Poster #789

Evaluation of the Cepheid HIV-1 Qual Point-of-Care Test for HIV Diagnosis at Birth

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BACKGROUND

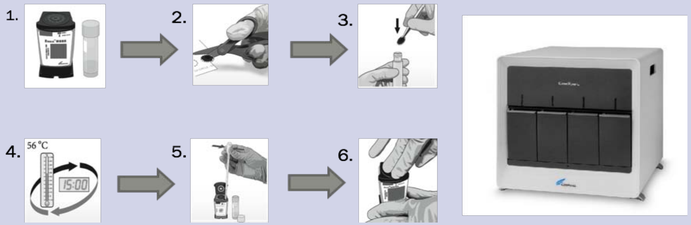
- Early infant HIV treatment reduces viral reservoir and improves long-term treatment outcomes, but early diagnosis remains a logistic challenge
- Use of HIV point-of-care (POC) tests may improve early infant diagnosis of HIV
- Accuracy of POC tests in first week of life and in setting of antiretroviral therapy (ART) is unknown

OBJECTIVE: Evaluate sensitivity and specificity of the Cepheid Xpert® HIV-1 Qual POC test as compared with the Roche Taqman HIV PCR platform to diagnose *in utero* infant HIV infection early in life

METHODS

- Infants < 96 hours of life were screened for HIV at 5 government hospital maternity wards and surrounding clinics in Botswana
- Infants received post-exposure ART with single-dose nevirapine and zidovudine, and most mothers received 3-drug ART in pregnancy and at delivery
- Dried blood spot samples initially run by PCR
- All PCR-positive screening samples and 75 HIV-exposed, PCR negative samples tested by Cepheid POC

Cepheid Workflow



RESULTS

Table 1: Maternal Characteristics by Transmitters/Non-Transmitters

	Transmitters (n=15)*	Non-Transmitters (n=75)‡
Median Maternal CD4 (range), cells/mm³∞	300 (79, 804)	N/A
Median Maternal VL (range), copies/mL∞	10,321 (67, 125093)	N/A
Maternal ART Regimen		
Atripla	9	37
Other	2	12
None	4	0

*Maternal CD4 and VL not available for 1 out of 15 transmitters
‡ART regimen available for 49 of 75 non-transmitters
∞CD4 and VL were not available for non-transmitters

Table 2: Infant Characteristics and Cepheid POC Result for HIV-Positive Infants

Baby	Child Baseline CD4	Child Baseline VL	AZT/NVP* at Birth?	Age at Screening (Hours)	Point-of-Care Result
A	5,159	1,661	Yes**	18.5	Negative
B	1,995	17,244	Yes	13.6	Positive
C	1,854	1,636	Yes	25.5	Positive
D	1,021	1,111,950	Yes	15.9	Positive
E	1,556	1,375	Yes	9.8	Positive
F	1,748	>10,000,000	Yes	6.6	Positive
G	1,634	<40	Yes	39.2	Positive
H	1,950	60,247	Yes	19.9	Positive
I	1,671	3,145	Yes	40.1	Positive
J	2,616	1,005	Yes	44.8	Positive
K	2,177	272	Yes	36.5	Positive
L	1,066	1,314	Yes	32.0	Positive
M	1,469	23,686	Yes	6.6	Positive
N	1,601	20,291	Yes	14.2	Positive
O	---	---	---	---	Positive
Median	**1,709.5**	**2,403**		**19.2**	

*single-dose NVP (10-15 mg po) and daily AZT (4mg/kg po twice daily)
**4 days after delivery

Table 3: Sensitivity and Specificity of Cepheid HIV-1 Qual POC

Xpert HIV-1 Qual	Roche CAP/CTM Positive (N=15)	Roche CAP/CTM Negative (N=75)
Positive	14	0
Negative	1	75
Totals	15	75

- **Sensitivity (14/15): 93.3% (95% CI: 68.1-99.8%)**
- **Specificity (75/75): 100% (95% CI: 96.1-100%)**

CONCLUSIONS

- Our study demonstrates high sensitivity and specificity for the Cepheid HIV-1 Qual POC assay within the first 96 hours of life in the setting of substantial maternal and infant antiretroviral exposure
- Cepheid POC testing platform screening may be a useful initial approach for early infant HIV diagnosis

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