EVALUATION OF THE EFFECTIVENESS OF THE NATIONAL PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT) PROGRAMME ON INFANT HIV MEASURED AT SIX WEEKS POSTPARTUM IN SOUTH AFRICA



Medical Research Council, South Africa
School of Public Health, University of the Western Cape,
National Department of Health, South Africa
Centers for Disease Control and Prevention/PEPFAR
National Institute for Communicable Diseases/National Health Laboratory Service
Wits Paediatrics HIV Diagnostics
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UNICEF





















Report Prepared by:

Principal Investigators

Ameena Goga Thu-Ha Dinh Debra Jackson

SAPMTCTE Study Group

Yogan Pillay
Gayle Sherman
Adrian Puren
Nonhlanhla Dlamini
Thabang Mosala
Siobhan Crowley

Carl Lombard
Selamawit Woldesenbet
Vundli Ramokolo
Wesley Solomon
Wondwossen Lerebo
Tanya Doherty

Thurma Goldman
Jeffrey Klausner
Katherine Robinson

Nathan Shaffer Mickey Chopra Copyright

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PRIMARY CONTACTS/PRINCIPAL INVESTIGATORS

Ameena Goga, MD

Paediatric Epidemiologist Medical Research Council, SA

Address: 1 Soutpansberg Road, Pretoria, 0001, Phone: +2782 302 3168

e-mail:

Ameena.Goga@mrc.ac.za

Thu-Ha Dinh, MD, MS

Medical Epidemiologist Centers for Disease Control and Prevention

Address: 1600 Clifton Rd

Atlanta, 30333

Phone: +1 404 639 8618

+2712 424 9000

e-mail: dvt1@cdc.gov; dinht@sa.cdc.gov

Debra Jackson, RN MPH DSc

Professor (Extraordinary)
School of Public Health
Univ. of the Western Cape
Address: PBX17 Modderdam

Road, Bellville 7535 *Phone:* +2783 327 7331

e-mail:

debrajackson@mweb.co.za

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ABBREVIATIONS AND ACRONYMS

AIDS Acquired Immunodeficiency Syndrome

ANC Antenatal Care

ART Antiretroviral therapy
ARV Antiretroviral (drug)

BCC Behaviour Change Communication

CDC Centers for Disease Control and Prevention

CHAI Clinton Health Access Initiative

DBS Dried Blood Spot

DHIS District Health Information System

DHS Demographic and Health Survey

DNA PCR DNA-based Polymerase Chain Reaction Test

EBF Exclusive Breast-Feeding
EID Early Infant Diagnosis

ELISA Enzyme-linked Immunosorbent Assay
HAART Highly Active Antiretroviral Therapy
HIV Human Immunodeficiency Virus

HIER Health Information, Evaluation & Research

HSRC Human Sciences Research Council

HSRU Health Systems Research Unit of the Medical Research Council

IMCI Integrated Management of Childhood Illnesses

LPT Late Post-partum Transmission
M&E Monitoring and Evaluation

MCWH Maternal Child & Women's Health

MCH Maternal and Child Health

MDG Millennium Development Goals

MPH Masters in Public Health
MRC Medical Research Council

MTCT Mother-to-child transmission (of HIV)

NDOH National Department of Health
NHLS National Health Laboratory Service

NICD National Institute for Communicable Diseases

NRF National Research Foundation

NSP National Strategic Plan, South Africa, 2007-2011
PEPFAR President's Emergency Plan For AIDS Relief
PITC Provider-Initiated Testing and Counseling

PSU Primary Sampling Unit

PMTCT Prevention mother-to-child transmission of HIV

RtHC Road to Health Chart

SAPMTCTE South African Prevention of Mother-to-Child Transmission Evaluation

Sd-NVP Single-dose Nevirapine

SoPH School of Public Health, University of the Western Cape

UNICEF United Nations Children's Fund

UNGASS United Nations General Assembly, Special Session

UWC University of the Western Cape

WHO World Health Organisation

EXECUTIVE SUMMARY

Introduction

Within ten years of implementing the national Prevention of Mother-to-Child Transmission of HIV (PMTCT) programme in South Africa interventions to prevent mother-to-child transmission (MTCT) of HIV are now offered in more than 95% of public antenatal and maternity facilities country-wide. However, this is the first national evaluation to determine the effectiveness of the National PMTCT programme. The 2010 South African PMTCT Evaluation (SAPMTCTE) will serve as a baseline to monitor the effectiveness of the antenatal and intrapartum aspects of the national PMTCT programme (i.e., early MTCT rates). The survey will be repeated in 2011 and 2012 (during which postnatal transmission at 6, 9, 12 and 18 months will also be measured) to track progress with reduction in MTCT rates during pregnancy, labour and delivery, and postpartum. This will provide a field-based, systematic approach to estimating the overall population-based transmission rate and the number of new paediatric infections at 4-8 weeks of infant age.

Aims and Objectives

The overall aim of this evaluation was to conduct a national facility-based survey to monitor the effectiveness of the South African National PMTCT programme. The primary objective was to measure rates of early MTCT of HIV at six weeks postpartum. The secondary objective was to periodically estimate coverage of key PMTCT interventions and services (e.g., HIV testing, CD4 cell count testing, infant antiretroviral (ARV) prophylaxis, infant feeding counselling).

Methods

A cross-sectional facility-based survey was conducted at immunisation service points at public primary health care/community health centres (PHC/CHC) in all nine provinces. This methodology was chosen as immunisation uptake at 6 weeks is >99% in South Africa. The survey aimed to capture known and unknown HIV-exposed infants, as well as PMTCT participants and non-participants. A biomedical marker (HIV enzyme-linked Immunosorbent Assay (ELISA) tests to identify HIV antibody) was used to identify HIV-exposed infants from infant dried blood spot (DBS) specimens. All DBS specimens reactive on ELISA testing were sent for DNA-based polymerase chain reaction tests (DNA PCR) to determine infant HIV infection status.

Infants aged 4-8 weeks attending PHC/CHC facilities for their six week immunisation were included. Hospitals and mobile clinics, very sick infants or infants aged <4 weeks or >8 weeks were excluded. The immunisation data from the 2007 District Health Information System (DHIS) were used to quantify the number of children that could be expected within facilities over a period of time and then stratify by size. Sample size was calculated so that valid national and provincial level estimates of MTCT could be ascertained. This resulted in between 34-79 facilities per province, 580 in total. Facilities were randomly selected within strata with probability proportional to size (3 strata). Caregiver/infant pairs were consecutively or randomly selected from facilities (depending on facility

size). Interviews were conducted and infant DBS drawn after receiving consent from caregivers for study participation. Mothers and infants were referred into HIV care, as appropriate. Data were collected using low cost cell phones and interview data were uploaded real time into a web-based database console. Analysis was weighted for sample realisation and at provincial level proportional to the live birth distribution of South Africa.

Results

A total of 10 820 eligible infants were identified from 572 facilities. Of these, 10 735 interviews were conducted and 10 178 (94%) DBS were drawn and analysed.

- The national weighted infant HIV-exposure prevalence was 32.0% (95% CI 30.7-33.3%).
- The national weighted MTCT rate measured at 4-8 weeks of infant age was 3.5% (95% CI 2.9-4.1%).
- The MTCT rate across provinces ranged from 1.4% to 5.9%.
- Among mothers who reported being HIV negative, 4.1% had HIV-exposed infants.
- Of all women participating 98.8 (95% CI 98.5-99.0%) received an HIV test during pregnancy and of these 98.6 (95% CI 98.4-98.9) got their HIV test results.
- Of the reported HIV-positive mothers 78.3% had a CD4 cell count done during pregnancy and 91.8% received either maternal highly active antiretroviral therapy (HAART) or mother/baby antiretroviral (ARV) prophylaxis.
- Only 35.1% intended to access early infant diagnosis services and 89% had received infant feeding counselling.
- Among HIV-positive women, 20% were exclusively breastfeeding, 62% formula feeding and 18% mixed feeding in the 8 days prior to the interview.

Conclusions and Recommendations

- 1. The national PMTCT survey found a 3.5% national MTCT rate in pregnancy and intrapartum with a greater than 4-fold differential range of rates across the nine provinces (1.4% to 5.9%).
- 2. Maternal HIV acquisition since the last HIV test was potentially high at 4.1% and therefore repeat HIV testing at 32 weeks pregnancy and couple testing is critical. Further data should collected to assess the contribution of false negative rapid test results to maternal potential HIV acquisition. In addition, more work is required to improve the quality of rapid HIV testing in the field.
- 3. Uptake of PMTCT services is high, with more than 98% of women getting HIV tested during pregnancy and 91.7% of HIV-positive mothers receiving ARV treatment or prophylaxis. However CD4 (78.3%) testing and early infant diagnosis (EID) (35.1%) uptake are lower and represent on-going missed opportunities in the PMTCT programme.
- 4. Early infant HIV testing uptake is high if offered to all infants (94%) at six-week immunisation visits, indicating that EID strategies that routinely offer infant HIV testing only to known HIV-exposed infants should be reviewed.

- 5. Given the measured MTCT rate in the early implementation phase of the revised 2010 South African PMTCT guidelines, virtual elimination of paediatric HIV infection is possible with intensified effort. However, postnatal transmission after 6 weeks also needs to be examined to assess achievement of <5% MTCT at 18 months of infant age.
- 6. Only 20% of HIV-positive women were exclusively breastfeeding, 62% were formula feeding and 18% were practicing high-risk mixed feeding, suggesting a need for increased attention to infant feeding.



FOREWORD BY THE MINISTER OF HEALTH

It gives me great pleasure to write this foreword to the Report of the First National Evaluation of the South African Prevention of HIV from Mother To Child Programme (PMTCT). South Africa is committed to improving child survival and reducing infant and under-five mortality. Integral to this is eliminating new adult HIV infections, reducing unwanted and unplanned pregnancies in HIV positive women; preventing HIV transmission from mother to child and providing care, treatment and support for HIV infected women and their infants. The 2010 DOH guidelines address the issue of care, treatment and support for HIV infected women and their infants. Preventing mother-to-child transmission of HIV is a critical intervention to eliminate paediatric HIV infections. South Africa started implementing a programme to prevent mother-to-child transmission of HIV in 2002, and this programme has expanded and improved in quality (e.g. improved coverage and more effective PMTCT regimens) over the past ten years.

The South African PMTCT Evaluation is the first national evaluation of mother-to-child transmission of HIV since its inception. Prior to this survey national data on MTCT rates was only available from the PCR tests done by the National Health Laboratory Services and data obtained from studies in selected geographic areas. This survey shows that South Africa has managed to reduce MTCT from between 20 and 30% (in the absence of any PMTCT intervention) to 3.5% by 8 weeks post-delivery. This represents a reduction in MTCT from 70,000 to less than 10,000 babies born HIV positive, per year, over the past ten years.

This success should be noted with pride, and all health care personnel who have worked tirelessly to implement the national PMTCT programme should be congratulated on this success.

However gaps still exist: (i) there is a greater than 4-fold difference in HIV transmission—rates between provinces; this relates to the difference in effective coverage of the PMTCT programme; (ii) 4.1% of women who reported being HIV-negative had infants who were HIV-exposed, indicating that use of condoms during pregnancy, repeat testing at 32 weeks pregnancy and couple testing is critical; (iii) only 20% of HIV positive women were exclusively breastfeeding, 62% were formula feeding and 18% were practicing mixed feeding suggesting a need for increased attention on infant feeding; (iv) the MTCT rate between six weeks and 18 months is unknown and therefore the overall transmission rate is still unknown and needs to be investigated.

The Department of Health will work with the Medical Research Council and partners to repeat this survey and include a follow-up component up to 18 months in 2012, and I look forward to these results. It is only with intensified effort that MTCT rates by eight weeks and beyond can be reduced and I ask all health care personnel to work collaboratively so that paediatric HIV infection can be even further reduced and we can achieve our targets of elimination of new paediatric infections in South Africa by 2015.

Maron Motsoaledi, MP

Minister of Health

DEFINITIONS

Caregiver	The person who feeds and looks after the child most of the week. This includes parents, legal guardians, family members, nannies or friends who routinely feed, bath, change nappies, or in particular reference to this study, bring the child for routine health services.
The Consortium	Health Systems Research Unit (HSRU) of the Medical Research Council (MRC) and School of Public Health of the University of the Western Cape (SoPH, UWC).
Early (4-8 weeks) HIV transmission rate among HIV-exposed infants	Number of DNA PCR positive infants and ELISA positive infants divided by the number of ELISA positive infants at 4-8 weeks.
Health care personnel	Health care providers and health care workers.
Health care provider	Any person providing health services in terms of any law, including in terms of the: • Allied Health Professions Act, 1982 (Act No.63 of 1982),
	 Health Professions Act, 1974 (Act No. 56 of 1974), Nursing Act, 2005 (Act No. 33 of 2005),
	 Pharmacy Act, 1974 (Act No. 53 of 1974), and Dental Technicians Act, 1978 (Act No. 19 of 1979).
Health care worker	Any person who is involved in the provision of health services to a user, but is not a health care provider. This includes lay counselors and community caregivers.
HIV-exposed infant	An infant born to a known HIV-positive mother and/or having a positive HIV antibody test result using DBS ELISA. Infant HIV exposure prevalence serves as an indirect marker of maternal HIV prevalence.
HIV-infected infant	An HIV-exposed infant having a positive HIV DNA PCR result.
HIV-uninfected infant	An HIV-exposed infant having a negative HIV DNA PCR result. (Note: In many cases, there is on-going risk of postnatal transmission through breastfeeding, so an early DNA PCR result indicates infection status at the time of the test, but not the final infection status).
HIV-positive mother	Defined for this survey as mothers whose infants have a positive DBS ELISA.
HIV status unknown	Refers to people (including children) who have not taken an HIV test or who do not know the result of their test.
Infant	A child from birth to 12 months of age.
Infant HIV infection prevalence	Proportion of confirmed HIV-positive (infected) infants among all infants tested during the study period, measured as number of positive DNA PCR

Maternal HIV prevalence	infant DBS divided by the total number of ELISA samples tested. In this study infant HIV infection prevalence at 6 weeks will be measured in infants age 4 to 8 weeks, who are attending routine immunisation clinic. It will be measured as a point prevalence with the numerator defined as those infants with a positive HIV DNA PCR test and the denominator of all infants tested using HIV ELISA on dried blood spots in the study. Number of positive (infant) DBS ELISA divided by total number of ELISA samples tested.
Maternal HIV Incidence/Maternal potential HIV acquisition during pregnancy	The number of positive infant DBS ELISA among mothers reporting an HIV-negative status during the interview divided by total number of mothers reporting an HIV-negative status during the interview. This indicator is likely a combination of the following scenarios: (i) mothers who do not wish to admit positive status and report being HIV negative; (ii) mothers who were tested during the window period; (iii) poor quality control or performance of rapid tests in the field causing false negative results at antenatal care (ANC) on HIV-infected women. Reported field sensitivities are as low as 87% to 95% depending on the rapid test used; and (iv) true acquisition of HIV after the last HIV test.
Mother-to-child transmission (MTCT)	Transmission of HIV from an HIV-positive woman to her infant during pregnancy, delivery or breastfeeding. The term is used because the immediate source of the infection is the mother, and does not imply blame on the mother.
MTCT rate	Defined for this survey as a numerator of HIV-positive infants (PCR positive) and denominator of HIV-exposed infants (infant ELISA antibody positive).
Routine offer of counselling and testing	HIV testing that is routinely offered to all ANC clients. Health care personnel provide group information first, followed by individually offering HIV tests. The patient/client has the option to decline testing at any stage of this process. The patient/client receives post-refusal counselling or post-test counselling as appropriate.
Transmission in PMTCT programme	Number of positive DNA PCR and positive ELISA divided by the number of ELISA positive mothers who recall taking ARV prophylaxis or HAART during pregnancy/delivery.
Transmission in those not participating in PMTCT Programme (missed opportunities)	Number of positive DNA PCR and positive ELISA divided by number of mothers who do not recall taking ARV prophylaxis or HAART during pregnancy/delivery.

1. INTRODUCTION

Internationally and nationally PMTCT has been recognised as an essential intervention to reduce HIV incidence in the population and to virtually eliminate new HIV infections in children. In 2010 the WHO Global Elimination of MTCT Initiative (WHO/UNICEF/UNFPA/UNAIDS, 2011) aims, *inter alia*, to reduce new paediatric HIV infections by 90% from the 2009 estimated baseline and reduce the overall, population-based HIV transmission rate (through MTCT) to <5% (<2% in the absence of breastfeeding or as measured at 6 weeks). The South African National Strategic Plan on HIV and AIDS and STIs, 2007-2012 (NSP) (NDOH, 2007) prioritises scaling up coverage of PMTCT to reduce MTCT to less than 5% by 2011.

In 2001 South Africa started implementing a programme to prevent HIV transmission from mother-to-child at 18-pilot sites. The first interventions included single-dose nevirapine (Sd NVP) during labour for the mother and to the baby within 72 hours of delivery; modified obstetric practices; infant feeding counselling and the provision of free commercial infant formula to HIV-positive mothers who avoided breastfeeding (NDOH, 2001). PMTCT interventions were scaled up in 2002 and in 2008 the national antiretroviral regimens for pregnant women were improved to dual therapy (AZT from 28 weeks with Sd-NVP at the outset of labour for pregnant women and Sd-NVP with AZT for baby).

In 2010, PMTCT interventions were further modified as shown in Table 1 (NDOH/SANAC, 2010). The 2010 modifications included routine HIV testing and counselling for pregnant women, dual therapy to prevent MTCT of HIV, HAART for pregnant women with CD4 cell count \leq 350 cells/µl, postnatal infant prophylaxis for breastfeeding HIV-positive women and intensified efforts to integrate PMTCT services into routine maternal and child health (MCH) services. These efforts are to meet the NSP targets of reducing the MTCT rate of HIV to less than 5% by 2011 and to meet the 4th and 6th Millennium Development Goals (MDGs) (i.e., 'reduce by two thirds, between 1990 and 2015, the under-five mortality rate' and 'have halted by 2015 and begun to reverse the spread of HIV/AIDS') (UN, 2011).

Table 1 2010 South African national PMTCT regimens

HIV-infected pregnant women							
Mother	Start all HIV-positive pregnant women on AZT at 14 weeks						
Pregnancy	CD4 cell count≤350 or WHO clinical stage						
	3 or 4: HAART	1 or 2					
	Note: WHO stages are defined at the end						
	of this section, for your information						
	Start AZT. Same day referral to ARV clinic Continue AZT 300 mg 12 hourly						
	for HAART. Stop AZT once HAART						
	initiated						
Labour and	Continue HAART as usual during labour	Single dose nevirapine (200mg) at					
delivery		onset of labour + AZT 300mg 12					
		hourly until the neonate is delivered					
Postnatally	Continue HAART as usual	TDF + FTC (Truvada) single dose					
		(stat) after delivery					

HIV-exposed infants						
Mother breastfeeds	Mother meets specified criteria and does not					
(and not on HAART)	breastfeed					
Daily infant nevirapine throughout the	Daily infant nevirapine for 6 weeks only					
breastfeeding period until 1 week after						
breastfeeding stops						

Within ten years of implementing the national PMTCT program in South Africa, PMTCT interventions are now offered in more than 95% of antenatal and maternity facilities country-wide. Small scale evaluations of MTCT rates have been conducted since 2001 (Table 2) providing results of PMTCT effectiveness at selected sites.

The National Health Laboratory Service (NHLS) report on PCR positivity at all sites offering PCR testing for infants. In addition, routine DHIS data provide information on the PMTCT programme but lack fixed denominators to calculate transmission, and thus PMTCT effectiveness, reliably. Consequently, there is not been a national evaluation to determine the effectiveness of the National PMTCT programme prior to the 2010 SAPMTCTE.

Table 2 Studies conducted on PMTCT effectiveness, SA, 2001-2009

	<2007	2008	2009
Sherman (2009) Rahima Moosa Hospital record review. (2001-2002) Sd NVP	8.0% 6 weeks		
Sherman (2004) Coronation Hospital record review (2001-2002) Sd NVP	8.7% 6 weeks		

	<2007	2008	2009
Coetzee (2006) Khayelitsha AZT from 34 wks (March-November 2003)	8.8% 6-10 wks		
Colvin (2007) Good Start study: 3 sites (P, R, U). Prospective cohort study (Oct 2002-Nov 2004)	P: 8.6% (4.5–14.5) R: 13.7% (8.9–19.8) U: 11.9% (8.3–16.3)		
Rollins (2007& 2009) KZN MTCT 7 clinics Aug 04–July '05 3 PHC facilities Nov '07- Feb '08,	20.2% 4-8 weeks	21.9% 4-8 weeks	
Sherman (2010) National MTCT NHLS data ≤ 2months		8.2%	5.8%

The 2010 SAPMTCTE will serve as baseline, and progress will be monitored over two subsequent years during which postnatal transmission will also be measured and field estimates of overall population-based transmission and new paediatric HIV infections will be calculated.

The 2010 SAPMTCTE aimed to conduct a facility-based survey to monitor the effectiveness of the South African National PMTCT programme. The primary objective of the 2010 SAPMTCTE was to measure rates of early MTCT of HIV at 4-8 weeks postpartum. The secondary objective was to periodically estimate coverage of key PMTCT interventions and services (e.g., HIV testing, CD4 cell count testing, infant ARV prophylaxis, infant feeding counselling).

2. METHODOLOGY

2.1 Survey Design and Justification

A cross-sectional facility-based survey, using a biomedical marker to determine MTCT rate, was conducted. The survey was conducted among caregiver-infant pairs who presented at their local primary health care facility for their infant's six-week immunisation (1st DTP dose) visit. South Africa reports >95% coverage of six week immunisation (1st DTP dose) (WHO, 2011), making these clinics an ideal catchment point for young infants -- of known or unknown HIV exposure status. This provided a convenient sample to determine overall PMTCT effectiveness with relatively limited selection bias.

This methodology has been proven effective in a South African context. Based on the approach recommended by Rollins et al. (2007 & 2009) we used a biomedical marker to identify infants exposed to HIV. Chantry et al. (1995) found that sero-reversion for ELISA in HIV-exposed infants was not seen prior to 17 weeks of age suggesting that most, if not all, infants aged 4-8 weeks will still have maternal antibodies in their bloodstream. This means that screening infants for the presence of HIV antibody would be a direct measure of infant HIV exposure and an indirect measure of maternal HIV infection prevalence.

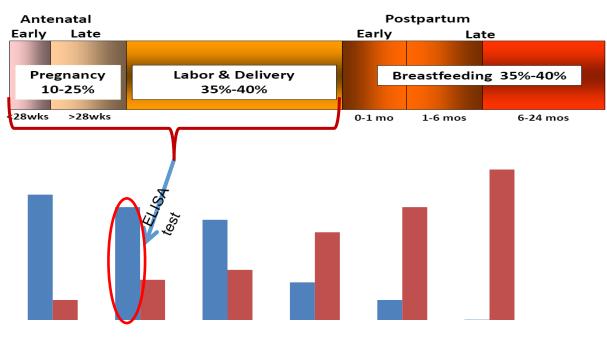


Figure 1 Using ELISA at biomedical marker to identify HIV-exposed infants

■ Mom's HIV antibody

This evaluation thus aimed to provide:

- 1) A valid estimate of MTCT and HIV infection prevalence in children aged 4-8 weeks, and
- 2) A reasonable estimate of coverage of key PMTCT programme indicators through 6 weeks postpartum.

2.2 Study Population and Inclusion/Exclusion Criteria

The study population comprised infants aged 4-8 weeks and their caregivers visiting public health facilities for the infant's 1st DTP dose between June-December 2010.

Inclusion Criteria

Study participants included 4-8 week old infants attending clinic for 1st DTP immunisation. Caregivers had to consent to participation (consent for maternal or caregiver interview and/or infant DBS).

Exclusion Criteria

Severely ill infants needing emergency medical care or urgent referral to the next level of care (e.g., infants who are vomiting everything or have convulsions; are lethargic or unconscious; or have severe pneumonia or severe dehydration) were excluded from the study.

2.3 Sampling

Sampling Frame

The public health facilities were stratified as: < 130, 130-300 and >300 immunisations per year, and data were extracted from the 2007 South African DHIS (Personal Communication C Hedberg, 2009). A strategic decision was made to exclude the small facilities (<130 immunisations per year) from the formal sampling frame. The 2008 national antenatal maternal HIV prevalence estimate of 29% (NDOH, 2009) was used as the cut-off point for classifying facilities as above or below national average for antenatal HIV prevalence. This stratification was only applied to facilities in the large stratum (>300 immunisations per year). A total of 23 strata across province, facility size and maternal HIV prevalence were utilised in the survey sampling frame and were sorted by province, size and maternal HIV prevalence.

Sample Size

ANC maternal HIV prevalence (NDOH, 2009) and estimated MTCT rates from a KwaZulu-Natal survey using similar methodology (Personal communication N. Rollins, unpublished data, 2009) were used to determine the sample size for each province. Specifying relative precisions of 30% to 50% for the expected MTCT rate across provinces plus a design effect of 2 indicated that a total sample size of 12 200 infant DBS specimens were needed. The sample size across provinces ranged from 1 800 (Gauteng) to 700 (Northern Cape).

Sampling

Stratified two-stage sampling was used. In the first stage, facilities (Primary sampling units - PSUs) were randomly sampled proportional to size (PPS) within each stratum. The method operated under the without-replacement-type selection (Lehtonen & Pakhinen, 1994). At the second stage a fixed number of infants per a facility was sampled. The fixed number was the median number of infants expected within the sampling window (three weeks) across the population of facilities within the stratum as determined from the detailed information of the sampling frame above. The fixed number of infants sampled in each facility within a stratum ensured a self-weighting sample. A sampling window of 3 weeks was used to realize the required sample. (Appendix#1)

2.4 Data Collection Tools

Data were gathered using a questionnaire adapted from several validated tools (Rollins et.al., 2007 & 2009; HSRC, undated; Nyblade & MacQuarrie, 2006; Tlebere et.al., 2007; Jackson et al. 2007). The questionnaire included information on maternal age, parity, socio-economic status, antenatal care, HIV testing, maternal HIV status, PMTCT care during pregnancy and delivery, infant feeding counselling, birth information, infant feeding practices, infant weight; immunisations, postnatal visits and illness since birth. Fathers/legal guardians/non-maternal caregivers were administered a shorter form of the questionnaire that excluded ANC and PMTCT information.

The study tool was piloted in the Western Cape and KwaZulu-Natal provinces to test it in English and at least one other official/local languages. Approximately 5-10 participants were administered the study tool in each language as part of the pilot. The primary objective was to test the flow of questions and basic understanding by the participants. The cell phone technology used for data collection, including skips and field data entry, was also examined and tested. Adjustments to the tool and/or cell phone data entry platform were made after the pilot as necessary.

2.5 Ethical Considerations

Written, signed, informed consent for all procedures in the study was obtained from each eligible caregiver for the interview and DBS sampling (separately). Informed consent was in the preferred language of the participants. The information sheet was written in plain lay words that could be easily understood by participants. A confidential Study ID was given to each participant and inserted in consent forms, lab forms and questionnaire for the purpose of data linking and auditing, and to provide the infants' blood test results to mothers or legal guardians. Care was taken to ensure that HIV-infected mothers who refused the study understood that their infant could be tested without participating in the study.

Ethical approval was obtained from the Medical Research Council (26 February 2010) and from each of the nine provincial research ethics committees. Ethical approval was also granted from the United States Centers for Disease Control and Prevention Atlanta (April 2010).

2.6 Data Collection Methods

Data collection commenced at different times in each province (Table 3). All data collection was completed by 1 December 2010.

Table 3 Data collection start and end dates in each province

DATA COLLECTION						
Province	Commenced	Completion				
KwaZulu-Natal	01-June-2010	22-Oct-2010				
Eastern Cape	14-June-2010	12-Nov-2010				
Western Cape	14-June-2010	22-Oct-2010				
Free State	23-June-2010	12-Nov-2010				
North West	23-June-2010	21-Oct-2010				
Gauteng	28-June-2010	29-Oct-2010				
Limpopo	29-June-2010	12-Nov-2010				
Northern Cape	29-June-2010	01-Dec-2010				
Mpumalanga	30-June-2010	29 Oct-2010				

Enrolment

Data collectors recruited mothers/caregivers from the PHC/CHC waiting room during immunisation days. Data collectors introduced themselves and the study verbally and in written form using a standardised information sheet. If the mother agreed to be interviewed, the interview was conducted in a private location. Mother/Infant pairs attending the sampled facilities to receive the infants' DPT first dose vaccination were approached to enroll in the study. A screening questionnaire was administered to determine eligibility and full informed consent forms were completed.

Cell Phone Technology for Data Collection

Electronic questionnaires were loaded on low-cost mobile phones using the Mobile Researcher software management solution. The Mobile Researcher system consists of three components: the handset, the web interface (data transport system) and web-based research console (Figure 2). The handset is the device on which the questionnaires are entered. Minimum handset functionality is ensured since phone is WAP (Wireless Application Protocol) enabled. The data is transferred via the GPRS (General Packet Radio Services) network using the WAP platform on the mobile phone. The web-based management console is a secure data capture centre that has controlled access.

Questionnaires were uploaded as they were completed to the central web management console and then removed from the phone, while fieldworkers were in an area of mobile reception. In areas where there was no mobile network reception, the questionnaire was stored on the phone until reaching an area with adequate mobile network coverage when data would be automatically

uploaded. The questionnaire responses were available on the web-based console every minute, allowing for real-time monitoring of data collection progress and analysis (Figure 3).

Figure 2 Design phase and data collection flow diagram for the cell-phone data collection system

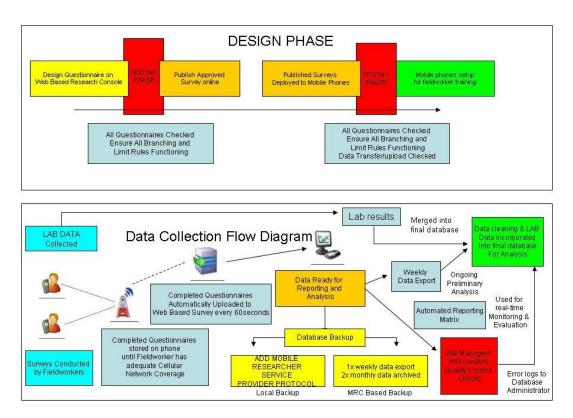
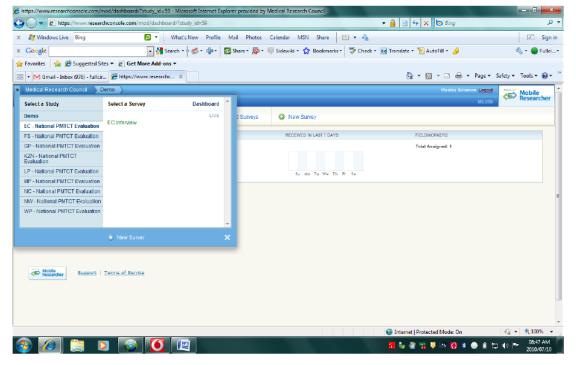


Figure 3 Example of SAPMTCTE Mobile Researcher web-based interface



2.7 Laboratory Methods

The National Institute for Communicable Diseases, a eivision of the South African National Health Laboratory Service (NHLS), conducted the testing. Questionnaires and DBS specimens were linked using unique study identification numbers and lab order numbers. DBS specimens collected from enrolled and consented infants were tested for HIV by means of a laboratory HIV ELISA test (Genscreen HIV antibody assay). In cases where this was reactive (i.e., identified an infant born to an HIV-positive mother), a qualitative DNA PCR (Amplicor HIV-1 DNA PCR version 2.0 assay, Roche Diagnostics, Branchburg, NJ) was performed to determine whether the infant was currently HIV-positive. In the case of a known HIV-positive mother, the study DBS specimens and testing replaced the expected routine EID testing. All results were sent to clinic of origin and returned to mother at either 10 or 14 week immunisation visit.

All aspects of the project were carried out according to strict standard operating procedures (SOPs), and testing was conducted under conditions of good laboratory practice. Specimens received in the laboratory were reviewed against the tracking lists/request form for correctness and adequacy of specimens. Each specimen received unique bar-coded identifiers for tracking and data extraction. Rejected specimens were accompanied by a rejection form with specified reasons and referred to field staff for correction. A tracking list of rejected specimens was held by the lab in electronic format. Specimens were tested and results entered into a LIMS (DISA) system; all results had three levels of review.

The algorithm for testing was decided based on the outcome of initial dual ELISA testing. All reactive specimens and every 10th non-reactive specimen were tested using a second ELISA, Vironostika (bioMérieux, France). A total of 690 specimens were included in the analysis. The agreement between the two tests was 99.4% and the sensitivity and specificity of the Genscreen assay was 99.7% and 99.2% respectively. Based on these results it was decided that a single ELISA test, Genscreen, be used. All reactive ELISA tests were referred for DNA testing. In the case of a laboratory ELISA equivocal result, HIV DNA testing was performed as a routine.

The procedure for DNA testing was by automated Ampliprep/Taqman v2.0 technology (Roche). Evaluation of HIV DNA PCR performance on DBS has demonstrated a sensitivity and specificity of 99.7% and 100% respectively (Stevens, W et al). The data extraction of ALL ELISA reactive results was by location code and the referral of spreadsheet to the DNA testing lab. ALL HIV DNA results were extracted and individual reports generated by name of infant for return to the facility where the infant was tested. The reports forms were standardised and had all the required information based on the original request form. All assays used for surveillance were validated and/or verified prior to use, accredited and the performance monitored by proficiency testing. In the case of discordant results between the mother's self-reported result and the laboratory result an algorithm using the two ELISAs, Western blot and DNA PCR was performed on the DBS to exclude lab error or false positive laboratory results.

The data was extracted to exclude personal patient identifiers and emailed to the researchers. The extracted data was in Excel format. Databases were validated and confirmed at two levels before release. The Excel spreadsheet was then merged with the questionnaire database fortnightly. Laboratory data were sent electronically from the laboratory. Tracking logs (study IDs) were used to link questionnaire data and blood test results. The tracking log was managed by the logistics manager.

Prior to the six-week survey, a study was conducted to validate the use of screening and confirmatory third generation ELISAs on DBS. This work was headed by Professors Gayle Sherman and Adrian Puren, and the samples and funding used for this validation study are part of a separate protocol.

2.8 Quality Control of Field Work

Every attempt was made to minimise errors which may result in variation in the collected data contributing to bias in the results. Quality control (QC) was defined as the operational procedures undertaken within the survey, as prescribed by the survey SOPs, to verify that the survey activities (e.g., interviews, obtaining informed consent forms, pre-test counselling, DBS collection, recording data, reporting data) were conducted in accordance with the defined quality standards. The SOPs focused on QC activities done by the field worker, field worker supervisor, quality control officer and the central team. QC activities aimed to improve the quality and validity of the collected data by:

- Identifying factors that may affect the accuracy and reliability of the data and addressing the identified factors;
- Preventing and correcting errors in the collection of data; and
- Ensuring that field activities align with the study SOPs.

2.9 Data Management

Data captured on the phones were protected with a write-only security model. Fieldworkers could modify and review data while the interview was in progress. Captured data was encoded and stored on the device in the Record Management system which ensured that only the Mobile Researcher application could access the data.

The data was transferred securely to the web console, which uses 128-bit strength encryption. Data storage and back up protocols are compliant to enterprise standards and database servers run RAID to ensure redundancy in case of disk failure.

The uploaded data was reviewed daily to ensure that all fieldworkers were submitting responses in accordance to scheduled work plans. The work plans were developed to achieve the required number of DBS per facility and key questions were identified in the database to estimate and track the collection of blood sample progress.

Questionnaire data was maintained by Mobile Researcher and exported to Excel for data analysis. Anonymised laboratory data (Study ID only) were exported to Excel for merging with questionnaire data. Consent verification from hard copy consent forms were entered into Excel and double checked. Interim data analysis was completed during the course of the study. Data from questionnaire, laboratory results and consent verification were all merged and cross-checked. Data without consent verification was not included for analysis. Duplicates and other inconsistencies across data sets were checked and cleaned according to data standards. Out-of-range and data consistency checks were completed as a component of initial data analysis.

2.10 Data Analysis

Sample Realisation

A total 572 of the 585 sampled clinics were included in final sample. Reasons for non-inclusion included clinic closure (temporary or permanent) or no longer administering immunisations. The overall realisation was 81% with three provinces having low realisation (Northern Cape, Eastern Cape and Limpopo).

Sample Weights

Sample weights were calculated for the survey to adjust for differential sampling design across provinces and the sample realisation (as outlined above). The data from provinces were weighted by using the proportional distribution of number of life births observed in 2008 for South Africa over provinces. The realisation weights were done at the district or provincial level depending on the sampled size and realisation within strata. For Northern Cape and Eastern Cape the realisation weighting was done at the provincial level. The realisation weights pertain to the per protocol sample size.

A survey analysis was done which took into account the stratification, the different sampling stages and the finite number of PSUs involved. A weighted analysis was done to obtain national estimates as well as provincial estimates. The infant HIV infection prevalence was estimated at the national population level and in the HIV exposed sub-population. These estimates all have 95% confidence intervals. Design effects are also reported. The survey specification and analysis was done in SAS version 9.2. Descriptive statistics of the demographic profile of the participants was done by province and country-wide, accounting for the survey design and realisation.

3. RESULTS

3.1 Sample Realisation and Survey Profile

Table 4 indicates the desired and actual sample size for questionnaire plus DBS sample and realised sample size per province and nationally. All but three provinces realised at least 80% of sample.

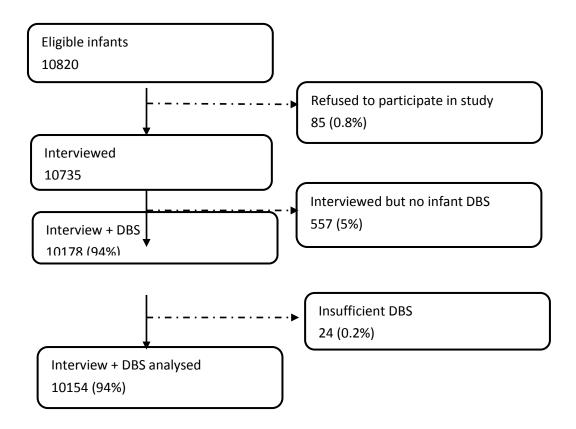
Table 4 2010 SAPMTCTE desired and actual sample size by province

Province	Desired SS	Actual SS # (% Desired SS)
Eastern Cape	1400	776 (55%)
Free State	1300	1143 (88%)
Gauteng	1800	1735 (96%)
KwaZulu-Natal	1400	1224 (87%)
Limpopo	1400	1022 (73%)
Mpumalanga	1600	1286 (80%)
Northern Cape	700	444 (63%)
North West	1200	1171 (98%)
Western Cape	1400	1381 (99%)
South Africa	12 200	10 182 (83%)

Weighting during analysis adjusted estimates in all provinces with lower than expected sample realisation.

Figure 4 details the final study profile for the survey. Of the eligible participants sampled 99.2% (10735/10820) consented for the study; 5% of these (557) had questionnaires but no DBS sample (refused or difficult heel stick blood draw). Twenty-four (0.2%) DBS were found insufficient for full analysis in the lab. Therefore of 10 820 eligible infants from sampled clinics during the study period (2-4 weeks per clinic), the final sample with questionnaire and analysed DBS was 10 154 (94%) infants.

Figure 4 2010 SAPMTCTE study profile



3.2 Sample Description and Characteristics

Table 5 provides a summary of selected characteristics of the SAPMTCTE survey sample.

Table 5 Selected socio-demographic observations of 2010 SAPMTCTE [# (%)]

Characteristics	Categories	ZA	EC	FS	GP	KZN	LP	MP	NC	NW	WC
Relationship to	Mother	10357 (96.7)	840 (95.3)	1136 (96.9)	1767 (98.4)	1293 (96.5)	1026 (93.8)	1272 (95.0)	449 (97.6)	1171 (97.0)	1403 (97.1)
child	Caregiver	378 (3.3)	41 (4.7)	37 (3.1)	30 9 (1.6)	47 (3.5)	68 (6.2)	66 (5.0)	11 (2.4)	36 (3.0)	42 (2.9)
Infant sandar	Male	5420 (50.6)	459 (52.1)	602 (51.6)	932 (52.1)	647 (47.9)	551 (50.3)	672 (50.3)	225 (48.9)	614 (50.9)	718 (49.7)
Infant gender	Female	5315 (49.4)	422 (47.9)	865 (48.4)	865 (47.9)	693 (52.1)	543 (49.7)	666 (49.7)	235 (51.1)	593 (49.1)	727 (50.3)
Age of mother	Mean (SE)	25.9 (0.1)	25.1 (0.2)	25.8 (0.2)	26.6 (0.1)	24.9 (0.2)	26.0 (0.2)	25.3 (0.1)	25.8 (0.2)	26.3 (0.2)	26.4 (0.1)
	None	231 (1.9)	22 (2.5)	11 (0.9)	28 (1.5)	21 (1.5)	17 (1.6)	40 (3.0)	16 (3.5)	64 (5.3)	12 (0.8)
Education of	Grade 1-7	1699 (14.9)	192 (21.8)	180 (15.1)	197 (10.9)	193 (14.5)	164 (15.3)	241 (17.9)	84 (18.3)	230 (19.1)	218 (15.1)
mother	Grade 8-12	8193 (77.1)	624 (70.8)	928 (79.4)	1437 (80.2)	1064 (79.5)	823 (75.0)	1007 (75.2)	342 (74.3)	867 (71.8)	1101 (76.2)
	Above Grade12	538 (5.4)	39 (4.4)	43 (3.7)	130 (7.1)	54 (4.0)	84 (7.5)	28 (2.1)	14 (3.0)	40 (3.3)	106 (7.3)
	Single	7799 (74.4)	668 (75.8)	743 (63.5)	1265 (69.9)	1214 (90.7)	759 (69.7)	1000 (74.8)	359 (78.0)	1004 (83.1)	787 (54.3)
Marital status of	Married/cohabitating	2850 (24.9)	210 (23.8)	424 (36.0)	518 (29.4)	121 (8.9)	331 (30.0)	322 (23.9)	97 (21.1)	193 (16.0)	634 (44.0)
mother	Widowed/divorced/ separated	51 (0.4)	2 (0.2)	3 (0.3)	10 (0.3)	1 (0.1)	3 (0.2)	4 (0.3)	2 (0.4)	5 (0.4)	21 (1.4)
	Brick/Cement block	8070 (73.6)	556 (63.1)	922 (78.6)	1384 (77.1)	830 (61.9)	974 (89.2)	1152 (85.7)	370 (80.4)	891 (73.8)	991 (68.5)
Main building	Informal material	1944 (17.8)	104 (11.8)	234 (19.8)	234 (22.7)	170 (13.3)	92 (8.3)	109 (8.4)	86 (18.7)	290 (24.0)	449 (31.1)
material of house	Traditional material/mud	721 (8.6)	221 (25.1)	17 (1.5)	3 (0.2)	340 (24.8)	28 (2.5)	77 (5.9)	4 (0.9)	26 (2.2)	5 (0.4)
Main source of drinking water	Piped in house or yard	8172 (72.3)	373 (42.3)	990 (85.1)	1657 (92.5)	819 (60.6)	511 (47.4)	1119 (83.9)	430 (93.5)	916 (75.9)	1357 (93.9)
anning nata	Not piped in house or yard	2563 (23.2)	508 (57.7)	183 (14.9)	140 (7.5)	521 (39.4)	583 (52.6)	219 (16.1)	30 (6.5)	291 (24.1)	88 (6.1)
Type of toilet	Flush toilet	5676 (50.9)	233 (26.4)	777 (66.4)	1525 (84.8)	319 (24.4)	183 (17.4)	393 (30.3)	403 (87.6)	532 (44.1)	1311 (90.7)
	Pit latrine	4659 (41.3)	554 (62.9)	366 (31.1)	260 (14.5)	971 (71.9)	838 (76.1)	901 (66.5)	36 (7.8)	652 (54.0)	81 (5.6)
	None	300 (2.3)	85 (9.6)	2 (0.2)	10 (0.6)	50 (3.8)	68 (6.0)	40 (2.9)	10 (2.2)	16 (1.3)	19 (1.3)
	Other	100 (0.5)	9 (1.0)	28 (2.3)	2 (0.1)	0 (0.0)	5 (0.4)	4 (0.3)	11 (2.4)	7 (0.6)	34 (2.4)
Main source of fuel	Electricity/gas/ paraffin	9874 (91.9)	862 (97.8)	1143 (97.3)	1782 (99.2)	1121 (83.4)	770 (71.4)	1184 (88.3)	449 (97.6)	1128 (93.5)	1435 (99.3)
IUCI	Other	861 (8.1)	19 (2.2)	30 (2.7)	15 (0.8)	219 (16.6)	324 (28.6)	154 (11.7)	11 (2.4)	79 (6.5)	10 (0.7)

Characteristics	Categories	ZA	EC	FS	GP	KZN	LP	MP	NC	NW	WC
Depletion of food supply in past 12 months	Yes	1776 (16.4)	216(24.5)	159 (13.7)	170 (9.8)	284 (21.6)	175 (15.1)	117 (8.9)	50 (10.9)	230 (19.1)	375 (26.1)
	No	8892 (83.1)	661 (75.0)	1012 (86.1)	1622 (89.9)	1047 (77.7)	917 (84.8)	1194 (89.1)	410 (89.1)	973 (80.6)	1056 (73.0)
Planned Pregnancy	Yes	4147 (38.3)	279 (31.2)	454 (38.5)	856 (47.8)	271 (20.1)	540 (49.9)	567 (42.1)	175 (38.0)	496 (41.1)	509 (35.1)
	No	6219 (58.5)	570 (64.7)	682 (58.4)	911 (50.6)	1027 (76.1)	489 (44.2)	702 (52.7)	273 (59.3)	671 (55.6)	894 (61.9)
	DKN	369 (3.1)	32 (3.6)	37 (3.1)	30 (1.6)	42 (3.2)	65 (5.9)	69 (5.2)	12 (2.6)	40 (3.3)	42 (2.9)

ZA: South Africa EC: Eastern Cape FS: Free State GP: Gauteng KZN: KwaZulu-Natal LP: Limpopo MP: Mpumalanga NC: Northern Cape NW: North West WC: Western Cape

Of note is that nationally 96.7% of infants were brought to the clinic by their mothers; 84% mothers were \geq 20 years of age; 82.5% mothers had completed grades 8-12 or more of school; 74.4% of mothers were single and 16.4% reported running out of food at some time during the past 12 months.

3.3 Infant HIV Infection Prevalence

Table 6 Weighted Infant HIV infection prevalence nationally and by province

Province	% Infant HIV Infection Prevalence	95% CI
Eastern Cape	2.0	1.1-2.9
Free State	2.4	1.6-3.2
Gauteng	1.1	0.6-1.5
KwaZulu-Natal	1.9	1.2-2.7
Limpopo	0.9	0.4-1.5
Mpumalanga	3.0	2.1-3.8
Northern Cape	0.3	0.1-0.6
Northwest	1.9	1.2-2.5
Western Cape	0.9	0.4-1.5
National	1.5	1.3-1.7

The national weighted infant HIV infection prevalence among infants aged 4-8 weeks attending child health clinics for their six week immunisation was 1.5% (95%CI: 1.3-1.7%). (Table 6) Infant HIV infection prevalence is the rate of HIV-positivity among all infants tested regardless of exposure which provides an indication of total burden of HIV disease in infants at 4-8 weeks of age.

3.4 National and Provincial Infant HIV Exposure and MTCT Rates

The national rate of infant HIV exposure was 32.0% (95%CI: 30.7-33.3%), with wide provincial variation. (Table 7) (Note: Infant HIV exposure prevalence is presumed to be roughly equivalent to maternal HIV prevalence.)

Among these HIV-exposed infants, the national rate of MTCT of HIV by 8 weeks is 3.5% (95%CI: 2.9-4.1%), with an almost 3-fold difference between provinces; the lowest rate of 1.4% (95%CI: 0.1-3.4) was found in the Northern Cape and the highest rate of 5.9% (95%CI: 3.8-8.0) in the Free State.

It is important to note that for the Eastern Cape and Northern Cape (*) provinces the point estimates are correct but the sample precision was less (wider confidence intervals). This was due to the lower sample realisation rates,

Table 7 Weighted infant HIV exposure and 4-8 week (early) MTCT of HIV by province

Province	Infant HIV exposure (%)	MTCT (%) 95% CI
Eastern Cape*	30.5 (26.9-34.2)	4.7 (2.4-7.0)
Free State	31.3 (29.1-33.5)	5.9 (3.8-8.0)
Gauteng	30.4 (27.9-33.0)	2.5 (1.5-3.6)
KwaZulu-Natal	44.3 (40.2-48.4)	2.9 (1.7-4.0)
Limpopo	23.9 (21.8-25.9)	3.6 (1.4-5.8)
Mpumalanga	37.0 (34.3-39.7)	5.7 (4.1-7.3)
Northern Cape*	16.0 (13.7-18.3)	1.4 (0.1-3.4)
Northwest	31.3 (29.0-33.5)	4.4 (2.9-5.9)
Western Cape	21.0 (17.0-25.0)	3.9 (1.9-5.8)
South Africa	32.0 (30.7-33.3)	3.5 (2.9-4.1)

3.5 National PMTCT Programme Cascade

Table 8 presents results for PMTCT programme indicators as per maternal report in all mothers interviewed. The percent of pregnant women with unknown HIV status prior to their first antenatal booking who had an HIV test during pregnancy was 98.8. Maternal receipt of HIV test results was also high at 98.6%. Of *ALL* mothers enrolled in the survey 29.4% reported being HIV-positive while HIV antibody was found in 32% of *ALL* infants – a 2.6% difference. Of concern is that of those *mothers who reported being HIV-negative*, 4.1% of their infants had HIV antibodies, suggesting a high rate of maternal potential acquisition of HIV infection during pregnancy. This rate also varied substantially across provinces from a low of 1.1% in the Western Cape to a high of 7.8% in Mpumalanga and Eastern Cape. The indicator 'Maternal potential HIV acquisition' is a combination of the following scenarios:

- (i) Mothers did not want to admit being HIV-positive and instead, reported being HIV negative. However, the 2010 data show that refusals for infant HIV testing were low and disclosure was high; thus the contribution that this scenario makes to the indicator is probably minimal.
- (ii) Mothers were tested during the window period.
- (iii) Poor QC/performance of rapid tests in the field causes false negative results at ANC on HIV-infected women. Reported field sensitivities are as low as 87% to 95% depending on the rapid test used.

(iv) True acquisition of HIV after the last HIV test – which for most mothers was during pregnancy.

Table 8 HIV testing & results among pregnant women (weighted analysis)

Province	% ANC HIV Test	% Tested who received result	% Mothers report being HIV- positive	%Infants of reported HIV- negative mothers who had HIV antibody
Factor Cons	97.5	98.1	27.1	7.8
Eastern Cape	(96.5-98.6)	(97.1-99.1)	(23.5-30.7)	(5.8-9.7)
Fron State	98.8	98.9	27.9	5.4
Free State	(98.3-99.2)	(98.5-99.4)	(25.7-30.1)	(4.3-6.4)
Cautong	99.1	99.3	28.3	3.0
Gauteng	(98.7-99.2)	(98.9-99.6)	(25.8-30.8)	(2.2-3.9)
KwaZulu-Natal	98.9	99.5	42.2	3.2
KWaZuiu-Natai	(98.3-99.2)	(99.1-99.9)	(38.1-46.2)	(2.1-4.4)
Limpono	98.6	97.0	19.4	5.1
Limpopo	(97.8-99.5)	(95.9-98.1)	(17.3-21.6)	(3.6-6.7)
Maumalanga	98.6	97.1	32.6	7.8
Mpumalanga	(97.8-99.3)	(96.3-98.0)	(29.7-35.5)	(5.8-9.7)
Northern Cape	99.3	96.7	14.4	2.2
Northern Cape	(98.9-99.8)	(95.7-97.6)	12.2-16.7)	(1.2-3.3)
North West	99.2	98.5	28.7	5.4
North West	(98.8-99.6)	(97.8-99.1)	(26.7-30.6)	(3.9-6.8)
Western Cape	98.6	98.8	19.9	1.1
western cape	(97.9-99.3)	(98.3-99.3)	(16.1-23.8)	(0.3-1.9)
South Africa	98.8	98.6	29.4	4.1
South Africa	(98.5-99.0)	(98.4-98.9)	(28.1-30.7)	(3.7-4.6)

Table 9 further shows PMTCT programme indicators for women who reported being HIV-positive: 78.3% of HIV-positive mothers reported getting a CD4 test result; taking HAART was reported by 33.1% of mothers reporting being HIV-positive, while 58.7% of HIV-positive mothers reported receiving both maternal and neonatal antiretroviral (ARV) prophylaxis. These two combined suggested that 91.8% of HIV-positive mothers received either HAART or ARV prophylaxis (**Figure 5**).

Table 9 PMTCT programme in reported HIV-positive mothers (weighted analysis)

Province	% Received CD4 Test	% Received ARV/HAART	% Mother & Infant Received ARV Prophylaxis	% Intended to obtain EID @ 6 weeks
Eastern Cape	67.6	23.0	63.5	21.6
	(60.2-75.1)	(16.9-29.0)	(55.3-71.7)	(14.9-28.4)
Free State	85.8	37.7	56.4	43.7
	(82.7-89.0)	(33.2-42.2)	(51.6-61.1)	(33.3-54.1)
Gauteng	74.6	40.1	52.8	42.5
	(69.8-79.4)	(34.9-45.3)	(47.1-58.4)	(32.6-52.4)
KwaZulu-	85.5	29.4	65.2	41.1
Natal	(82.1-88.8)	(25.5-33.3)	(61.1-69.3)	(30.5-51.6)
Limpopo	68.3	33.3	54.3	28.4
	(61.0-75.5)	(27.3-39.4)	(47.3-61.3)	(20.4-36.5)
Mpumalanga	69.5	27.5	56.1	29.8
	(65.5-73.5)	(23.3-31.7)	(51.8-60.3)	(23.1-36.5)
Northern	88.7	28.6	58.7	1.6
Cape	(83.0-94.3)	(19.6-37.6)	(51.1-66.3)	(0.1-4.0)
North West	81.7	33.7	57.4	3.6
	(78.3-85.1)	(29.1-38.4)	(52.4-62.5)	(1.6-5.7)
Western	89.6	34.2	60.0	37.9
Cape	(86.8-92.5)	(27.9-40.6)	(52.7-67.3)	(28.8-47.0)
Courte Africa-	78.3	33.1	58.7	35.1
South Africa	(76.4-80.4)	(30.8-35.3)	(56.3-61.1)	(30.6-39.6)

Only 35.1% of reported HIV-positive mothers indicated that they planned to obtain early infant diagnosis (EID) for their infant during their six week immunisation visit (ranging from 1.6% in Northern Cape to 42.5% in Gauteng).

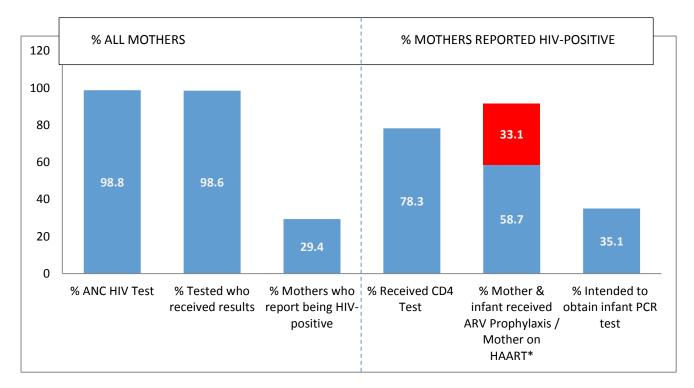


Figure 5 PMTCT service uptake (PMTCT cascade) in South Africa

3.6 Demographic Characteristics, MTCT and the PMTCT Cascade by Province

3.6.1 Eastern Cape

Eastern Cape achieved a sample realisation of 55%. This was due to a high number of medium size clinics requiring extended resources. Furthermore in the Eastern Cape many infants presenting for six week immunisation were older than 8 weeks of age. This was especially the case in large urban clinics. These infants were not eligible for enrolment into the survey.

General Description of Provincial Sample

Table 10 presents characteristics of respondents in the Eastern Cape province. Similar to the national trend, the majority of the respondents are single (75.8%) mothers (97.3%), with education level of grade 8-12 (70.8%). In comparison with other provinces, Eastern Cape has a significant percentage (24.5) of respondents that reported experiencing depletion of food in the household in the last 12 months. Economic status indicators also show that pit latrines (62.9%) and not piped water (57.7%) are utilised by the majority of the respondents.

Table 10 Baseline characteristics of Eastern Cape SAPMTCTE survey participants

Characteristics	Categories	%	95% CI
Polationship to shild	Mother	97.3	93.9-96.8
Relationship to child	Caregiver	4.7	3.2-6.1
Mean age of mother (range)	25.1 (1 ₋	4-52)	
Infant gender	Male	52.1	48.7-55.5
illiant gender	Female	47.9	44.5-51.3
	None	2.5	1.6-3.4
Education of mother	Grade 1-7	21.8	18.4-25.1
Lucation of mother	Grade 8-12	70.8	67.4-74.3
	Above Grade 12	4.4	3.0-5.9
Marital status of mother	Single	75.8	73.1-78.6
iviantai status oi motnei	Married/cohabitating	23.8	21.1-26.6
	Brick/Cement block	63.1	55.5-70.7
Main building material of house	Informal material	11.8	8.1-15.5
	Traditional material/mud	25.1	18.6-31.5
Main source of drinking water	Piped in house or yard	42.3	34.8-49.8
	Not piped in house or yard	57.7	50.2-65.2
Type of toilet	Flush toilet	26.4	19.6-33.3
	Pit latrine	62.9	56.6-69.1
	None	9.6	5.9-13.4
	Other	1.0	0.4-1.7
Main source of fuel	Electricity/gas/paraffin	97.8	96.9-98.8
iviaiii source or ruer	Other	2.2	1.2-3.1
Depletion of food supply in past 12	Yes	24.5	18.9-30.1
months	No	75.0	69.4-80.6

Infant HIV Exposure and MTCT Rate in Eastern Cape Province

Text box 1 shows that infants' HIV exposure was 30.5%, with a 2.0% early infant HIV infection prevalence and a 4.7% (95%CI: 2.4-7.0) MTCT rate at 4-8 weeks. The larger confidence interval attached to this estimate is due to the smaller sample size attained in Eastern Cape. The percent of reported HIV-negative mothers whose infants had HIV antibodies (presumed maternal HIV acquisition after the initial HIV test) was 7.8% (95% CI 5.8-9.7), the highest in South Africa (along with Mpumalanga).

Text Box 1: Eastern Cape infant HIV exposure and MTCT

Infant HIV Exposure % (95%CI)	Infant HIV infection prevalence at 4-8 weeks	MTCT @ 4-8 weeks:%(95%CI)	%Infants of reported HIV- negative mothers who had HIV antibody
30.5 (26.9-34.2)	2.0 (1.1-2.9)	4.7 (2.4-7.0)	7.8 (5.8-9.7)

PMTCT Service Uptake (PMTCT Cascade) in the Eastern Cape Province

Figure 6 indicates that Eastern Cape has a fairly high antenatal HIV testing rate (97.5%) but ARV prophylaxis/HAART coverage of 86.5%. Coverage of CD4 count and intended EID is low in Eastern Cape.

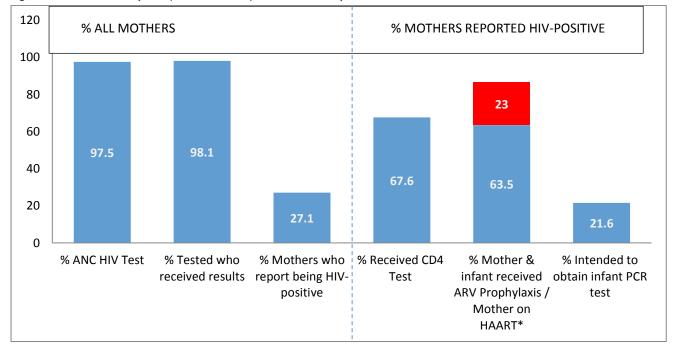


Figure 6 PMTCT service uptake (PMTCT cascade) in the Eastern Cape

Note: The first three indicators apply to all mothers, while the last three apply only to those who reported being HIV-positive. Red indicates the percentage receiving HAART while blue indicates the percentage receiving ARV prophylaxis.

3.6.2 Free State

The survey attained 88% of targeted sample size in the Free State.

General Description of Provincial Sample

In the Free State 63.5% of mothers were single. More than 85% had piped water and electricity, gas or paraffin fuel source, while only 66.4% had a flush toilet. (Table 11)

Characteristics	Categories	%	95% CI
Relationship to child	Mother	96.9	96.2-97.7
	Caregiver	3.1	3.2-6.1
Mean age of mother – mean (range)	25.8 (14-48)		
Infant gender	Male	51.6	49.6-53.6
	Female	48.4	46.4-50.4
Education of mother	None	0.9	0.5-1.4
	Grade 1-7	15.1	13.3-16.8

Characteristics	Categories	%	95% CI
	Grade 8-12	79.4	77.5-81.3
	Above Grade 12	3.7	2.7-4.6
Marital status of mother	Single	63.5	61.0-66.0
	Married/cohabitating	36.0	33.5-38.5
Main building material of house	Brick/Cement block	78.6	76.3-80.9
	Informal material	19.8	17.7-22.0
	Traditional material/mud	1.5	0.9-2.1
Main source of drinking water	Piped in house or yard	85.1	81.5-88.8
	Not piped in house or yard	14.9	11.2-18.5
Type of toilet	Flush toilet	66.4	60.9-72.0
	Pit latrine	31.1	25.5-36.6
	None	0.2	0.0-0.3
	Other	2.3	1.3-3.4
Main source of fuel	Electricity/Gas/Paraffin	97.3	96.1-98.6
	Other	2.7	1.4-3.9
Depletion of food supply in past 12	Yes	13.7	11.6-15.8
months	No	86.1	84.0-88.2

Infant HIV Exposure and MTCT Rate in Free State Province

Text Box 2 shows that infants HIV exposure was 31.3% with a 2.4% early infant HIV infection prevalence and a 5.9% (95%CI: 3.8-8.0%) MTCT rate at 4-8 weeks is the highest in South Africa. The percentage of infants with reported HIV-negative mothers who were actually HIV-exposed (presumed maternal HIV acquisition) is also second highest in the country at 5.4% (95%CI: 4.3-6.4).

Text Box 2: Free State Infant HIV Exposure and MTCT

Infant HIV Exposure % (95%CI)	Infant HIV infection prevalence at 4-8 weeks	weeks:%(95%CI)	%Infants of reported HIV-negative mothers who had HIV antibody
31.3 (29.1-33.5)	2.4 (1.6-3.2)	5.9 (3.8-8.0)	5.4 (4.3-6.4)

PMTCT Service Uptake (PMTCT cascade) in the Free State Province

Figure 7 shows uptake of HIV testing (98.8%) and coverage of ARV prophylaxis/HAART is fairly high in Free State (94.1%). CD4 testing was at 85.8%. The high presumed maternal potential HIV acquisition may explain the high MTCT rate although, more detailed investigations are needed to examine 'effective coverage' of the PMTCT cascade (i.e., despite high CD4 cell and HAART/prophylaxis uptake adherence to ARVs was low) and support for mothers post-HIV diagnosis and during pregnancy. Adherence and care and support data were not gathered in 2010.

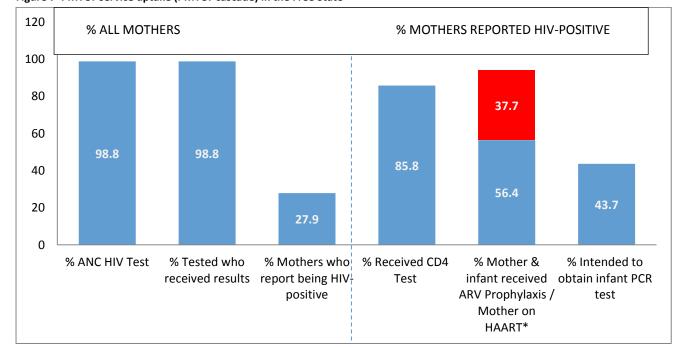


Figure 7 PMTCT service uptake (PMTCT cascade) in the Free State

3.6.3 Gauteng

The SAPMTCTE in Gauteng province attained 96% of targeted sample size.

General Description of Provincial Sample

Socioeconomic indicators show that compared to other provinces, participants in Gauteng Province have higher rates of flush toilet and electricity, gas or paraffin fuel source (Table 12).

Table 12 Baseline characteristics of Gauteng SAPMTCTE survey participants

Characteristics	Categories	%	95% CI
Relationship to child	Mother	98.4	97.8-99.0
	Caregiver	1.6	1.0-2.2
Mean age of mother (range)			26.6 (13-49)
Infant gender	Male	52.1	49.8-54.3
	Female	47.9	45.7-50.2
Education of mother	None	1.5	0.9-2.2
	Grade 1-7	10.9	9.3-12.5
	Grade 8-12	80.2	77.7-82.7
	Above Grade 12	7.1	5.4-8.9
Marital status of mother	Single	69.9	65.3-74.4
	Married/cohabitating	29.4	24.8-33.9
Main building material of house	Brick/cement block	77.1	73.3-80.8

Characteristics	Categories	%	95% CI
	Informal material	22.7	19.0-26.5
	Traditional material/mud	0.2	0.0-0.4
Main source of drinking water	Piped in house or yard	92.5	90.0-94.9
	Not piped in house or yard	7.5	5.1-9.9
Type of toilet	Flush toilet	84.8	81.6-88.0
	Pit latrine	14.5	11.5-17.6
	None	0.6	0.0-1.2
	Other	0.1	0.0-0.3
Main source of fuel	Electricity/gas/paraffin	99.2	98.8-99.6
	Other	0.8	0.4-1.2
Depletion of food supply in past 12	Yes	9.8	7.3-12.3
months	No	89.9	87.4-92.4

Infant HIV Exposure and MTCT Rate in Gauteng

Text Box 3 shows that infants' HIV exposure was 30.4%, with a 1.1% early infant HIV infection prevalence and a 2.5% (95%CI: 1.5-3.6%) MTCT rate at 4-8 weeks. Maternal potential HIV acquisition was 3% (2.2-3.9%).

Text Box 3: Gauteng Infant HIV Exposure and MTCT

Infant HIV Exposure %	Infant HIV infection	MTCT @ 4-8	%Infants of reported
(95%CI)	prevalence at 4-8	weeks:%(95%CI)	HIV-negative mothers
	weeks		who had HIV antibody
30.4 (27.9-33.0)	1.1 (0.6-1.5)	2.5 (1.5-3.6)	3.0 (2.2-3.9)

PMTCT service uptake (PMTCT cascade) in Gauteng

Gauteng has achieved close to 100% (99.1% tested and 99.3% received test) HIV testing rate. Coverage of ARV prophylaxis or HAART is 92.9% with 40.1% of women on HAART, the highest of any province. However, CD4 count is only 74.6% and intended EID coverage while higher than other provinces is still below half (42.5%). (Figure 8)

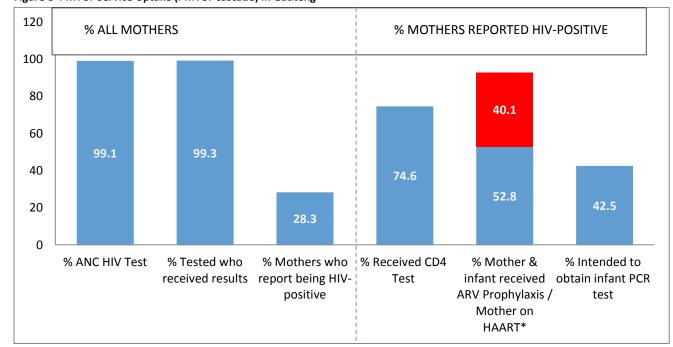


Figure 8 PMTCT Service Uptake (PMTCT cascade) in Gauteng

3.6.4 KwaZulu-Natal

The SAPMTCTE in KwaZulu-Natal attained 87% of targeted sample size.

General Description of Provincial Sample

KwaZulu-Natal had a very high rate of single mothers at 90.7%, while brick/cement block house and piped water were just above 60%, and 21.6% of participants described depletion of food supply in the past 12 months. (Table 13)

Table 13 Baseline characteristics of KwaZulu-Natal SAPMTCTE survey participants

Characteristics	Categories	%	95% CI
Relationship to child	Mother	95.5	95.4-97.5
	Caregiver	3.5	2.5-4.6
Mean age of mother (range)	24.9 (1	4-47)	
Infant gender	Male	47.9	45.2-50.7
	Female	52.1	49.3-54.8
Education of mother	None	1.5	0.7-2.3
	Grade 1-7	14.5	11.6-17.3
	Grade 8-12	79.5	76.3-82.6
	Above Grade 12	4.0	2.8-5.2
Marital status of mother	Single	90.7	89.0-92.4
	Married/cohabitating	8.9	7.2-10.6

Characteristics	Categories	%	95% CI
Main building material of house	Brick/Cement block	61.9	55.5-68.3
	Informal material	13.3	9.0-17.6
	Traditional material/mud	24.8	18.3-31.4
Main source of drinking water	Piped in house or yard	60.6	52.8-68.4
	Not piped in house or yard	39.4	31.6-47.2
Type of toilet	Flush toilet	24.4	17.8-30.9
	Pit latrine	71.9	65.2-78.5
	None	3.8	1.0-6.5
	Other	0.0	
Main source of fuel	Electricity/Gas/Paraffin	83.4	78.8-88.0
	Other	16.6	12.0-21.2
Depletion of food supply in past 12	Yes	21.6	16.2-27.0
months	No	77.7	72.3-83.1

Infant HIV Exposure and MTCT Rate in KwaZulu-Natal

Text Box 4 shows that infants HIV exposure was 44.3%, with a 1.9% early infant HIV infection prevalence and a 2.9% (95%CI: 1.7-4.0%) MTCT rate at 4-8 weeks. Among infants whose mothers reported being HIV negative 3.2% (95%CI: 2.1-4.4%) were HIV exposed (maternal potential HIV acquisition after the initial test).

Text Box 4: KwaZulu-Natal HIV Infant Exposure and MTCT

Infant HIV Ex % (95%CI)	kposure	Infant HIV infection prevalence at 4- 8 weeks	MTCT @ 4-8 weeks:%(95%CI)	%Infants of reported HIV-negative mothers who had HIV antibody
44.3 (40	0.2-48.4)	1.9 (1.2-2.7)	2.9 (1.7-4.0)	3.2 (2.1-4.4)

PMTCT service uptake (PMTCT cascade) in the KwaZulu-Natal

In KwaZulu-Natal, close to 100% of pregnant mothers receive testing and test results. More than 85% of HIV-positive mothers received their CD4 cell count test result. ARV/ART coverage was also high (94.6%). The high uptake of CD4 cell count results, together with the high percentage of pregnant women and infants receiving ARV prophylaxis or HAART may explain the lower MTCT rate in KwaZulu-Natal. (Figure 9) Similar to other provinces, coverage of intended EID is low at 41.1%, but compared to other provinces, KwaZulu-Natal is the second highest in its EID coverage.

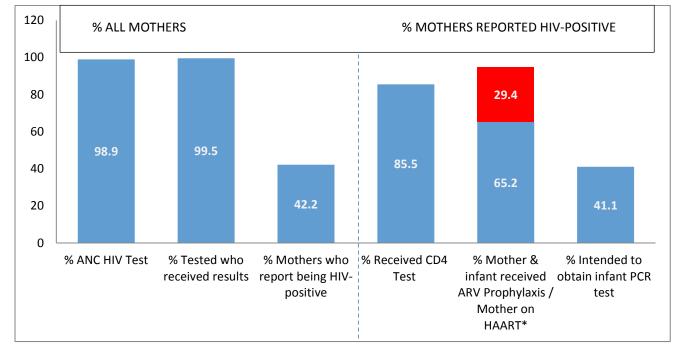


Figure 9 PMTCT service uptake (PMTCT cascade) in KwaZulu-Natal

3.6.5 Limpopo

The SAPMTCT Evaluation in Limpopo province attained 73% of targeted sample size.

General Description of Provincial Sample

Limpopo showed a slightly higher rate of caregivers (other than mothers) bringing infants to services (6.2%) and slightly lower percentage of single mothers (69.7%) compared to South African national rates. (Table 14)

Table 14 Baseline characteristics of Limpopo SAPMTCTE survey participants

Characteristics	Categories	%	95% CI
Relationship to child	Mother	93.8	92.4-95.2
	Caregiver	6.2	4.8-7.6
Mean age of mother (range)	26.0	(14-47)	
Infant gender	Male	50.3	47.4-53.2
	Female	49.7	46.8-52.6
Education of mother	None	1.6	1.0-2.3
	Grade 1-7	15.3	12.6-18.0
	Grade8-12	75.0	71.9-78.1
	Above Grade12	7.5	6.0-9.0
Marital status of mother	Single	69.7	66.0-73.4
	Married/cohabitating	30.0	26.4-33.7
Main building material of house	Brick/Cement block	89.2	87.2-91.2

Characteristics	Categories	%	95% CI
	Informal material	8.3	6.3-10.2
	Traditional material/mud	2.5	1.6-3.5
Main source of drinking water	Piped in house or yard	47.4	41.5-53.4
	Not piped in house or yard	52.6	46.6-58.5
Type of toilet	Flush toilet	17.4	12.4-22.4
	Pit latrine	76.1	71.4-80.8
	None	6.0	4.2-7.9
	Other	0.4	0.1-0.8
Main source of fuel	Electricity/Gas/Paraffin	71.4	65.6-77.2
	Other	28.6	22.8-34.4
Depletion of food supply in past 12	Yes	15.1	12.0-18.1
months	No	84.8	81.7-87.8

Infant HIV Exposure and MTCT Rate in Limpopo

Text Box 5 shows that infants' HIV exposure was 23.9%, with a 0.9% early infant HIV infection prevalence and a 3.6% (95%CI: 1.4-5.8%) MTCT rate at 4-8 weeks. Among infants whose mothers reported being HIV-negative 5.1% (95%CI: 3.6-6.7%) were HIV-exposed.

Text Box 5: Limpopo HIV Infant Exposure and MTCT

Infant HIV Exposure %	Infant HIV infection	MTCT @ 4-8	%Infants of reported
(95%CI)	prevalence at 4-8	weeks:%(95%CI)	HIV-negative mothers
	weeks		who had HIV antibody
23.9 (21.8-25.9)	0.9 (0.4-1.5)	3.6 (1.4-5.8)	5.1 (3.6-6.7)

MTCT service uptake (PMTCT cascade) in the Limpopo

The PMTCT cascade shows that less than 70% of mothers received their CD4 cell count test result and 87.6% of HIV positive mothers received ARV prophylaxis or HAART. (Figure 10)

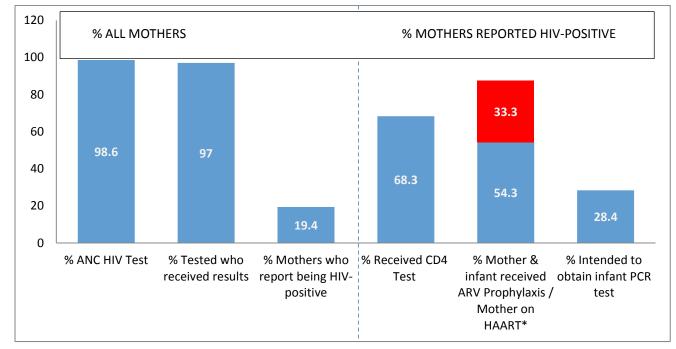


Figure 10 PMTCT service uptake (PMTCT cascade) in Limpopo

3.6.6 Mpumalanga

The SAPMTCTE attained 80% of targeted sample size in the province of Mpumalanga.

General Description of Provincial Sample

In Mpumalanga more than 80% of study participants have brick/cement block houses, piped water in house or yard, and electricity, paraffin or gas cooking fuel, but only 30.3% have a flush toilet. Only 8.9% described depletion of food supply in the past 12 months. (Table 15)

Table 15 Baseline characteristics of Mpumalanga SAPMTCTE survey participants

Characteristics	Categories	%	95% CI
Relationship to child	Mother	95.0	94.3-95.8
	Caregiver	5.0	4.2-5.7
Mean age of mother (Range)	25.3	3 (13-46)	
Infant gender	Male	50.3	48.1-52.5
	Female	49.7	47.5-51.9
Education of mother	None	3.0	2.3-3.7
	Grade 1-7	17.9	15.7-20.2
	Grade 8-12	75.2	72.9-77.5
	Above Grade 12	2.1	1.3-2.9
Marital status of mother	Single	74.8	72.6-77.1
	Married/cohabitating	23.9	21.7-26.2
Main building material of house	Brick/Cement block	85.7	82.5-88.9

Characteristics	Categories	%	95% CI
	Informal material	8.4	5.9-10.8
	Traditional material/mud	5.9	3.8-8.0
Main source of drinking water	Piped in house or yard	83.9	79.9-87.9
	Not piped in house or yard	16.1	12.1-20.1
Type of toilet	Flush toilet	30.3	23.9-36.7
	Pit latrine	66.5	60.1-72.8
	None	2.9	1.8-4.0
	Other	0.3	0.1-0.6
Main source of fuel	Electricity/Gas/Paraffin	88.3	65.6-77.2
	Other	11.7	22.8-34.4
Depletion of food supply in past 12	Yes	8.9	6.6-11.2
months	No	89.1	86.6-91.6

Infant HIV Exposure and MTCT Rate in Mpumalanga

Text Box 6 shows that infants' HIV-exposure was 37.0%, with a 3.0% early infant HIV infection prevalence and a 5.7% (95%CI: 4.5-7.9%) MTCT rate at 4-8 weeks. This is the second highest MTCT among South African provinces. Among infants whose mothers reported being HIV-negative 7.8% (95%CI: 5.8-9.7) were HIV-exposed, the highest among South African provinces (along with Eastern Cape).

Text Box 6: Mpumalanga HIV Infant Exposure and MTCT

Infant HIV Exposure %	Infant HIV infection	MTCT @ 4-8	%Infants of reported
(95%CI)	prevalence at 4-8	weeks:%(95%CI)	HIV-negative mothers
	weeks		who had HIV antibody
37.0 (34.3-39.7)	3.0 (2.1-3.8)	5.7 (4.1-7.3)	7.8 (5.8-9.7)

PMTCT service uptake (PMTCT cascade) in the Mpumalanga

Mpumalanga also had a high coverage of testing. (Figure 11) However the high rate of HIV-exposed infants whose mothers reported being HIV-negative suggests that these mothers and babies would not have received any ARV prophylaxis and this, coupled with the poor PMTCT cascade above (<70% mothers receiving CD4 cell count results; 83.6% receiving ARV prophylaxis or HAART and adherence to these regimens is not known i.e. 'effective coverage' is unknown) potentially explains the high MTCT rate in Mpumalanga province.

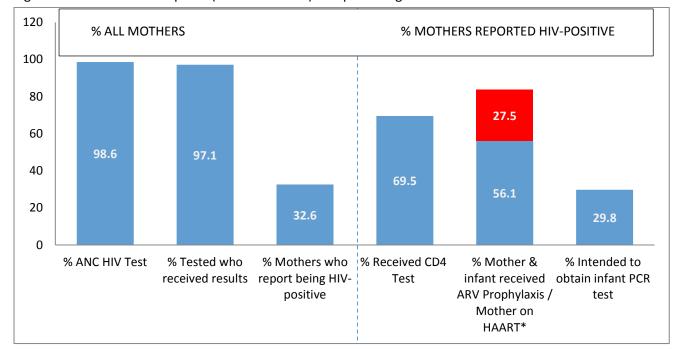


Figure 11 PMTCT service uptake (PMTCT cascade) in Mpumalanga

3.6.7 Northern Cape

Northern Cape achieved a sample realisation of 63%. This was due to a high number of medium-size clinics in the sample requiring disproportionate resources.

General Description of Provincial Sample

In Northern Cape 78.0% of mothers were single. More than 80% of families had Brick/Cement house, piped water and flush toilets. Only 10.9% reported depletion of food supply in the past 12 months (Table 16)

Table 16 Baseline characteristics of Northern Cape SAPMTCTE survey participants

Characteristics	Categories	%	95% CI
Relationship to child	Mother	97.6	96.7-98.5
	Caregiver	2.4	1.5-3.3
Mean age (range)	25.8 (1	.4-45)	
Infant gender	Male	48.9	46.1-51.7
	Female	51.1	48.3-53.9
Education of mother	None	3.5	2.6-4.4
	Grade 1-7	18.3	16.1-20.4
	Grade 8-12	74.3	71.8-76.9
	Above Grade 12	3.0	1.9-4.2
Marital status of mother	Single	78.0	75.0-81.1
	Married/cohabitating	21.1	18.0-24.1

Characteristics	Categories	%	95% CI
Main building material of house	Brick/Cement block	80.4	77.5-83.4
	Informal material	18.7	15.9-21.5
	Traditional material/mud	0.9	0.4-1.3
Main source of drinking water	Piped in house or yard	93.5	91.6-95.4
	Not piped in house or yard	6.5	4.6-8.4
Type of toilet	Flush toilet	87.6	85.1-90.1
	Pit latrine	7.8	5.9-9.8
	None	2.2	1.4-3.0
	Other	2.4	1.7-3.0
Main source of fuel	Electricity/Gas/Paraffin	97.6	96.7-98.5
	Other	2.4	1.5-3.3
Depletion of food supply in past 12	Yes	10.9	8.1-13.6
months	No	89.1	86.4-91.9

Infant HIV Exposure and MTCT Rate in the Northern Cape

Text Box 7 shows that infants' HIV-exposure was 16.0%, with a 0.3% early infant HIV infection prevalence and a 1.4% (95%CI: 0.1-3.4%) MTCT rate at 4-8 weeks. The larger confidence interval attached to this estimate is due to the smaller sample size attained in Northern Cape.

Text Box 7: Infant HIV Exposure and MTCT Rate Northern Cape

Infant HIV Exposure %	Infant HIV infection	MTCT @ 4-8	%Infants of reported
(95%CI)	prevalence at 4-8	weeks:%(95%CI)	HIV-negative mothers
	weeks		who had HIV antibody
16.0 (13.7-18.3)	0.3 (0.1-0.6)	1.4 (0.1-3.4)	2.2 (1.2-3.3)

PMTCT service uptake (PMTCT cascade) in the Northern Cape

Northern Cape has the lowest intended early infant diagnosis coverage of all provinces. Very few (1.6%) HI- positive mothers indicated an intention to receive infant testing service at the 6-week immunisation visit. However, the second highest CD4-cell count uptake is reported in the Northern Cape, at 88.7%. Other PMTCT cascade indicators of the province have above 90% coverage, similar to other provinces. The rate of maternal potential HIV acquisition was 2.2% (upper limit 3.2%). The low MTCT rate is likely due to the high coverage of the PMTCT cascade in Northern Cape and the lower HIV acquisition rate compared with other provinces.

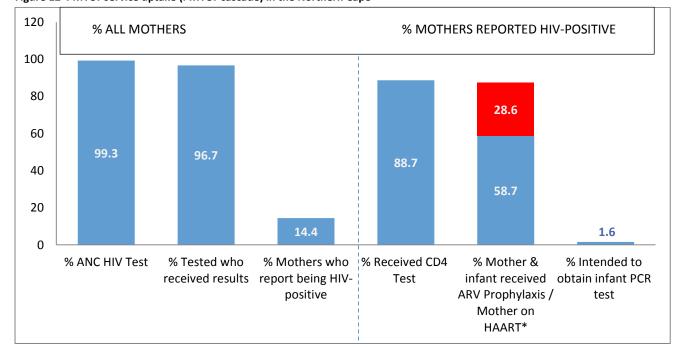


Figure 12 PMTCT service uptake (PMTCT cascade) in the Northern Cape

3.6.8 The North West Province

The SAPMTCTE in the North West province attained 98% of targeted sample size.

General Description of Provincial Sample

In North West province 83.1% of mothers were single. Just over 70% of families had brick/cement houses and piped water, but fewer than half had a flush toilet (44.1). Reported depletion of food supply in the last 12 months was 19.1%.

Table 17 Baseline characteristics of North West SAPMTCTE survey participants

Characteristics	Categories	%	95% CI
Relationship to child	Mother	97.0	96.1-97.9
	Caregiver	3.0	2.1-3.9
Mean age (range)	26.3 (1	4-46)	
Infant gender	Male	50.9	48.9-52.8
	Female	49.1	47.2-51.1
Education of mother	None	5.3	3.6-7.0
	Grade 1-7	19.1	16.1-22.0
	Grade 8-12	71.8	67.9-75.8
	Above Grade 12	3.3	2.2-4.4
Marital status of mother	Single	83.1	80.8-85.6
	Married/cohabitating	16.0	13.6-18.4
Main building material of house	Brick/Cement block	73.8	70.7-76.9

Characteristics	Categories	%	95% CI
	Informal material	24.0	21.1-26.9
	Traditional material/mud	2.2	1.2-3.1
Main source of drinking water	Piped in house or yard	75.9	71.3-80.4
	Not piped in house or yard	24.1	19.6-28.7
Type of toilet	Flush toilet	44.1	37.1-51.0
	Pit latrine	54.0	47.1-61.0
	None	1.3	0.8-1.9
	Other	0.6	0.1-1.0
Main source of fuel	Electricity/Gas/Paraffin	93.5	91.4-95.5
	Other	6.5	4.5-8.6
Depletion of food supply in past 12	Yes	19.1	16.4-21.7
months	No	80.6	78.0-83.3

Infant HIV Exposure and MTCT Rate in North West Province

Text Box 8 shows that infants' HIV-exposure was 31.3%, with a 1.9% early infant HIV infection prevalence and a 4.4 (95% CI 2.9-5.9%) MTCT rate at 4-8 weeks. Of infants whose mothers reported being HIV-negative 5.4% (95% CI 3.9-6.8%) were HIV-exposed.

Text Box 8: Infant HIV Exposure and MTCT Rate in North West Province

Infant HIV Exposure % (95%CI)	Infant HIV infection prevalence at 4-8	MTCT @ 4-8 weeks:%(95%CI)	% Infants of reported HIV-negative mothers
	weeks		who had HIV antibody
31.3 (29.0-33.5)	1.9 (1.2-2.5)	4.4 (2.9-5.9)	5.4 (3.9-6.8)

PMTCT Service Uptake (PMTCT cascade) in the North West Province

North West study participants had close to 100% HIV testing rate, but lower coverage of CD4 count (81.7%) and EID services. The province ranked as the second lowest in intended EID coverage. Only 3.6% of HIV-positive mothers in the sample intended to receive EID at the time of immunisation visit. The higher rate of infants with reported HIV-negative mothers who were HIV-exposed and who would not have received any PMTCT interventions, coupled with a only a 91.1% coverage of ARV prophylaxis / HAART may explain the somewhat higher MTCT rate measured in the North West province.

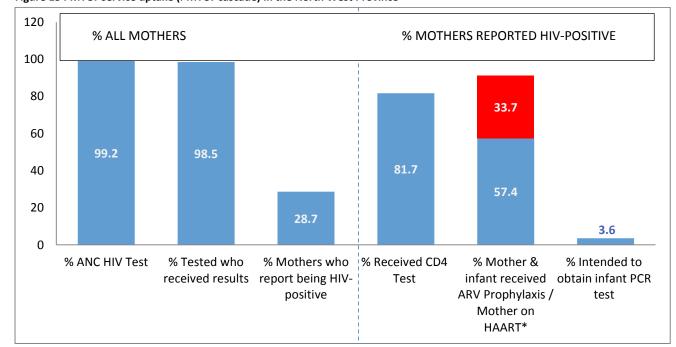


Figure 13 PMTCT service uptake (PMTCT cascade) in the North West Province

3.6.9 Western Cape

The SAPMTCTE in the Western Cape attained 99% of targeted sample size.

General Description of Provincial Sample

The majority of Western Cape participants reported use of piped water (in house) (93.9%), flush toilet (90.7%) and electricity, gas or paraffin (99.3%) for their fuel needs. However, a substantial percentage (31.1%) of the participants reported living in a house built from informal materials. A large percentage (26.1%) of respondents also reported that they experienced food shortage at least once in the last 12 months.

Table 18 Baseline characteristics of Western Cape SAPMTCTE survey participants

Characteristics	Categories	%	95% CI				
Relationship to child	Mother	97.1	96.3-97.9				
	Caregiver	2.9	2.1-3.7				
Mean age (range)	26.4 (14-47)						
Infant gender	Male	49.7	47.4-52.0				
	Female	50.3	48.0-52.6				
Education of mother	None	0.8	0.3-1.3				
	Grade 1-7	15.1	12.2-17.9				
	Grade 8-12	76.2	73.0-79.4				
	Above Grade 12	7.3	5.1-9.5				
Marital status of mother	Single	54.3	50.5-58.1				

Characteristics	Categories	%	95% CI
	Married/cohabitating	44.0	40.2-47.8
Main building material of house	Brick/Cement block	68.5	63.3-73.7
	Informal material	31.1	26.0-36.3
	Traditional material/mud	0.4	0.1-0.6
Main source of drinking water	Piped in house or yard	93.9	91.9-95.8
	Not piped in house or yard	6.1	4.2-8.0
Type of toilet	Flush toilet	90.7	88.4-93.0
	Pit latrine	5.6	3.5-7.7
	None	1.3	0.6-2.0
	Other	2.4	1.5-3.3
Main source of fuel	Electricity/Gas/Paraffin	99.3	99.0-99.7
	Other	0.7	0.3-1.0
Depletion of food supply in past 12	Yes	26.1	22.9-29.2
months	No	73.0	69.9-76.0

Infant HIV Exposure and MTCT Rate in Western Cape

Text Box 9 shows that infants' HIV-exposure was 21.0%, with a 0.9% early infant HIV infection prevalence and a 3.9% (95% CI 1.9-5.8%) MTCT rate at 4-8 weeks. The percent of HIV-exposed infants whose mothers reported being HIV-negative was the lowest in the Western Cape at 1.1%.

Text Box 9: Infant HIV Exposure and MTCT Rate in Western Cape

Infant HIV Exposure %	Infant HIV infection	MTCT @ 4-8	%Infants of reported
(95%CI)	prevalence at 4-8	weeks:%(95%CI)	HIV-negative mothers
	weeks		who had HIV antibody
21.0 (30.7-33.3)	0.9 (0.4-1.5)	3.9 (1.9-5.8)	1.1 (0.3-1.9)

PMTCT service uptake (PMTCT cascade) in the Western Cape

The Western Cape had close to 100% (98.8%) antenatal HIV testing rate. Almost all (98.7%) mothers who had antenatal HIV testing received their result. About 94.2% of the HIV-positive mothers were on either HAART or ARV prophylaxis (including infant prophylaxis if mother is not on HAART). Similar to other provinces, the majority of the mothers did not plan to receive EID services during the sixweek immunisation visit.

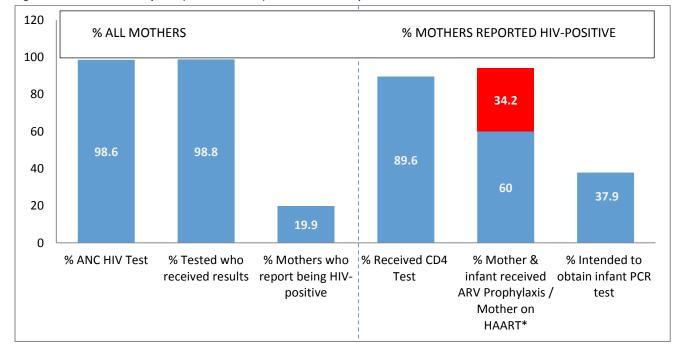


Figure 14 PMTCT service uptake (PMTCT cascade) in the Western Cape Province

3.7 Infant Feeding

HIV-positive mothers who recalled receiving infant feeding counselling during antenatal care was 89.2% with a range from 77.9% in Limpopo to 92.4% in Gauteng and KwaZulu-Natal.

Among <u>all</u> infants (regardless of HIV exposure status) 44.8% (95% CI 43.23-46.3%) were mixed breastfeeding; 28.0% (95% CI 25.6-29.4%) were exclusively breastfed in the 8 days prior to the 4-8 week interview and 27.2% (95% CI 26.1-28.3%) received no breast milk.

We categorised HIV-exposed infants who received breast milk plus any other milk or food (not including prescribed medicines) over the past eight days as being at-risk as they were practicing mixed breastfeeding. This ranged from a low of 7.0% in the Western Cape to a high of 32.8% in Limpopo, with a national average of 18.1% (Table 19). It is interesting to note that the province with the lowest rate of infant feeding counselling had high rates of at risk infant feeding in HIV-exposed infants.

Table 19 Infant feeding practices amongst HIV exposed infants over the past 8 days by province

Province	Mother reportedly received infant feeding counseling during ANC % (95% CI)	At Risk/ Mixed Feeding % (95% CI)
Eastern Cape	82.4 (76.1-88.8)	20.3 (16.6-23.9)
Free State	91.6 (88.7-94.6)	22.9 (19.1-26.8)
Gauteng	92.4 (89.7-95.1)	14.8 (11.4-18.1)
KwaZulu-Natal	92.4 (90.0-94.8)	14.0 (10.5-17.5)
Limpopo	77.9 (72.0-83.7)	32.8 (27.0-38.7)
Mpumalanga	91.5 (88.4-94.6)	29.7 (26.0-33.4)
Northern Cape	81.0 (73.3-88.6)	23.9 (16.1-31.8)
North West	81.5 (76.1-86.8)	21.3 (17.5-25.1)
Western Cape	85.3 (80.5-90.1)	7.0 (4.3-9.6)
South Africa	89.2 (87.8-90.6)	18.1 (16.5-19.7)

Among mothers of HIV-exposed infants 20.4% (95% CI 18.5-22.3%) were practicing exclusive breast feeding (EBF), 61.5 (59.2-63.8) formula feeding (no breast milk) and 18.1% (95% CI 16.5-19.7%) mixed breast feeding in the eight days prior to the interview. Among non-breastfed HIV-exposed infants, none were exclusively formula fed (i.e., non-breastfed infants were always given something else such as water, traditional medicines or solids).

Comparing feeding rates in HIV-exposed infants across provinces shows most provinces falling in the national average except Northern Cape and Western Cape. The Northern Cape had the highest rate of exclusive breast feeding rate (43.7%; 95% CI 37.0-50.3) and the lowest formula feeding (no breast milk) (32.4%; 95% CI 26.3-38.5), while the Western Cape had the lowest EBF rate of only 7.9% (95% CI 5.3-10.4) and the highest formula feeding at 85.1% (95% CI 81.3-89.0). It should be noted that 'no breastmilk' does not imply formula feeding only without other fluids or foods as highlighted above.

4.1 Infant HIV Exposure

Figure 15 indicates the 2010 maternal HIV prevalence in mothers from the antenatal sentinel surveillance by province (NDOH, 2011). There is close agreement with the SAPMTCTE provincial level estimates of presumed maternal HIV prevalence based on HIV antibody found in infant DBS.

The national rate for the SAPMTCTE was 32.0% with a 95% confidence interval of 30.7-33.3%, which is consistent with the ANC sentinel surveillance estimate of 30.2% (95% CI 29.4-30.9) from 2010. As would be expected the SAPMTCTE result is slightly higher as it is taken 6 weeks postnatal rather than early pregnancy considering that some women will seroconvert during pregnancy. The similarity between the SAPMTCTE and the ANC Sentinel Surveillance data lend strong validity to the SAPMTCTE results as they are consistent with national and provincial representative maternal HIV prevalence estimates.

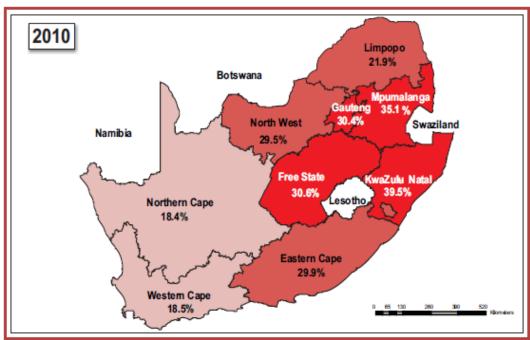


Figure 15 Maternal antenatal HIV prevalence by province in South Africa

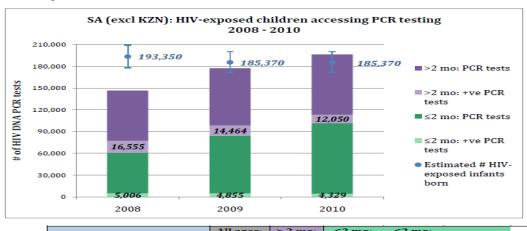
4.2 Mother-to-Child Transmission of HIV

Figure 16 presents data from the National Health Laboratory Service (NHLS) DNA PCR data warehouse (Personal Communication, Prof. Gayle Sherman, 2011) for infants less than 2 months old. These estimates do not include KwaZulu-Natal nor do they include secondary and tertiary hospital data. Nevertheless the results are similar to the SAPMTCTE data and indicate a sharply decreasing trend in MTCT in the past three years which is very encouraging. Additional analysis of NHLS data including data from KwaZulu-Natal, and restricting data to quarters 3 and 4 of 2010 (same time period as this survey) suggest positive DNA PCR rates of 3.5% which further declines to 3.2% when

only primary health care facilities are considered. SAPMTCTE 4-8 week results are therefore consistent with NHLS routine data. While these different data sources have varying methods, limitations and strengths the underlying message is that MTCT has reduced substantially in South Africa over the past three years and at present is less than 5%.

Figure 16 NHLS Early Infant Diagnosis PCR <2 months old 2008-2010 (from Sherman, 2010)

HIV PCR TESTING PERFORMED NATIONALLY (EXCLUDING KWAZULU NATAL) 2008 – 2010:



		Estimated # HIV-exposed infants born	All ages: Total tests	> 2 mo: Total tests	≤2 mo: Total tests	≤2 mo: Positive tests	≤2 mo: % positivity	EID coverage
2	2008	193 350 (178 031 - 209 024)	146 514	85 755	60 759	5 006	8.2%	31.4%
2	2009	185 370 (171 407 - 200 144)	177 329	93 494	83 835	4 855	5.8%	45.2%
2	2010	185 370 (171 407 - 200 144)	196 254	94 935	101 319	4 329	4.3%	54.7%

The MTCT rate measured at six weeks in recent PMTCT studies (not operational settings) using somewhat similar regimens to the South African 2010 PMTCT policy include:

- SWEN (2008) Sd NVP peripartum and daily in infant until 6 weeks; 2.5% MTCT at 6 weeks;
- Mitra (Kilewo et.al., 2008) -ZDV/3TC peripartum and 3TC postnatally; MTCT 3.8% at 6 weeks); and
- Kesho Bora (2011) AZT/NVP in mothers vs. HAART for mothers; MTCT 5.0% versus 3.3% respectively at 6 weeks).

The SAPMTCTE results compare favourably with these results. Achievement of results similar to trials in a national PMTCT programme is very encouraging.

Provincial Variation in MTCT

There was a greater than 4-fold difference in MTCT across the 9 provinces in South Africa, ranging from 1.4 in Northern Cape to 5.9 in the Free State. The provincial variation in MTCT is probably due to the differences in 'effective coverage' and quality of the PMTCT programme including uptake of C4 cell count testing results, repeat HIV testing at 32 weeks, appropriate ARV prophylaxis/HAART for HIV-positive women, and adherence to PMTCT regimens. More detailed explorations of quality and adherence to PMTCT prophylaxis or HAART is needed to understand MTCT rates in some of the provinces such as Free State.

Maternal potential HIV acquisition also varies across provinces and somewhat mirrors MTCT rates. Mothers who report being HIV-negative but are in fact HIV-positive are at higher risk of transmission as they would not have accessed ARV therapy in the perinatal period and if they actually acquired a new infection during pregnancy they are at particularly high risk of transmission.

4.3 PMTCT Cascade

Missed opportunities along the PMTCT cascade of services (Stringer et.al., 2003) can reduce both the coverage and quality of the PMTCT programme. HIV Testing in ANC clinics is the entry point into the PMTCT programme. High coverage of this and each subsequent step reduces missed opportunities for care. In this study, ANC HIV testing and receipt of results by mothers were almost universal 98.8% but services further along the cascade were not as high, with only 78.3% of HIV-positive mothers getting a CD4 count. A percentage of 91.8% of mothers and infants received ARV prophylaxis or treatment according to protocol. However, this data does show improvement over a previous report from KwaZulu-Natal where prior to a quality improvement intervention only 85% of women were tested in ANC, 40% received a CD4 test and only 15% were given appropriate ARV prophylaxis (Doherty et.al., 2009). After the intervention, the data from the Doherty study was comparable to the SAPMTCTE with 98% ANC HIV testing, 97% CD4 testing and 68% appropriate ARV prophylaxis. There has been an effort in South Africa in the last few years to improve the PMTCT programme through interventions like the one described by Doherty et.al. (2009) as well as others (e.g. Best Practices in Prevention of Mother-to-Child Transmission (PMTCT) of HIV South Africa; NDOH/MRC/UWC/UNICEF/USAID, 2009). These efforts are clearly impacting PMTCT, as shown by programme indicators and infant outcomes (early MTCT) as described in this report.

Of *ALL* mothers enrolled in the survey, 29.4% reported being HIV-positive while HIV antibody was found in 32% of *ALL* infants. Of concern is that of those *mothers who reported being HIV negative*, 4.1% of their infants had HIV antibodies, suggesting a high rate of maternal potential acquisition of HIV infection during pregnancy. This rate also varied substantially across provinces from a low of 1.1% in the Western Cape to a high of 7.8% in Mpumalanga and Eastern Cape. The indicator 'Maternal potential HIV acquisition' is a combination of the following scenarios:

- (i) Mothers do not wish to admit being HIV-positive and reported being HIV negative. The 2010 data show that refusals for infant HIV testing were low and disclosure was high; thus the contribution that this scenario makes to the indicator is probably minimal.
- (ii) Mothers were tested during the window period.
- (iii) Poor QC/performance of rapid tests in the field caused false negative results at ANC on HIV-infected women. Reported field sensitivities are as low as 87% to 95% depending on the rapid test.
- (iv) True acquisition of HIV after the last HIV test which for most mothers was during pregnancy.

Regardless of the cause this group of women and infants represent a substantial missed opportunity for care as the mothers and infants did not receive ARV prophylaxis or appropriate counselling. The high rate of maternal potential HIV acquisition is also worrying as it is higher than previously reported (3%) in a study conducted in KwaZulu-Natal (Moodley et al., 2009).

4.4 Early Infant Diagnosis

Intention to obtain a PCR test for their infant in reported HIV-positive mothers is only just above one-third. This low figure is very concerning. While Provider Initiated Testing and Counseling (PITC) in the six week immunisation clinic should note infant's HIV-exposure on the Road-to-Health Card and offer infant PCR testing, the NHLS data, Figure 16 suggests recent coverage is only just above half of what would be expected. This study could not measure EID rates as the study tested all infants present in a clinic and took the place of the routine EID programme during the period of the study in each clinic. However, low intention by mothers to obtain early infant HIV testing combined with other missed opportunities along the PMTCT cascade noted in this report and the low reported coverage by NHLS suggest that universal offer of testing (PITC) for all infants at 6 weeks of age, linked with the six-week immunisations, may reduce missed opportunities to identify HIV-positive infants in need of ARV therapy.

4.5 Infant Feeding

Infant feeding per caregiver recall for the past 8 days suggests substantial mixed breastfeeding regardless of HIV status of the mother. This is very consistent with other sources of data for South Africa (NDOH/MRC, 2003; Tylleskar et al., 2011) and is of great concern. Poor infant feeding can be expected to result in higher postnatal transmission of HIV after the 4-8 weeks of age and increased infant morbidity and mortality. So while the decrease in MTCT seen in the 4-8 week period is very encouraging, these gains could be negated through poor infant feeding and postnatal transmission. Infant feeding needs to be urgently addressed and postnatal transmission and HIV-free survival urgently need to me measured and monitored in order to track progress to meet national strategic goals of less than 5% MTCT overall. Improved infant feeding counselling should assist with this goal. It was very interesting to note, in our data, that the Limpopo province which had the lowest reported infant feeding counseling for HIV-positive mothers also had the highest rate of mixed/atrisk infant feeding.

5. STRENGTHS AND LIMITATIONS OF SAPMTCTE

Strengths

This evaluation provides estimates using a national and provincial population-based representative sample of infants 4-8 weeks of age. It also provides data on indicators of the PMTCT programme and potential maternal sero-conversion during pregnancy.

Limitations

The following limitations are found in this survey:

The data is facility-based using infants presenting for immunisation. Infants who do not come for immunisation or have already died by 6 weeks of age are not included in the sample suggesting a possible under-estimation of infant HIV infection prevalence.

Maternal Incidence (sero-conversion during pregnancy) was based on self-reports of previous HIV-negative status and presence of HIV antibodies in infant ELISA test. Mothers may not accurately report their previous HIV status for a variety of reasons, such as fear of stigma and disclosure. Confidentiality was assured and discussed as part of the informed consent process and a private place was secured for the conduct of interviews in an attempt to reduce this potential limitation.

Coverage of PMTCT programme indicators was via maternal recall and was not verified with maternal antenatal or intrapartum records, however the recall period was relatively short (generally less than 3-6 months).

Two-stage cluster random sampling was used. The primary sampling unit was primary health care clinics reporting at least 130 immunisations per year from the 2007 DHIS data. Therefore this sample excluded smaller primary health care facilities due to logistic reasons and secondary and tertiary facilities, mobile clinics and other facilities in order to focus on PMTCT in the primary health care services. Therefore this survey is not representative of these excluded facilities.

Finally, this survey was conducted from June to December 2010. The new PMTCT guidelines were introduced in April 2010 so most facilities would likely have been in transition to the new guidelines during the period of the study. This survey was not meant to measure efficacy of any particular protocol or PMTCT ARV regimen but only to evaluate the performance of the overall PMTCT programme as implemented during the time of the study using MTCT at 6 weeks of infant age as the outcome measure. Also since the survey outcome is at 6 weeks of infant age, postnatal transmission of HIV is not measured in this study.

6. CONCLUSION AND RECOMMENDATIONS

Based on the 2010 SAPMTCT evaluation (the first national evaluation of the PMTCT programme in South Africa), the National PMTCT programme resulted in 3.5% national MTCT rate in pregnancy and intrapartum. A reduction is noted from the approximately 30% transmission that would occur during pregnancy, labour and delivery in the absence of PMTCT interventions. A decreasing trend in MTCT is also shown by the NHLS data. This could contribute towards a reduction in HIV-incident infection at a population level and to virtual paediatric HIV elimination, providing postnatal PMTCT interventions are intensified.

The approximately greater than four-fold difference in MTCT rate across provinces (1.4% to 5.9%) is likely due to the differences in the quality of the PMTCT programme across provinces, including different PMTCT coverage of ARV prophylaxis and HAART, and substantial differences in HIV-exposed infants whose mothers reported being HIV-negative as these infants are potentially as highest risk and did not benefit from appropriate ARV prophylaxis.

Maternal potential HIV acquisition during pregnancy was potentially high at 4%, necessitating an intensification of the policy of repeat testing at 32 weeks and implementation of couple testing to identify discordant couples and counsel them about HIV prevention. Further data should to be collected to assess the contribution of false negative rapid test results to maternal potential HIV acquisition and work is needed to improve the quality of rapid HIV testing in the field.

Infant HIV test uptake was high if offered to all caregivers bringing their infants for six week immunisation (92% in the SAPMTCT survey versus 55% who come for HIV testing and are captured by NHLS data). The high acceptance of infant HIV testing among SAPMTCTE participants highlights the need to review infant HIV testing strategies so that provider-initiated early infant testing is offered at all six-week immunisation visits and at all child health service delivery points. This will increase EID coverage and provide PMTCT to unknown HIV-exposed infant

The poor feeding practices during the first 6 weeks postpartum highlights the need to strengthen infant feeding counselling, adherence to postnatal prophylaxis and to monitor MTCT and HIV- free survival from 6 weeks to 18 months and HIV-free survival beyond six weeks.

Although the data suggests a greater than 80% reduction in MTCT from 25% - 30% (no PMTCT interventions) to 3.5%, virtual paediatric HIV elimination will only be possible with intensified efforts and a change in approach towards infant feeding. Estimated targets to reach the 2015 South African national targets would be MTCT rates of less than 2% at 6 weeks and less than 5% at 18 months (WHO/UNICEF/UNFPA/UNAIDS, 2011). Gaps in effective PMTCT coverage for all steps in the PMTCT cascade need to be addressed, and postnatal MTCT must be prevented through improved infant feeding and expanded coverage of the postnatal prophylaxis programme.

Further work by the SAPMTCTE Study Group supported by the National Department of Health will be conducted in 2011 and 2012 to track progress with MTCT reduction at six weeks and to track progress with MTCT reduction between six weeks and 18 months.

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CO-INVESTIGATORS: SAPMTCTE STUDY GROUP

Principal Investigators

- Ameena Goga
- Thu-Ha Dinh
- Debra Jackson

Medical Research Council

- Carl Lombard (Statistician)
- Selamawit Woldesenbet
- Vundli Ramokolo
- Wesley Solomon
- Nothemba Kula
- Tanya Doherty

National Department of Health:

- Yogan Pillay.
- Thabang Mosala.
- Nonhlanla Dlamini

NICD/NHLS

- Gayle Sherman.
- Adrian Puren.

University of the Western Cape:

• Wondwossen Lerebo.

UNICEF:

• Siobhan Crowley

PEPFAR/CDC:

- Thurma Goldman
- Jeffrey Klausner
- Katherine Robinson

Provincial Departments of Health, South Africa

TECHNICAL ADVISORS:

- Mickey Chopra UNICEF
- Nathan Shaffer WHO

APPENDIX I: SAMPLE SIZE AND SAMPLING

(See next page)

SAMPLE SIZE CALCULATION BY PROVINCE

	Antenatal HIV Prevalence 2007	% antenatal HIV test (%)	% admin of PMTCT to babies	Estimated Coverage (prevalence X %tested X %admin to baby)	Est. not Covered	Transmission Rate in exposed assuming SD NVP MTCT=15% & untreated MTCT=29% (Rollins)*	Overall Population Prevalence per 100 kids	Same precision across province	Same relative precision across province (%)	sample size for 30% relative precision	Sample size for design effect** of 2 & relative precision 30%	Overall population prevalence per 100 kids (%)	Varying precisio n by province	Varying relative precisio n by province (%)	Sample size using varying precisio n level without design effect	Sample size using varying precisio n level with design effect** of 2
SA	29	67	47	31.5%	68.5%	24.6%	7.1%	2.1	30	575	1150					
11104					0= 00/	40.00/	4.00/			4000	22-2			_,	-10	4.400
WC*	15	97	75	72.8%	27.3%	13.0%	1.9%	0.6	30	1989	3978	1.9	1.0	51	716	1400
NC	14	81	70	56.7%	43.3%	21.1%	2.9%	0.9	30	1336	2672	2.9	1.8	60	350	700
EC	24	73	35	25.6%	74.5%	25.4%	6.1%	1.8	30	680	1360	6.1	1.8	30	700	1400
FS	29	70	52	36.4%	63.6%	23.9%	6.9%	2.1	30	560	1120	6.9	2.0	29	617	1300
KZN	37	66	52	34.3%	65.7%	21.4%	7.9%	2.4	30	485	970	7.9	2.0	25	699	1400
MP	34	56	36	20.2%	79.8%	26.2%	8.9%	2.7	30	428	856	8.9	2.0	22	779	1600
LP	20	74	54	40.0%	60.0%	23.4%	4.7%	1.4	30	878	1756	4.7	1.5	32	703	1400
NW	29.9	86	50	43.0%	57.0%	23.0%	6.9%	2.1	30	560	1119	6.9	2.0	29	601	1200
GP	31	65	27	17.6%	82.5%	26.5%	8.2%	2.5	30	463	926	8.2	2.0	24	723	1800
Total										7379	14758					12200

ANC Prevalence & Coverage Data from DHIS

^{*}WC & KZN assume full coverage dual therapy - Rollins KZN Study is 7%

^{**} Design Effect = 1+(100-1)*(ICC=.01)=2

SAMPLING

Table 3 - number of facilities needed to be sampled from each province to collect data within 3wks (4 weeks for Northern Cape) duration from each facility. Note DTP1 = 1st DTP

WESTERN CAPE

Strata	Total Annual DTPDTP#	Percentage	Sample Size Proportional	Median Yearly Clinic DTP1 Number	Media 3-week Clinic DTP1 Number	Number of Facilities to be Visited
Small clinics (< 130 DTPDTP1#)	4537					20
Medium size clinics (130-300 annual DTPDTP1#)	15953	17.85	250	192	11	23
Large size (annual DTPDTP1 #>300) but low prev clinics	62884	70.38	985	535	31	32
Large size (annual DTPDTP1 #>300) but high prev clinics	10517	11.77	165	857	49	3
Overall Total	89354	100	1400			58 (or 78 if small facilities are included)

EASTERN CAPE

Strata	Total Annual DTPDTP for the province	Percentage	Adjusted Percentage	Sample size proportional	Sample size adjusted proportional	Median yearly clinic DTP1 number	Median 3 week clinic DTP1 number	number of facilities need to be visited	Number of facilities that should be visited based on adjusted distribution
Small clinics (<130 DTPDTP1#)	25862							20	20
Medium size clinics (130-300 annual DTP1#)	41620	36.38	30	509	420	186.5	11	47	39
large size (Annual DTP1 #>300) but low prev clinics	41646	36.40	43	510	602	459	26	19	23
large size (Annual DTP1 #>300) but high prev clinics	31141	27	27	381	378	402	23	16	16
Overall Total	114407	100	100	1400	1400			83	78 (or 98 if small facilities are included)

FREE STATE

Strata	Total Annual DTP for the province	Percentage	Sample size proportional	Median yearly clinic DTP1 number	Median 3 week clinic DTP1 number	number of facilities need to be visited
Small clinics (<130 DTP1#)	4880					20
Medium size clinics (130-300 annual DTP1#)	14418	27.34%	355	201	12	31
large size (Annual DTP1 #>300) but high prev clinics	38326	72.66%	945	404	23	41
Overall Total	52744	100%	1300			72 (or 92 if small facilities are included)

GAUTENG

Strata	Total Annual DTP for the province	Percentage	Sample size proportional	Median yearly clinic DTP1 number	Median 3 week clinic DTP1 number	number of facilities need to be visited
Small clinics (<130 DTP1#)	1926					20
Medium size clinics (130-300 annual DTP1#)	15359	8.95%	161	237.5	14	12
Large size (Annual DTP1 #>300) but low prev clinics	33023	19.25%	347	549	32	11
Large size (Annual DTP1 #>300) but high prev clinics	123199	71.80%	1292	629	36	36
Overall Total	171581	100%	1800			59 (or 79 if small facilities are included)

KWAZULU-NATAL

Strata	Total Annual DTP for the province	Percentage	Sample size proportional	Median yearly clinic DTP1 number	Median 3 week clinic DTP1 number	number of facilities need to be visited
Small clinics (<130 DTP1#)	7365					20
Medium size clinics (130-300						
annual DTP1#)	40070	20.84%	292	209	12	24
large size (Annual DTP1						
#>300) but low prev clinics	6505	3.38%	47	536.5	31	2
large size (Annual DTP1						
#>300) but high prev clinics	145661	75.77%	1061	483	28	38
						64 (or 84 if small
Over all Total	192236	100%	1400			facilities are included)

LIMPOPO

Strata	Total Annual DTP for the province	Percentage	Sample size proportional	Median yearly clinic DTP1 number	Median 3 week clinic DTP1 number	number of facilities need to be visited
Small clinics (<130 DTP1#)	7166					20
Medium size clinics (130-300 annual DTP1#)	41027	33.89%	474	206	12	40
large size (Annual DTP1 #>300) but low prev clinics	80048	66.11%	926	470.5	27	34
large size (Annual DTP1 #>300) but high prev clinics	0	0.00%	0		0	0
Over all Total	121075	100%	1400			74 (or 94 if small facilities are included)

MPUMALANGA

Strata	Total Annual DTP for the province	Percentage	Adjusted percentage	Sample size proportional	Sample size adjusted proportional	Median yearly clinic DTPDTP1 number	Median 3 week clinic DTPDTP1 number	number of facilities need to be visited	number of facilities need to be visited based on adjusted distribution
Small clinics (<130 DTP1#)	4545							20	
Medium size clinics (130-300 annual DTP1#)	20858	26.73%	20%	428	320	225	13	33	25
large size (Annual DTP1 #>300) but low prev clinics	0	0.00%		0	0	0	0	0	0
large size (Annual DTP1 #>300) but high prev clinics	57172	73.27%	80%	1172	1280	439	25	46	51
Overall Total	78030	100%	100%	1600	1600			79	76

NORTHERN CAPE

Strata	Total Annual DTP for the province	Percentage	Sample size proportional	Median yearly clinic DTP1 number	Median 4 week clinic DTP1 number	number of facilities need to be visited
Small clinics (<130 DTP1#)	2475					20
Medium size clinics (130-300 annual DTP1#)	7766	51.82%	363	207.5	16	23
large size (Annual DTP1 #>300) but low prev clinics	7221	48.18%	337	400	32	11
large size (Annual DTP1 #>300) but high prev clinics	0	0.00%	0		0	
Overall Total	14987	100%	700			34 (or 54 if small facilities are included)

NORTH WEST

Strata	Total Annual DTP for the province	Percentage	Sample size proportional	Median yearly clinic DTP1 number	Median 3 week clinic DTP1 number	number of facilities need to be visited
Small clinics (<130 DTP1#)	8758					20
Medium size clinics (130-300 annual DTP1#)	22925	34.26%	411	204.5	12	35
large size (Annual DTP1 #>300) but low prev clinics	24100	36.02%	432	413	24	18
large size (Annual DTP1 #>300) but high prev clinics	19887	29.72%	357	432.5	25	14
Over all Total	66912	100%	1200			67 (or 87 if small facilities are included)

Each province was divided into three strata:

- Stratum 1 includes clinics and CHCs that have annual Dtp1st dose 130-300 based on the 2007 DHIS data.
- Stratum 2 includes clinics & CHCs with 300 and above Dtp1st dose & HIV prevalence below the national (<29%) rate based on the 2007 DHIS and 2008 antenatal survey data respectively.
- Stratum 3 includes clinics & CHCs with 300 & above Dtp1st dose (based on the 2007 DHIS data) & HIV prevalence above the national rate based on the 2007 DHIS data & 2008 antenatal survey data respectively.

In the small facilities stratum, 20 facilities were selected for situational analysis. Out of these 20 facilities only 10 were selected based on the feedback from the situational analysis.

Provinces that do not have the third stratum

Western Cape, Limpopo and Northern Cape do not have a third stratum: there is no district with >29% HIV prevalence and high delivery rate (>300 immunisation) in these provinces. However, for Western Cape, we had a sub-district level data from the ANC survey, which indicated that Khayelitsha sub-district has more than 29% HIV prevalence. So, the third stratum was created from large clinics in Khayelitsha. We were not able to do the same for Limpopo and Northern Cape, as we did not have sub-district level HIV prevalence data (from the ANC survey) for the two provinces.

Reduced sample size for Northern Cape to 700

There were 96 facilities that could be sampled in the Northern Cape; but logistically 96 clinics was not an achievable target within the allocated time. Consequently the researchers reduced the number of facilities that needed to be visited to 53.

Adjusting weighting for Mpumalanga and Eastern Cape

The number of facilities needed to be sampled for Mpumalanga and Eastern Cape was 79 and 83 respectively. In addition, most of the facilities were from medium sized clinics. As this might be difficult to achieve with available logistics capacity, we slightly shifted the weighting to the large clinics (see column D), hence the number of facilities needed to be sampled from medium facilities decreased from 47 to 39 for the Eastern Cape and from 33 to 25 for Mpumalanga (see column J). This was logistically feasible.

In Free state, we had only two strata - we grouped the last two strata as one stratum. The second strata (large and low HIV prevalence clinics) in Free state had only 0.74% weighting which translates to sampling only 1 facility from the second stratum. Since sampling cannot be done for one facility, the second stratum is combined with the third stratum thus we have only two strata for Free state.

EVALUATION OF THE EFFECTIVENESS OF THE NATIONAL PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT) PROGRAMME ON INFANT HIV MEASURED AT SIX WEEKS POSTPARTUM IN SOUTH AFRICA

