Southern African HIV Clinicians Society

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Our Issues, Our Drugs, Our Patients

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Linking mothers with the diagnosis and care of HIV-exposed infants

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15TH APRIL 2016

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Overview

- Background and Methods
- Linking/Identifying the delivering mother
- Birth diagnosis of the HIV-exposed neonate
- Care of the HIV-infected neonate
- Links to later testing

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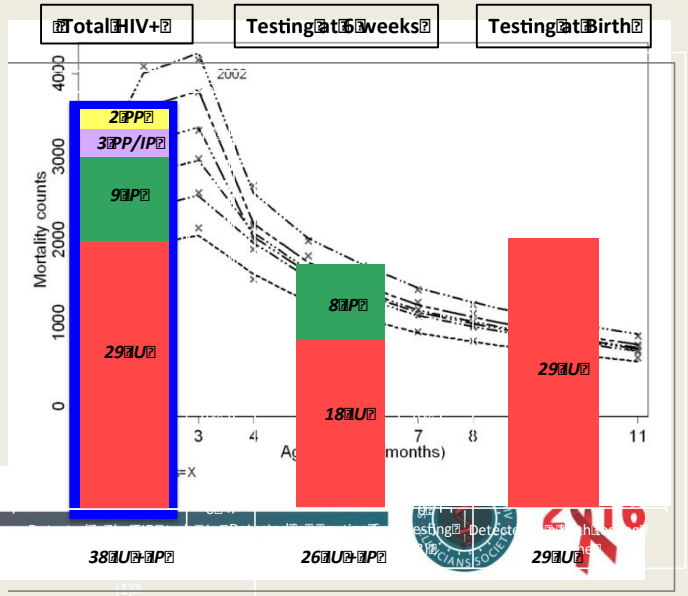
Origins of birth diagnosis

2002-2007: Sd Nevirapine, maternal ART as of 2004/2005 if CD4<200
2008-2010: Mum: CD4<200 → HAART; CD4>=200 → AZT from 28 weeks + sd NVP at labor;
Baby: Sd NVP at birth + 7 day AZT. HIV test at 4-6 weeks
April 2010: HAART (≤350 CD4) or AZT from 14 weeks + Infant NVP for 6 weeks or thro' BF
April 2013: HAART(FDC) to all mothers from time of diagnosis to the end of breastfeeding + Infant 6 weeks NVP
January 2015: HAART (FDC) to all mothers life long, 6-12 weeks NVP to baby, +/- AZT

- Transmission has moved from 20-40% down to 2%
- Early peak of mortality remains
- Changing ratio of IU/IP infection
- Late ART initiation, high mortality
  - Despite 6 week testing
  - Birth testing therefore started



Context of the project

- Mother and Child Hospital with busy maternity (~1000 deliveries/month, approximate HIV prevalence: 23%)
- Initially targeted testing (Sept 2013-May 2014)
- **Expanded to universal testing (June 2014 – ongoing), today's focus**
- Ethics approval – University of the Witwatersrand, support of the Department of Health
- Associated project of concurrent POC testing since October 2014
- Early treatment studies for all identified infants – not discussed here

General Objectives

- Ensure all **HIV-exposed infants** and their **HIV-positive mothers** are identified
- Ensure all **HIV-infected infants** with detection possible at birth are identified
- Ensure all identified infected infants are **linked to care**
- Ensure all infants remain in care and **achieve long term suppression** while their **mothers remain healthy**

Specific Objectives

- Assess **feasibility** of doing **diagnostic birth testing** at hospital with busy maternity
- Assess **transmission rate** and **risk factors for transmission** at birth
- Assess **success of linking infants to care**

Logistic Structure / Methods

- Systematic process to determine maternal HIV status
  - Maternal interview, record review (midwives/counselors)
  - Identify known positive mothers – detailed interview/consent for birth testing
  - Identify mothers of unknown status
  - Identify mothers with negative status – note guideline change during project
- Adequate numbers of trained staff
  - Counselors, nurses, phlebotomist, data capturers
- Registers and electronic database to document testing activities and results
- Protocols and systems to manage newly identified HIV+ moms/babies
  - Ensure results are received, returned to mothers, addressed by clinicians, maternal and infant ARVs initiated

Staffing for newborn HIV diagnostic testing program at RMMCH

- Screening ±900 women per month, 30/day **(Mon-Sun)**
  - Brief interview to ascertain HIV status
  - HIV test for women with negative or unknown status
  - Requires counselling and data-capturing staff who work hand-in-hand with birth testing/counselling staff
- ~200 HIV-exposed deliveries/month, 8-10/day
  - 4 full-time counselors: counsel mothers on postnatal ward 7 days/week – detailed interview (coping/PMTCT processes/feeding)
  - 1 full-time nurse: supervise counselors, draw blood
  - 2 data-capturers: reporting, results retrieval, patient tracking
  - *Weekly* clinic where moms obtain results (Integrated with routine ARV/EID clinic)
  - Need to ensure weekend testing coverage
- Birth/Delivery is a potential focal point for assessment of maternal care up to then and appropriate onward referral for both mother and baby

Logistic Structure / Methods

- Infant exam
  - Ballard score to assess physical maturity/gestation
- Infant Blood test
  - Standard of Care – PCR test sent to laboratory, 0.5 ml EDTA whole blood - Roche COBAS® TaqMan® HIV-1 Qualitative Test (Version 2)
  - Study Procedure 1 – Dried Blood Spot (DBS) collection – purpose – additional sample for diagnostic dilemmas
  - Study Procedure 2 – PCR test sent to on site POINT of CARE laboratory for Genexpert test, 0.5 ml EDTA whole blood - Xpert® HIV-1 Qual - Cepheid

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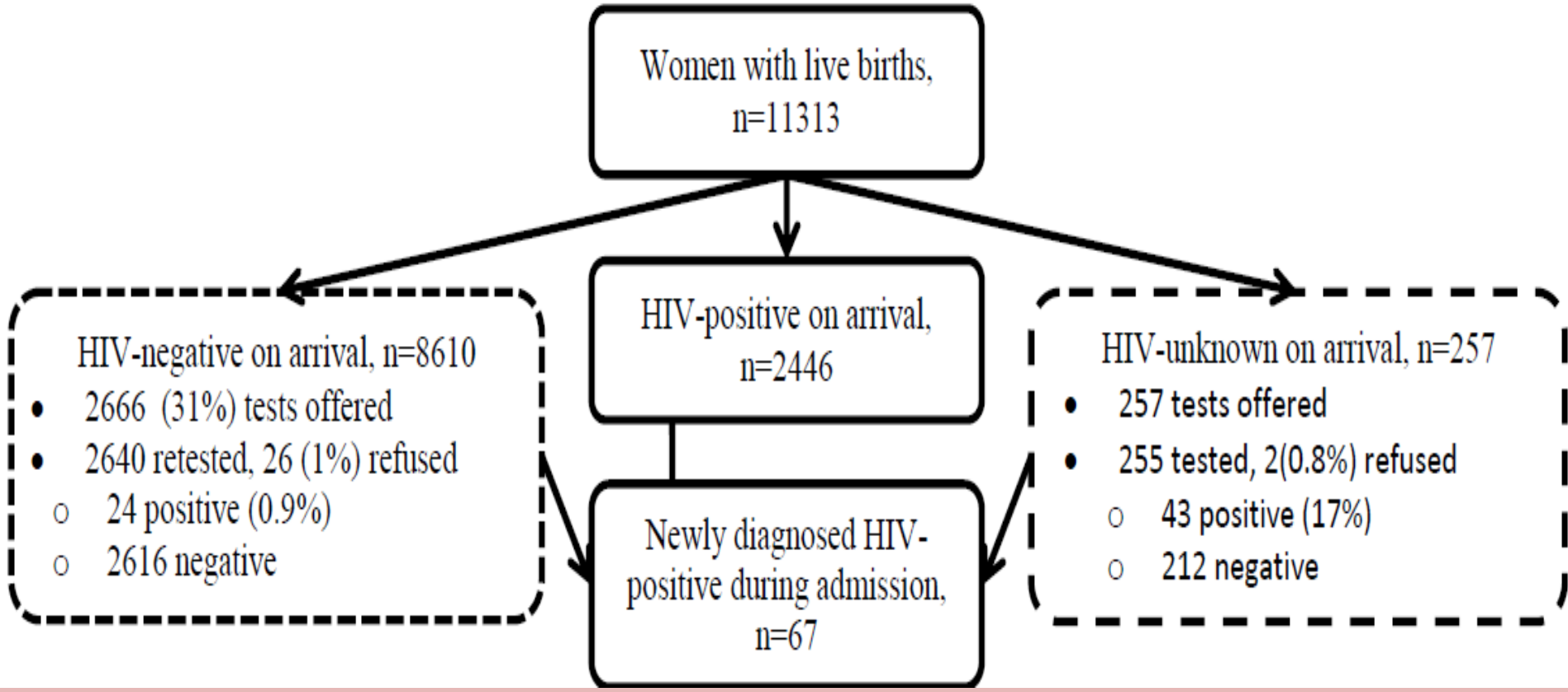
Identification of HIV-positive mothers – June 2014 to May 2015



Important points

- *Maternal* **Testing and Retesting** vital components
- 67 newly diagnosed women
  - =2.3% of the women tested
  - =2.7% of all identified HIV-positive women
  - Rate of maternal HIV test refusal was <1%

Discussing diagnosis with mothers

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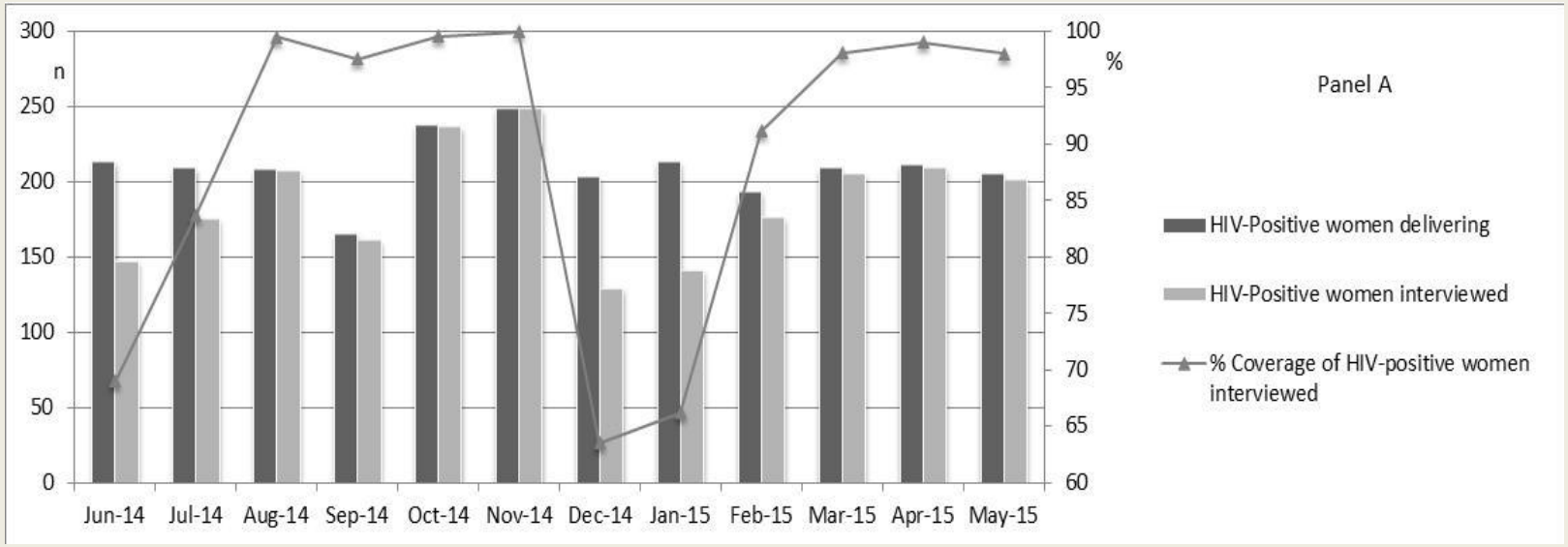
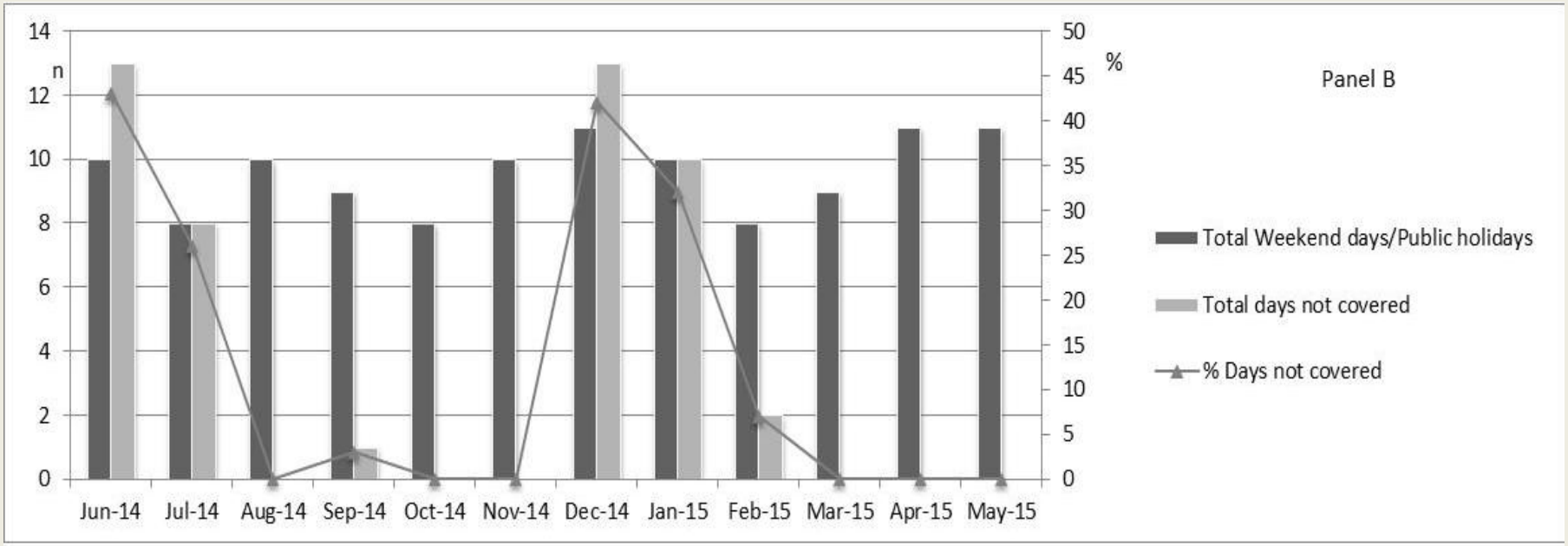


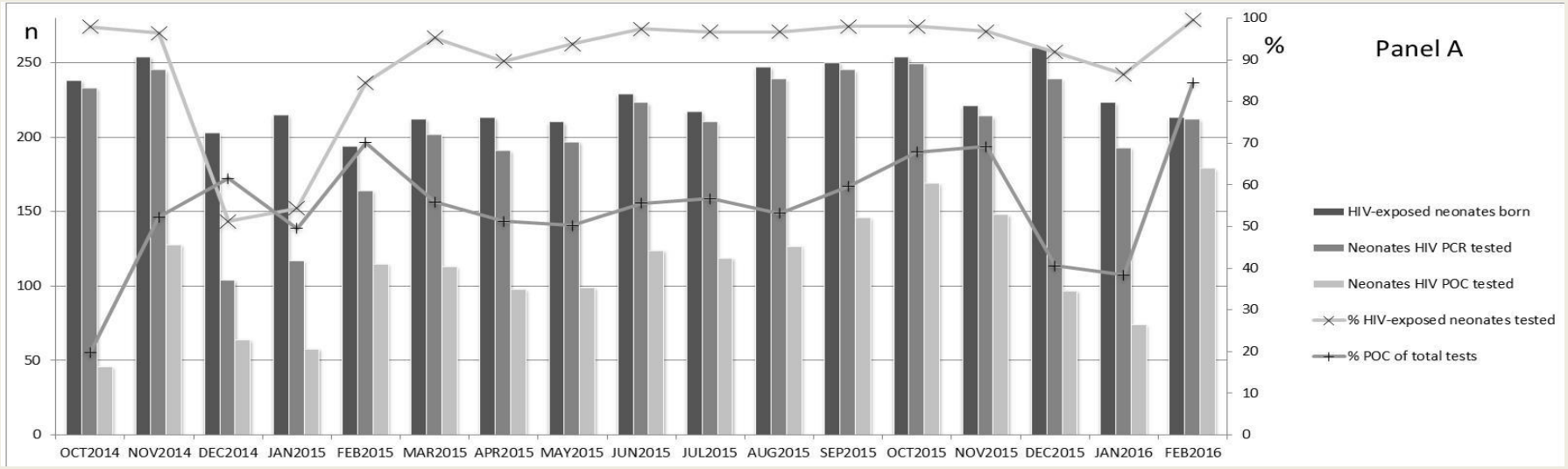
- Difficulties reaching mothers at the start of the programme and during festive period

Weekends and Public holidays



- Weekends and public holidays form a significant component of the work

Testing Infants LAB vs POC



- As time goes on – laboratory testing coverage improves
- New challenge – introduction of POC testing

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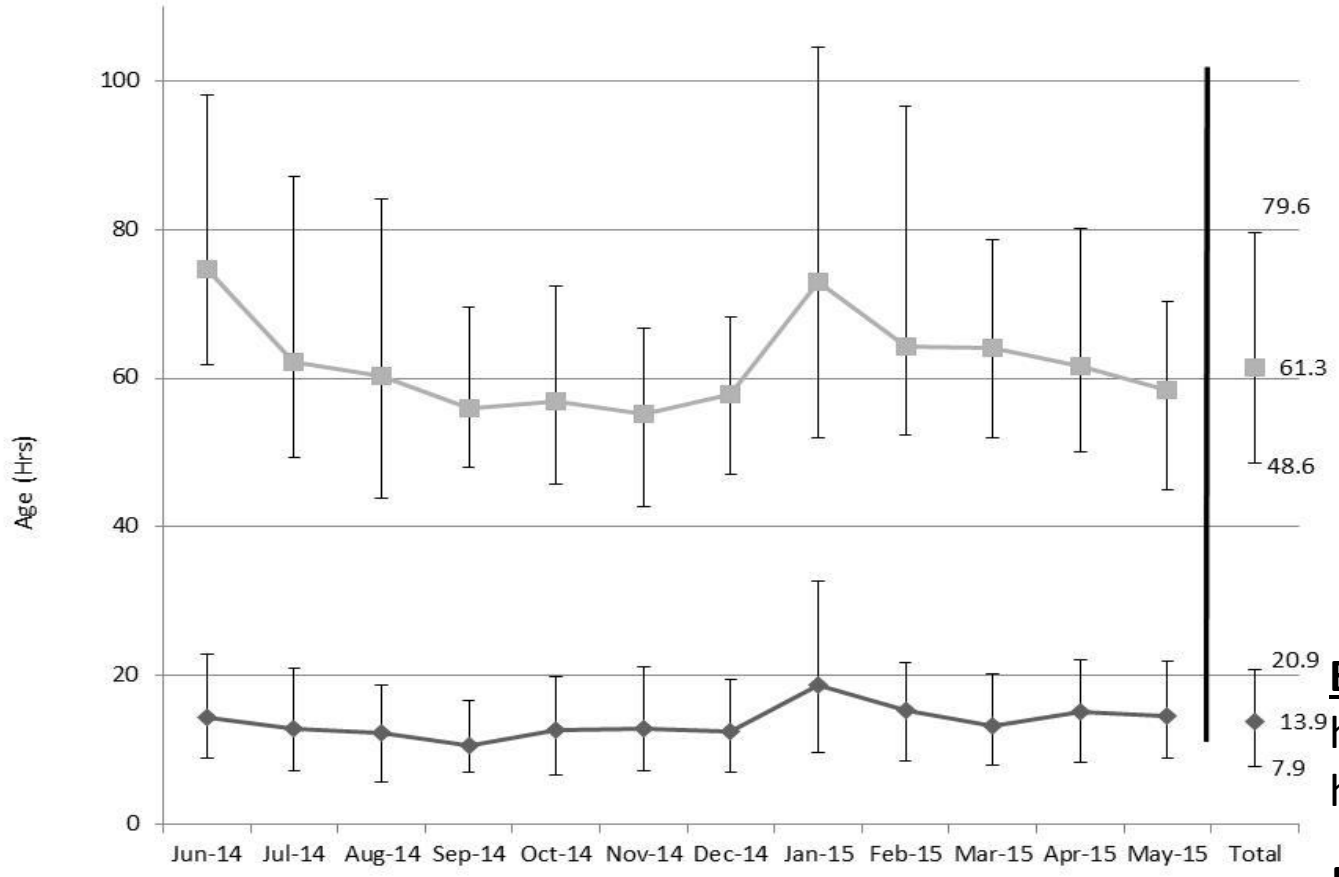
Timing of laboratory test and result



Time to result 45.1 hours (IQR: 33.6-60.3 hours)

Birth PCR was 13.9 hours (IQR: 7.6-20.9 hours)

NVP Dose: 0.33 hours (IQR: 0.2-1.5)

Timing of test and result

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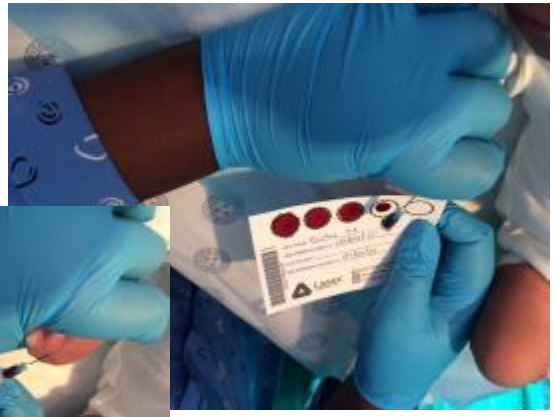
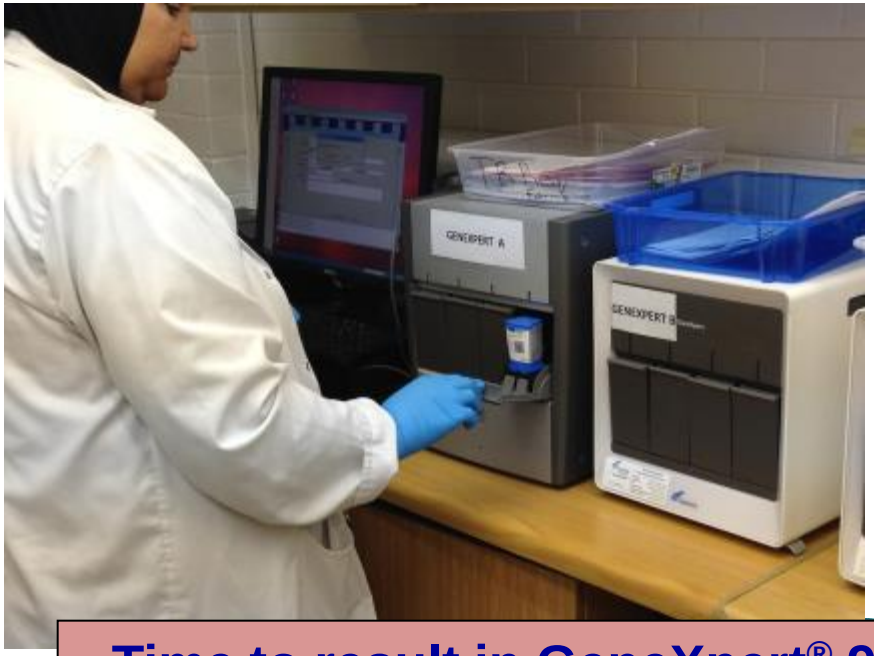
- >95% of neonates had blood drawn after NVP dose

Birth testing – POINT OF CARE component

- Point of care testing
  - Cepheid HIV-1 Qual Xpert
  - Run concurrently with NHLS PCR
  - Started October 2014
  - ~70% coverage of week days/non-public holidays
  - Expanded to Sundays recently

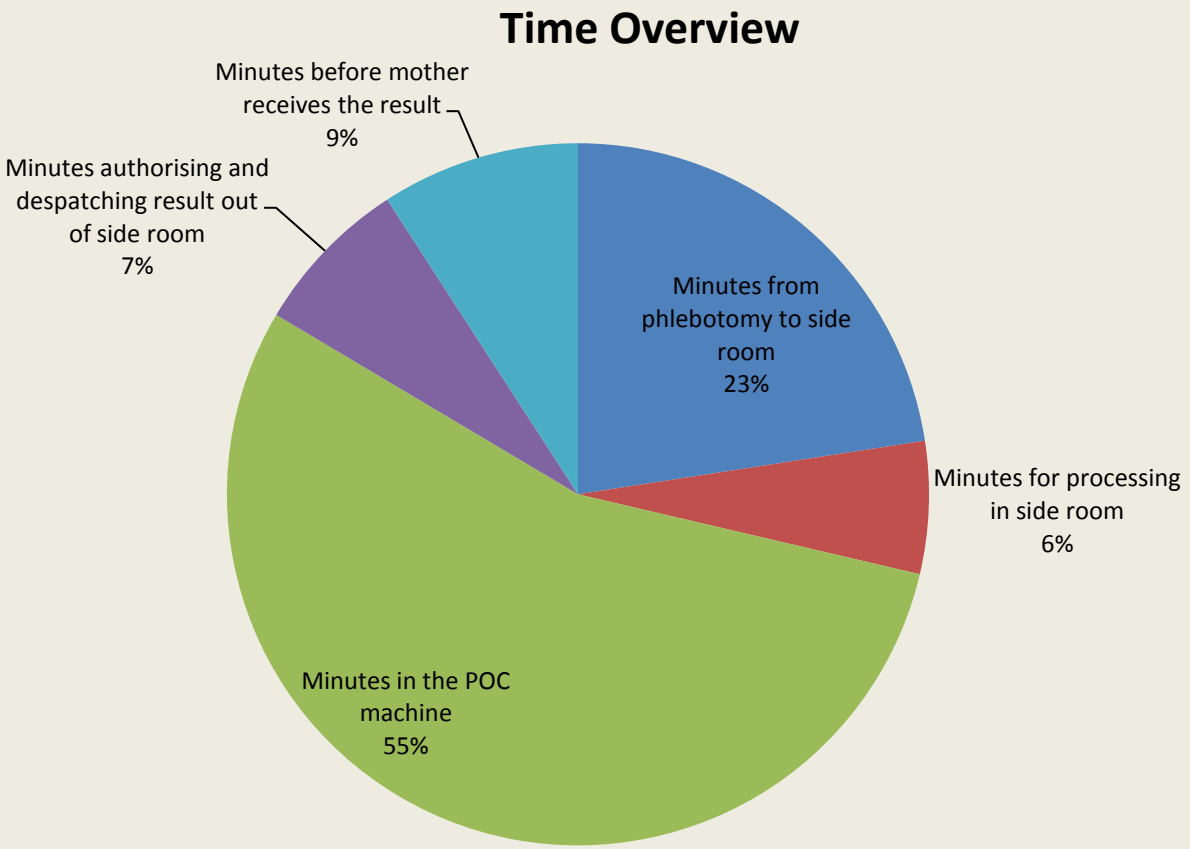




Time to result in GeneXpert® 90 min.

Time from baby's point of view

Time for POC test



Update:
Outcomes – tests June 2014-Sept 2015

- Infants tested – n=3073
  - 43 cases where no result was received
- Infants with result – n=3030
  - Positive – n= 44 = 1.45% (1.0-1.9%)
  - Indeterminate – n= 10 = 0.33% (0.1-0.5%)
  - Negative – n= 2976 = 98.2%

Update:
Outcomes – tests June 2014-Sept 2015

- Infants with indeterminate – n= 10 = 0.33% (0.1-0.5%)
- On further testing and follow-up
  - 3 infants show an HIV-infected status
  - 7 infants so far show HIV-uninfected status
- Indeterminates
  - Initial : 10/54 => 18.5% of all non-negative results with uncertain result/diagnostic dilemma
  - Final : 7/54=> 13.0% of all non-negative results considered as HIV-negative

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Returning results and follow-up

- Two components
  - POC
  - Lab result
- System for return for results
  - POC – aim to give result straight away
  - LAB – appointment given for 7-10 days post delivery

Returning results and follow-up where POC available

- POC result available n= 1188
  - Negative – n= 1172
    - Received negative POC result – n=1022 (87%)
    - Received negative lab result – n= 585 (49.9%) – includes 65 mothers who did not receive their POC result on the day of birth – therefore **93%** of mothers received the infant's result either POC or LAB
  - Positive – n=16
    - Received positive POC result – n=16 (100%)
      - One mother elected not to receive the result on the same day and returned 10 days later as agreed
      - Two mothers infants where tested on a Sunday and they received their infant's result on the Monday
  - Start of treatment
    - 15 infants where started on ART at a median of 1 day age (one infant at 11 days
    - One mother elected not to start and returned only much later

Returning results and follow-up where NO POC available

- No POC result available n= 1833
  - Negative – n= 1802
    - Received negative lab result – n= 935 (51.9%)
  - Positive – n=31
    - Received positive LAB result – n=26 (84%) on site
    - Received positive LAB result at other site – n=3 (10%)
    - Did not receive positive LAB result – n= 2 (6%)
      - One infant likely travelled soon after birth and mother could not be reached
      - One infant's mother could not be reached
  - Start of treatment
    - 29 infants (94%) started ART at a median of 8 days

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Important later tests

- All HIV-negative mothers require later retesting
- Infant require follow-up testing
  - ASAP if birth diagnosis was missed
  - All HIV-negative infants at ten weeks
  - 18 weeks, post breastfeeding, 18 months

Concluding Remarks

- Large project with multiple logistic considerations and challenges
- Possible to achieve maternal and infant identification
- Comprehensive holistic care needed
- 7 days a week
- Diagnostic dilemmas require attention
- Active tracking needed to keep infants in care

Study Team

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- On site:
  - Dr Martie Conradie
  - Sr Mokupi Manaka
  - Sr Lerato Mthombeni, Sr Ntebogeleng Malevu
  - Ms Zanele Msomi
  - Ms Lois Nakan, Ms Liezl Pienaar
  - Dr Pam Murnane
  - Ms Kapila Bhowan
  - B-Block team, Prof Coovadia, Dr Strehlau and her team
  - Data capturers: Nonhlanhla Mogashoa, Puleng Gabela, Malose Lebelo
  - Counselors: Promise Duma, Boitumelo Molatudi, Patricia Mdau, Jacqueline Kgosana, Jabu Dlamini
- Off site
  - NICD – Prof Gayle Sherman, Prof Caroline Tiemessen and team
  - New York – Prof Louise Kuhn, Prof Elaine Abrams
  - Cepheid – Dipti Lallubhai, Gwynn Stevens and team
  - NIH – Dr Rohan Hazra and team
  - BARC – Dr Carole Wallis
  - NHLS – Dr Sergio Carmona, Dr Lucia Hans

Thank you!

ANY QUESTIONS