The National Department of Health

PREGNANCY REGISTRIES

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Overview

Introduction

KZN Pregnancy Exposure Registry - Birth Outcomes Surveillance

WC Pregnancy Exposure Registry - Birth Outcomes Surveillance
Pregnancy Registry
Observational prospective cohort of women receiving a medicine(s) of interest as part of their routine clinical care who are enrolled voluntarily during gestation, before outcome can be known. Participants are followed until the end of pregnancy or longer to systematically collect information on specific pregnancy outcomes and evaluate their frequency relative to a scientifically valid reference population(s).
WHO Global Surveillance of drug safety in pregnancy

- Birth defect surveillance project with CDC funding and WHO technical support, 2016 - 2020
- Queen Elizabeth Hospital in Blantyre: 8000 deliveries, 1000 HIV positive, 37 babies with major birth defects - at end July 2017
- Expansion in September 2017 at Mangochi and Ntcheu, and Bwaila Hospital, Lilongwe – 4 sites
- Method: (i) surveillance maternal and birth outcomes (ii) case–control study examining risk factors associated with major BDs

- ARV pregnancy registry: National Department of Health
- Two provinces Kwazulu Natal (since 2013) and Western Cape Province (2018)

- MoH Botswana Harvard Partnership
- Tsepamo study
- Approximately 88,000 births, 15,000 HIV positive on ART, as of April 2018
- 3200 exposed to DTG based regimen
- NTD signal May 2018
- More sites

- Pregnancy registry starting - MSF in Malawi, Mozambique initiating, Uganda (CDC protocol), Kenya, ...

WHO / TDR
Central registry for epidemiological surveillance of drug safety in pregnancy

SOUTH AFRICA

MALAWI

BOTSWANA

OTHERS .... MSF, Brazil, MOZAMBIQUE UGANDA

KZN PER/BOS

Wentworth Hospital (not sentinel site)
PMMH: 60 80 – c/s pm

PMMH → ±12 000 deliveries p.a.

Inkosi Albert Luthuli H (not sentinel site)

PER Sites

Umlazi D
KwaMakutha
Umlazi L (until Jan 2014)
Umlazi U21
Non-PER clinics
PMMH: built 1964 (KwaZulu Government)

“COMBO” Hospital - predominantly regional but provides primary and tertiary level care (KZN + EC)

1200 + beds

Provides all regional level care except Urology

Referral Centre to approximately 30 clinics from South Durban

No District Hospital
KZN PER/BOS

- PMMH: built 1964 (KwaZulu Government)
- "COMBO" Hospital - predominantly regional but provides primary and tertiary level care (KZN + EC)
- 1200 + beds
- Provides all regional level care except Urology
- Referral Centre to approximately 30 clinics from South Durban
- No District Hospital
DEPARTMENT OF OBS & GYNAECOLOGY
• Largest in KZN (amongst the largest in SA)
• 350 beds
• maternity (average 1000-1100 births per month)
• Gynaecology (40 beds)
• CTOP
• Research units
• PMTCT (Philasande)
• 15 theatre slates per week (approximately 350 CS per month)
Deliveries Captured

Percent of the deliveries are captured

89.5% of deliveries captured and analysed
(23,568/26,341) Oct 13 to Oct 15

99.82 (96 to 100) captured
Apr 2017 to Sep 2017
HIV & ARVs

- HIV positive 39.2% (9,217/23,568)
- 98.7% on treatment
- TDF/FTC/EFV (92.3%)
- NVP (5.8%), majority switch to EFV
- Stavudine (0.8%)
- Zidovudine (1.3%)
- Protease inhibitor (0.6%)
Stillbirths, Neonatal Deaths And Miscarriages

FDC T1 exposure did not have an increase in adverse birth outcomes of stillbirths, neonatal deaths and miscarriages
Low Birth Weight

Weight <2,500g
13.8% (3,243/23,568)

- 22% less among infants with T1 FDC exposure
  not statistically significant.
- 12% less post T1 FDC exposure
  not statistically significant
Preterm Delivery

- before 37 week
- **20.7% (4,877/23,568)**
- T1 and later FDC exposure was significantly protective against *preterm delivery*
Birth Defects

Birth defects 0.67% (157/23,568)

Infants that were exposed to TDF/FTC/EFV (FDC) (T1) did not have an increase in birth defects as compared to: HIV unexposed and/or HIV-exposed infants whose mothers were not on any ART.

Post T1 exposure to FDC was shown to be protective, not statistical significance.
Review panel, among other tasks

- Determine whether the defects were major or minor
- ICD-10 classification
- Include or exclude in the risk factor analyses for medicine or environmental exposures
SUCCESS

- Efavirenz
- History taking
- Birth defect recording
- Diagnosis and classification
- Continuity of care
- Electronic capturing of Data
- Analysis of Prospective Data – need improvement
Challenges

- Human Resources
- IT - Lack of connectivity/networking
The Western Cape Pregnancy Exposure Registry-Birth Outcomes Surveillance programme is a sentinel site-centred prospective cohort situated within the Provincial population registry;

Provincial population registry is based on electronic record linkage using the unique patient identifier.

In order to avoid an expensive, parallel system staff are embedded at the sites and data are captured from the Provincial stationary using the electronic information systems already in use at Provincial facilities (i.e. PHCIS).

System strengthening and support are emphasized to improve clinical care and clinical record-keeping thereby improving data quality.
Western Cape Pregnancy Exposure Registry/Birth Defect Surveillance

Validation of data collected from Maternity Case Record

Data capture at sites by clerical staff embedded in facilities
WC PER/BDS Challenges

• Dependent on routine clinical data:
  • System strengthening – clinical examination & record keeping
  • Documenting drug histories
  • Documenting clinical examinations
  • Examination of stillborn infants

• Fetal autopsy

• Issue of infant identifiers (folder number) at MOUs & hospitals, esp. stillbirths: linkage

• Multiple patient identifiers

• PHCIS: operational database

• Accurate diagnosis of congenital disorders: photographs
Conclusion

- Implementation of a Pregnancy Registry is a complex task requiring a multi-disciplinary team, inclusive of partners and academics.
- Without partner support, we would not have reached this milestone.
- Involvement of various sections within the department is critical from inception.