Preliminary results

Routine early infant testing Rwanda

CROI meeting on infant Dx

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Background Rwanda

- HIV prevalence 5.1%
- ~18,000 infants born to HIV+ mothers / year*
- Only 11.9% of HIV-exposed children followed up and tested at age 15 months*
- Pediatric ART implemented at various sites and PCR capacity at National Reference Lab
- Since September 2005 national program for routine early infant PCR-testing

*estimates MoH Rwanda

Objectives of routine early infant testing national program

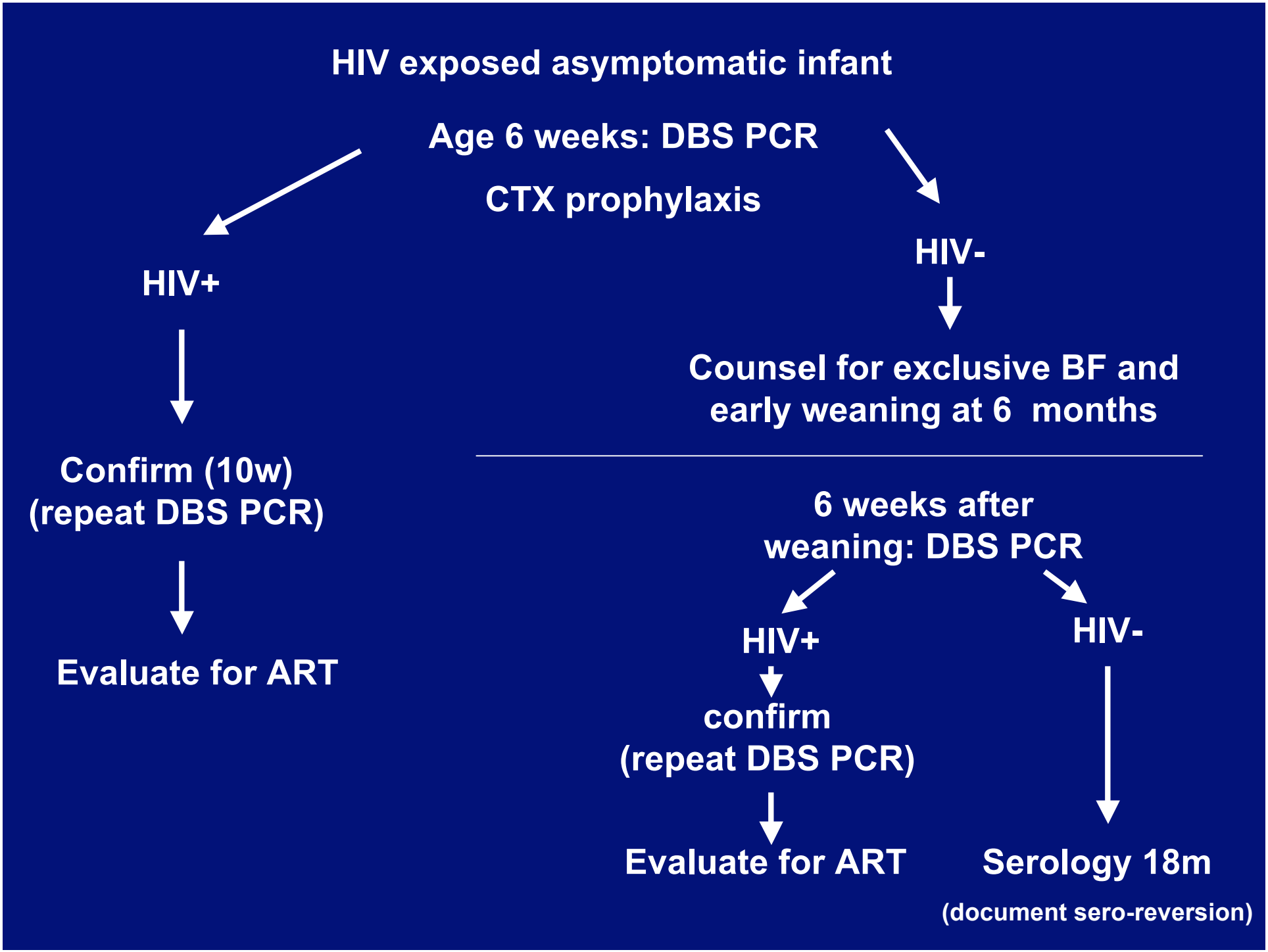
- Identify infants born to HIV+ mothers at possible entry points (e.g. routine vaccination, nutrition centers etc.)
- Offer HIV testing using DBS DNA PCR
- Start Cotrimoxazole prophylaxis
- Initiate ART if HIV-infected

Routine early infant testing

- Program coordinated by MoH Rwanda
- Started as “first phase” of national program at three health centers in the capital Kigali in October 2005
- Commitment to rapid scale-up and expansion
- Program is supported by Emergency Plan through various partners

Methods

- Mothers counseled to bring ANC card with coded HIV status to f/u visits
- ANC card stapled to vaccination card: HIV-exposure of child can be determined
- All children 6 weeks-18 months tested with DNA PCR and started on CTX
- DBS preparation through heel prick
- Specimens sent to lab on a weekly basis
- Test results collected at the lab weekly


HIV exposed asymptomatic infant
Age 6 weeks: DBS PCR
CTX prophylaxis
HIV+
Confirm (10w)
(repeat DBS PCR)
Evaluate for ART
HIV-
Counsel for exclusive BF and
early weaning at 6 months
6 weeks after
weaning: DBS PCR
HIV+
confirm
(repeat DBS PCR)
Evaluate for ART
HIV-
Serology 18m
(document sero-reversion)

Description of the clinics

Site	Gikondo	Masaka	Muhima
location	urban	rural	urban
level	health center	health center	hospital
# 1st ANC visits / month	~200	~110	~220
# women tested HIV+ / month	~20	~10	~25
# children HIV tested / month (age 15 months)	~5	~2	~2

Baseline characteristics

- Observation period Oct-Dec 2005
- 3549 children seen at follow-up visits
- Mother HIV-status known for 2423 children (68%)

- 177 children (7.3%) HIV-exposed:

– Sex male* (%)	73	(45.9%)
– Median age months (IQR**)	5.4	(2.8-10.3)
• <2 months	23	(13.0%)
• 2-18 months	154	(87.0%)

* N = 159

**IQR = interquartile range

Breastfeeding

- "Ever breastfed" (%) 155 (95.7%) n=162
- Currently breastfeeding 80 (50%) n=160
- Months breastfed 5.6 (3.8 – 6.4) n= 57
  median (IQR)
  (children who stopped BF)

Referral between PMTCT and ARV programs

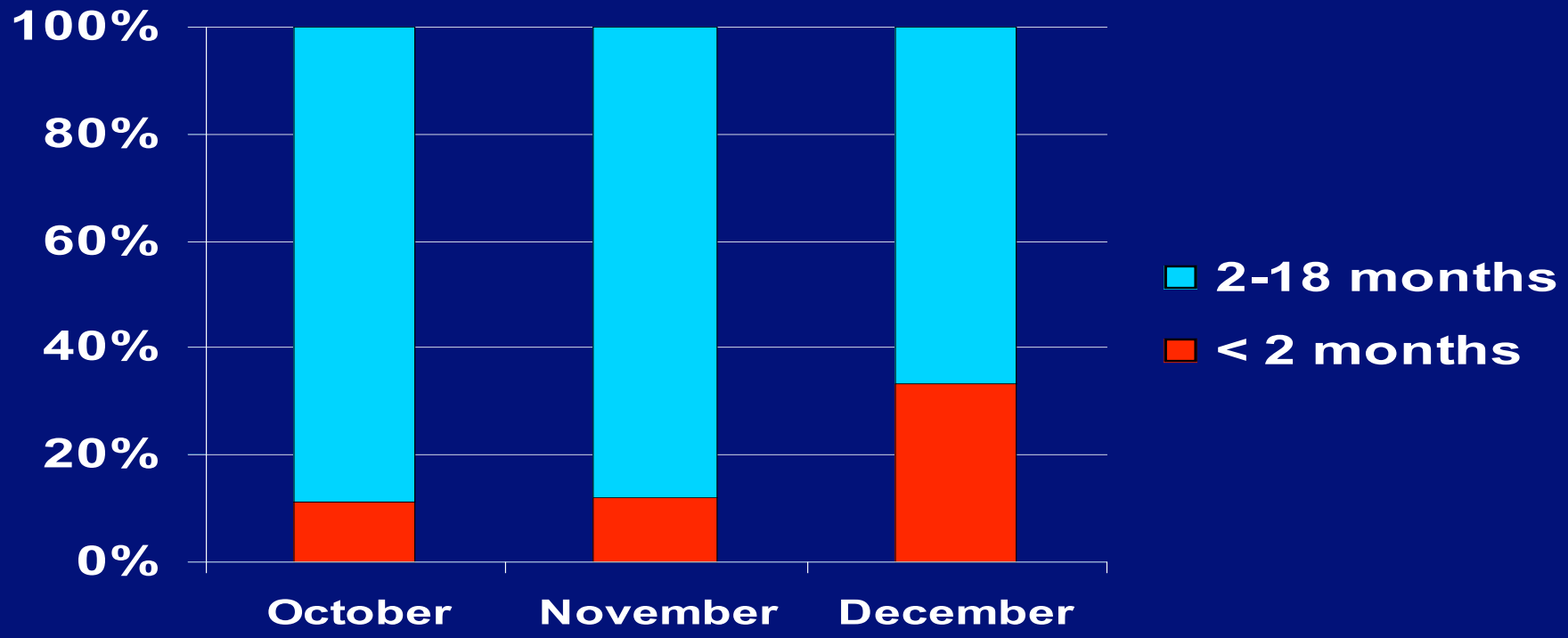
- 61% (96/157)
  of mothers were evaluated for eligibility of ART (CD4 count) during pregnancy

- 27% (23/85)
  were eligible for ART (CD4 cell count <350)

Results

- Main reasons for visit (children):
  - <2 months: f/u vaccination visit
  - 2-18 months: HIV test
- All 177 HIV-exposed children were started on CTX prophylaxis

Proportion of Children Tested for HIV by Age Group
Phase One of Routine Early Infant Testing
Rwanda, Oct - Dec 2005



n = 123

n = 41

n = 12
data incomplete

HIV test results
Rwanda Oct-Dec 2005

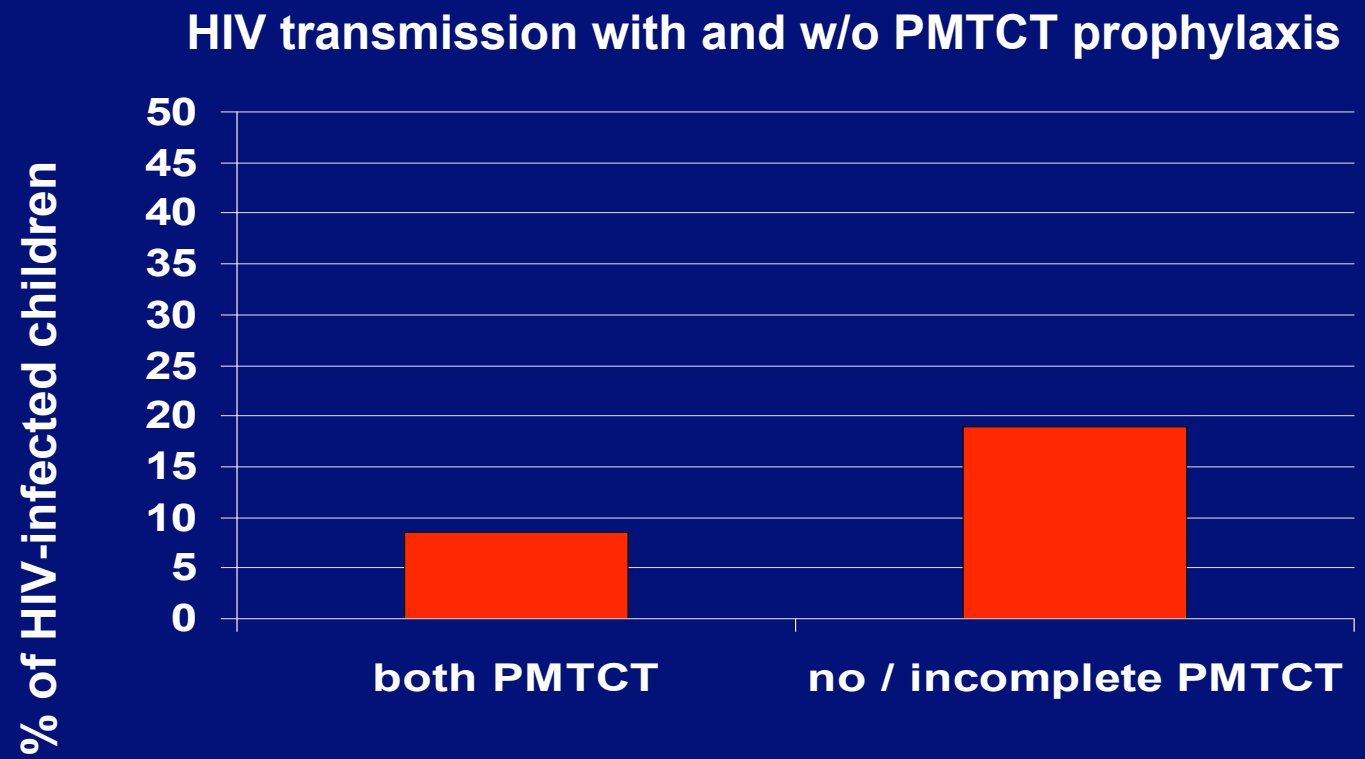
	<2 M	2-18 M	total
Positive	3 (16%)	17 (12%)	20 (12%)
Negative	16 (84%)	128 (88%)	144 (88%)
total	19	145	164

Test turn around time:

Between blood draw and test result back on site (days)

Median (range) **17 (9 – 54)**

Early infant testing as tool to evaluate effectiveness of PMTCT programs



n=106

n=58

*majority SD NVP

(OR 2.5; 95% CI = 0.9-7.2)

Limitations

- **Numbers small**
- **Sites not yet fully integrated the program**
- **Data collection not completely standardized**

Challenges

- **Confirmation of positive test result time-consuming (need extra visit)**
  - **Only 4/20 performed**
  - **At least 2 children died before confirmation of initial positive test result**
- **Quality assurance**
  - **3 initial positive PCR negative on confirmation**
  - **Lab re-tested all positives and 10% negatives, all tests confirmed on original sample**
  - **Mislabeling? Contamination? QA procedures?**

Challenges

- Database management critical
  - Lab and program databases not linked
  - Monitoring of HIV-infected children
  - Unique identifier – best strategy?
- Identification and follow-up of HIV-exposed children
- Procedure if maternal HIV status is unknown?

Next steps

- Evaluate and review protocol after 6 months / 500 children tested
  - Immediate clinical evaluation for ART if 1st PCR pos
    - Further diagnostic testing (incl. PCR confirmation)
    - No delay for initiating ART
  - Rapid test as screening if child >9 months
  - Integrate information on HIV exposure / HIV test results / feeding practice on vacc. card

Next steps

- Need for focal point for program coordination and supervision

- Develop plan for expansion
  - Sites in Kigali
  - Rural sites
  - PCR capacity in 2nd lab (decentralized)
    - Envisioned lab capacity 25,000 PCR / year

Thanks

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