Province of the
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STUDY
GROUP

SHORT-TERM MATERNAL AND FETAL OUTCOMES IN THE CONTEXT OF OPTION B+ STRATEGY IN SOUTH AFRICA: FINDINGS FROM PROSPECTIVE COHORT STUDY

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BACKGROUND

Efficacy of HAART IN PMTCT

- Mma Bana Study (Shapiro et al., 2010); AZT/3TC/ABC or Lop/rit vs AZT/3TC/NVP
  - Overall MTCT of 1.1% at six months
  - No difference in VL suppression
  - Treatment limiting adverse effect 2% vs 11%

- Kesho Bora Study (Kesho Bora Study Group, 2011); AZT/3TC/Lop/rit vs AZT+sNVP+Truvada
  - MTCT of 3.3% vs. 5% at six weeks
  - 5.4% vs 9.5% at six months
  - 5.6% vs. 10.7% at 12 months

- Promise Study (Fowler et al., 2015)
  - MTCT; AZT/3TC/Lop/rit = 0.5%
  - MTCT; TDF/FTC/Lop/rit = 0.6%
  - AZT+sNVP+Truvada = 1.8%

……Research Gap

- The field performance of the new PMTCT guideline at the health facilities level especially in the Eastern Cape Province has not received scholarly investigations.

- Findings may generate scientific evidence on MTCT, inform policy interventions and programmatic re-engineering in the Eastern Cape, South Africa

STUDY OBJECTIVES:

- To evaluate the effectiveness of WHO Option B+ on the peri-partum viral load.

- To assess the rate of in-utero MTCT of HIV infection within the cohort.

- To examine the associations of clinico-demographic factors on the peri-partum viral load and incident infant HIV infections.

.....Methodology

- Design: Retrospective cohort analysis (1st Phase of the ELPCS).
- Settings: Frere hospital, CMH and Bisho hospital, Eastern Cape
- Study population: Pregnant women on HAART and their infants.
- Sample size: A total of 1709 mother/infants were recruited serially across the study sites.
- Ethical approval was granted by WSU & ECDoH.
- CEOs gave permission. Written informed consent by participants.

- Confidentiality & privacy of participants information were respected in accordance with Helsinki Declaration.
- Trained research assistants used tablet computer to obtain relevant data on: demography, lifestyles, obstetric history, HIV history, HAART monitoring and opportunistic infections.
- Medical records were extracted for additional data.
- Results of investigations were extracted from NHLS and medical records.

Operational Definitions

- Peri-partum viral load: within the month of delivery (in accordance with the standard of practice at the study settings). Categorised as;
  - Suppressed <20 RNA copies/ml
  - Low viraemia <1000 RNA copies/ml
  - Probable virological failure ≥1000 RNA copies/ml
- Birth PCR: in accordance with NDoH PMTCT guideline 2015
- CD4 count: categories; Normal >500, mild immunosuppression =350-499, advanced immunosuppression =200-349 and severe immunosuppression <200 (WHO, 2006).
- Statistical analysis: simple descriptive statistics and bivariate analysis were conducted using SPSS version 21.0

Results

Table 1. Demographic characteristics of participants (N=1)

Variables	Frequency	n (%)
Age		
≤19	60	3.5
20-24	331	19.5
25-29	459	27.0
30-34	452	26.6
35-39	303	17.8
40-44	96	5.6
Marital Status		
Married	312	18.3
Single	1187	69.5
Cohabiting	186	10.9
Divorce/Separated	24	1.4
Area		
Rural	585	34.2
Semi urban	792	46.3
Urban	332	19.4
Education Level		
No formal Education	5	0.3
Grade 1-6	115	6.7
Grade 7-12	1479	86.5
Tertiary	110	6.4
Employment Status		
Unemployed	1277	74.7
Employed	432	25.3

Alcohol Use		
Drank during pregnancy	230	13.8
Quit drinking during pregnancy	431	25.2
Never drank	1043	61.0
Smoking status		
Smoke during pregnancy	92	5.9
Quit smoking during pregnancy	80	4.7
Never smoke	1529	89.5
Gestational age at booking		
First trimester	210	12.3
Second	1229	71.9
Third	270	15.8
Knowledge of HIV status prior to booking		
Positive	1356	80.1
Negative	87	6.7
Unknown	233	13.2
On HAART at booking		
No	390	28.1
Yes	998	71.9
Parity Deliveries		
1	521	30.5
≥2	1188	60.5

MAIN OUTCOME MEASURE

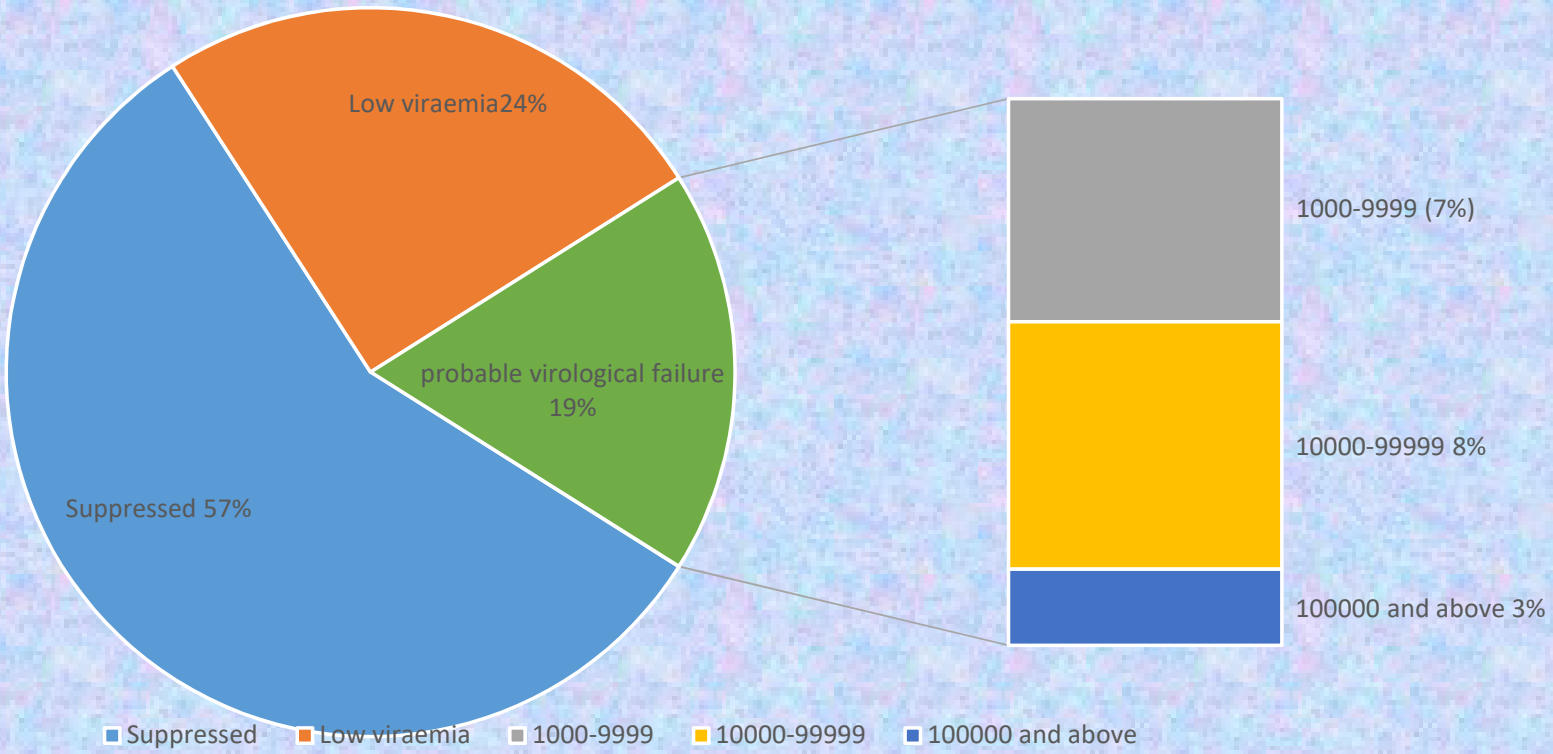

Fig 1. Rate of Peri-partum Viral Load Suppression

Table 2. Demographic Determinants of Peri-partum Viral Suppression (Bivariate analysis)

Variable	Suppressed	Low viraemia	Probable virological failure	p-value
Age				
≤19	**27(49.1)**	**14(25.5)**	**14(25.5)**	**0.006**
20-24	**131(46.8)**	**84(30.0)**	**65(23.2)**	
25-29	**223(56.9)**	**101(25.8)**	**68(17.3)**	
30-34	**224(58.5)**	**96(25.1)**	**63(16.4)**	
35-39	**175(66.0)**	**51(19.2)**	**39(14.7)**	
40-44	**50(58.8)**	**22(25.9)**	**13(15.3)**	
Marital status				
Married	**183(66.8)**	**58(21.2)**	**33(12.0)**	**0.004**
Single	**541(53.9)**	**267(26.6)**	**195(19.4)**	
Cohabiting	**98(60.1)**	**35(21.5)**	**30(18.4)**	
Divorce/separated	**10(43.5)**	**9(39.1)**	**4(17.4)**	
Residence				
Rural	**280(56.9)**	**110(22.4)**	**102(20.7)**	**0.219**
Semi urban	**387(56.9)**	**182(26.8)**	**111(16.3)**	
Urban	**165(56.7)**	**77(26.5)**	**49(16.8)**	
Education				
No formal education	**2(50.0)**	**1(25.0)**	**1(25.0)**	**0.116**
Grade 1-6	**55(66.3)**	**12(14.5)**	**16(19.3)**	
Grade 7-12	**712(55.8)**	**329(25.8)**	**235(18.4)**	
Tertiary	**63(63.0)**	**27(27.0)**	**10(10.0)**	
Employment status				
Unemployed	**592(54.6)**	**277(25.5)**	**216(19.9)**	**0.001**
Employed	**240(63.5)**	**92(24.3)**	**46(12.2)**	

Table 3. Clinical Determinants of Peri-partum Viral Suppression (Bivariate analysis)

Variables	Suppressed	Low viraemia	Probable Virological Failure	p-value
Defaulted ARV				
Yes	**51(33.1)**	**39(25.3)**	**64(41.6)**	**0.00**
No	**731(59.3)**	**318(25.8)**	**183(14.9)**	
Self reporting of adherence				
Yes	**656(60.1)**	**277(25.4)**	**158(14.5)**	**0.00**
No	**154(47.2)**	**82(25.2)**	**90(27.6)**	
Regular pick up of ARV				
Yes	**667(59.3)**	**290(25.8)**	**167(14.9)**	**0.00**
No	**131(50.0)**	**59(22.5)**	**72(27.5)**	
Viral load at booking				
Suppressed	**506(93.7)**	**24(4.4)**	**10(1.9)**	**0.00**
Low viraemia	**58(26.7)**	**140(64.5)**	**19(8.8)**	
Probable virological failure	**38(18.4)**	**48(23.2)**	**121(58.5)**	
Disclosure				
Yes	**641(58.9)**	**271(24.9)**	**177(16.3)**	**0.01**
No	**186(51.0)**	**97(26.6)**	**82(22.5)**	
On HAART at booking				
Yes	**519(61.1)**	**183(21.5)**	**148(17.4)**	**0.007**
No	**179(52.2)**	**101(29.4)**	**63(18.4)**	
Gestational age at booking				
First trimester	**87(49.4)**	**43(24.4)**	**46(26.1)**	**0.01**
Second trimester	**627(59.1)**	**261(24.6)**	**173(16.3)**	
Third trimester	**118(52.2)**	**65(28.8)**	**43(19.0)**	

SECONDARY OUTCOME MEASURE

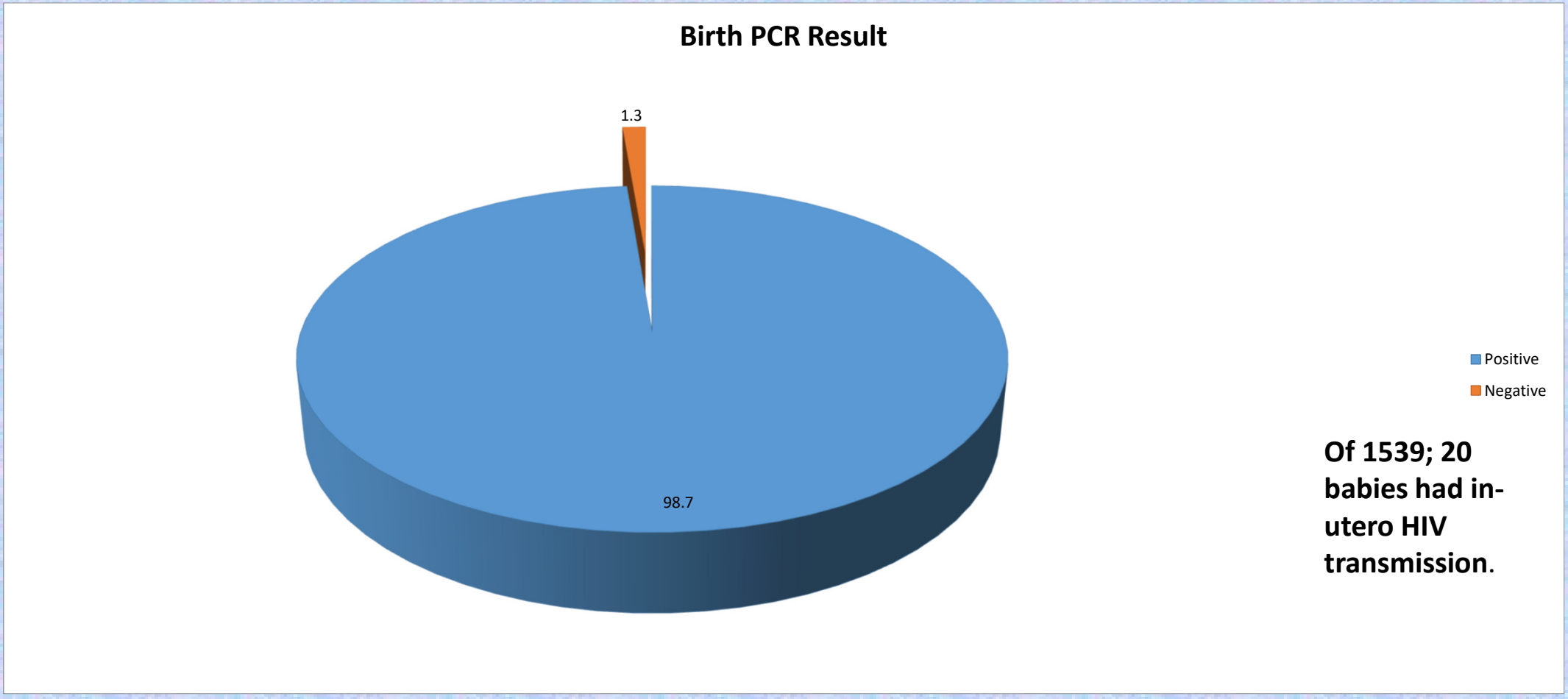

Fig 2. Positive Birth PCR (Intra-uterine mother-to-child transmission)

Table 4. Determinants of MTCT (Bivariate analysis)

Variable	Negative	Positive	p-value
Employment status			
Unemployed	**1139(98.7)**	**15(1.3)**	**0.58**
Employed	**400(98.8)**	**5(1.2)**	
Marital status			
Married	**291(99.0)**	**3(1.0)**	**0.68**
Single	**1053(98.5)**	**16(1.5)**	
Cohabiting	**172(99.4)**	**1(0.6)**	
Divorce/separated	**23(100.0)**	**0(0.0)**	
Mode of delivery			
Caesarean section	**705(99.0)**	**7(1.0)**	**0.216**
Vaginal	**815(98.4)**	**13(1.6)**	
Defaulted ARV			
Yes	**176(96.2)**	**7(3.8)**	**0.004**
No	**1278(99.1)**	**11(0.9)**	
Self reporting of adherence			
Yes	**1156(99.1)**	**11(0.9)**	**0.041**
No	**326(97.6)**	**8(2.4)**	

On time pick up of ARV			
Yes	**1194(99.0)**	**12(1.0)**	**0.086**
No	**257(97.7)**	**6(2.3)**	
On HAART			
Yes	**912(98.7)**	**12(1.3)**	**0.392**
No	**338(99.1)**	**3(0.9)**	
HIV Status at booking			
Positive	**1244(98.2)**	**16(1.3)**	**0.723**
Negative	**76(97.4)**	**2(2.6)**	
Unknown	**219(98.1)**	**2(0.9)**	
Peri-partum Viral Load			
Suppressed	**786(99.5)**	**4(0.5)**	**0.00**
Low viraemia	**347(99.4)**	**2(0.6)**	
Probable virological failure	**234(96.7)**	**8(3.3)**	

DISCUSSION

- Significant finding of 0.4% risk of MTCT if peri-partum viral suppression is achieved; corroborates findings of PROMISE STUDY (MTCT of 0.56%) (Fowler et al., 2015).

- Peri-partum virological failure were predicted by markers of poor adherence; prior default, self-report of non-adherence, irregular pick up of medications, and being single and unemployed.

- WHO early warning indicators (2010) focused on these parameters for HAART outcome monitoring.

- Sero-conversion rate during pregnancy of 6.7%; higher than national rate of 3.3% (Dinh et al., 2015).

Limitations

- Self-reporting of adherence/nonadherence
- Few study sites

Strength of the study

- Large sample size
- All exposed infants were screened
- HIV-infected infants were linked to care for HAART initiation; women with probable failure were managed according to guideline

CONCLUSIONS

- Findings support the goal of elimination; however, peripartum viral load suppression might be the key to achieving this.
- Significant progress on the implementation of WHO Option B+ strategy in BCM/Amathole districts.
- Clinicians need to monitor viral load aggressively during pregnancy and post-delivery to achieve the goal of suppression and PMTCT.
- To what extent does the single dose Nevirapine at birth confer resistance mutations in HIV infected infants and the degree of effectiveness of prophylaxis in exposed-infants?

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Cecilia Makiwane Hospital Management

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