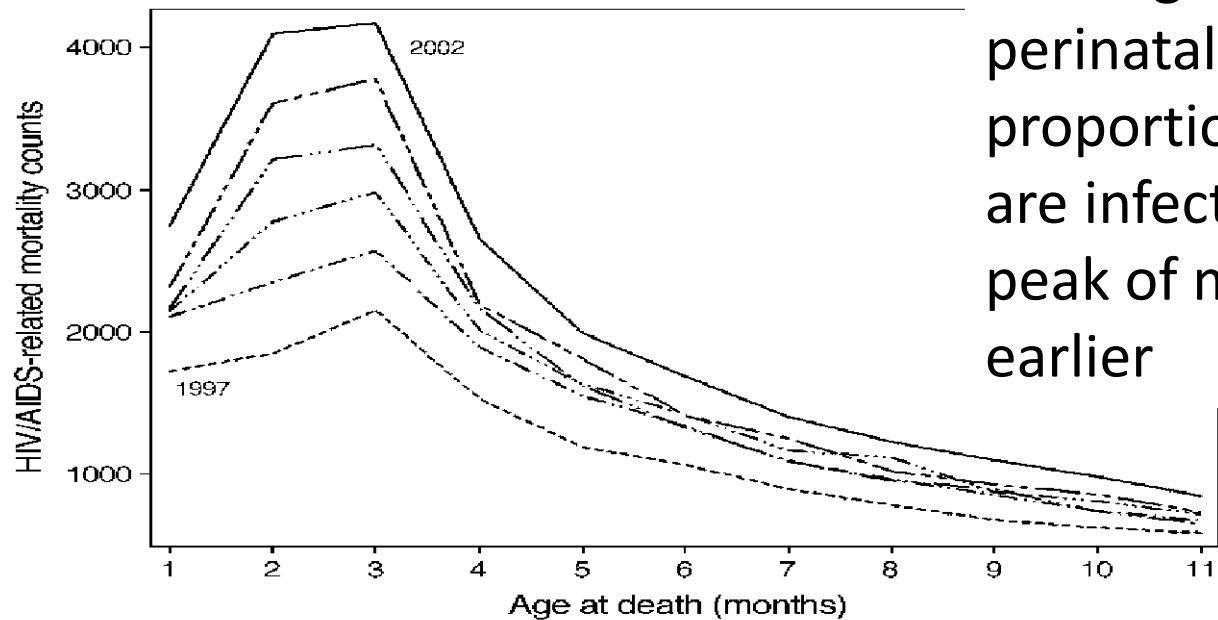
* Click on the Indicators in the Key (Negative , Positive), to Customize View to either Positive or Negative only

Average Age of Testing



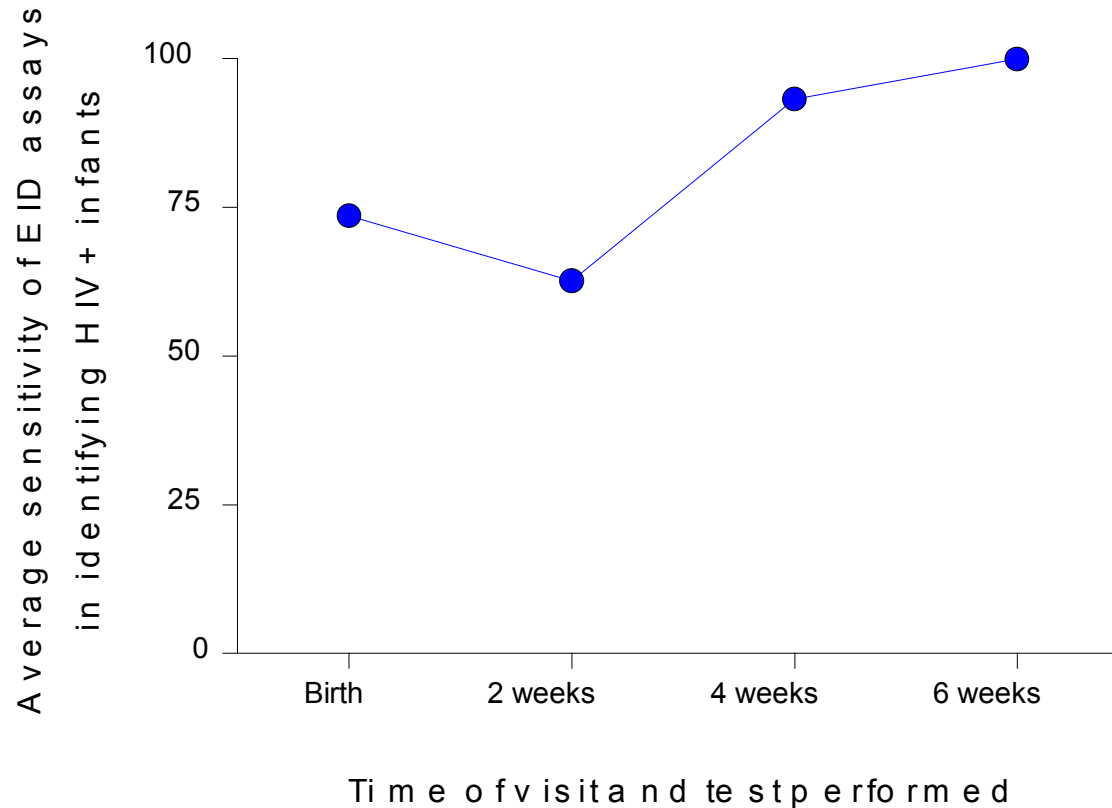
<http://www.nascop.org/eid>

The peak of infant mortality due to HIV is well before median age at testing



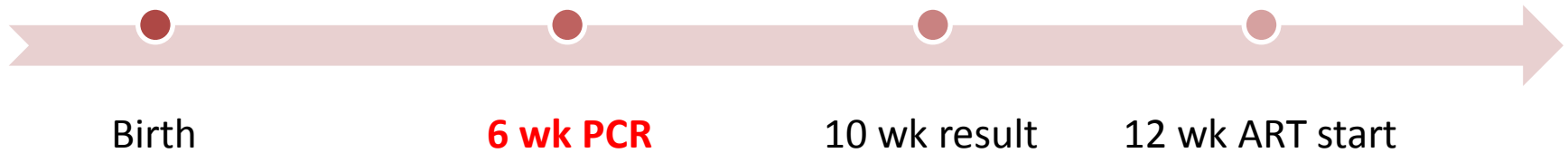
As we get better at preventing perinatal transmission so proportionally more infants are infected *in utero*, and the peak of mortality is getting earlier

In the age of maternal ART and infant prophylaxis we may have lower sensitivity than we think, especially at 2 weeks

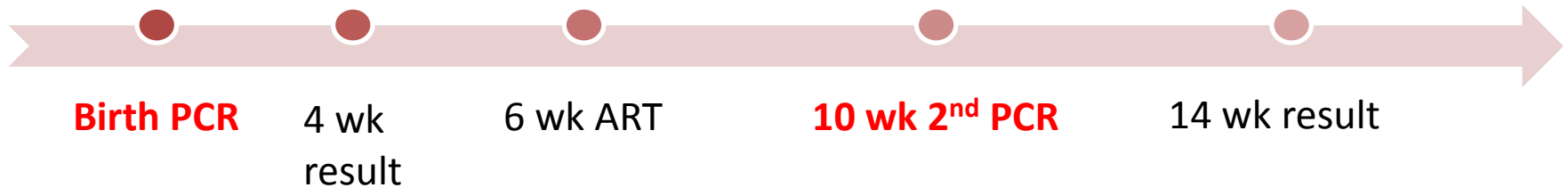


Solution: A possible change to the EID testing algorithm?

2010 Guidelines



Possible new recommendations



Take Home Messages

- Given the complexity – we have made huge progress and established new paradigms for sample transport/ result return
- We are missing **many many** opportunities to identify HEI and need to expand access to screening and EID – not just at PMTCT but also at EPI and other clinical settings
- There is poor retention across the continuum – in fact, **most** children are lost. Simple approaches such as identifying focal points, improving tools for follow up, and PoC EID need to be studied
- The **peak of mortality is earlier than when we are testing....**should there be a change in the guidance?
- **Money is a problem.** Much of the progress and scale up has happened because of UNITAID's commodity and programmatic funding – what happens next?