Data sharing experience from Zika outbreak in Brazil

Ricardo Ximenes
on behalf of MERG
1. Data sharing in Pernambuco - MERG
2. Harmonization of Protocols
3. Zika Image Sharing Platform
4. Data sharing – ZIP study
Data sharing experience, Zika in Brazil

- **Aug – Sep**: Increased awareness of neonates with microcephaly
- **Oct**: SES-PE receives notifications from doctors
- **Oct**: Picture suggestive of congenital infection
- **Oct**: Beginning of investigation of SES-PE, SVS/MS² and OPAS
- **11th Nov**: Declaration of National Public Health Emergency
- **1st Feb 2016**: Public Health Emergency of International Concern (PHEIC) WHO
- **18 Feb**: Notification of Zika virus cases – SINAN Brazil
Data sharing experience, Zika in Brazil

DATA STRUCTURE
- One platform
- One database
- Common form
- Specific form
- Data entry in each site
- Different levels of access

Fiocruz
- DATA PLATFORM Management

HC-UFPE
- Form neurodevelopment
- Identification
- Specific data
- common form

HUOC-UPE
- Forms DIP & neuro
- Identification
- Specific data
- common form

IMIP
- Forms DIP & neuro
- Identification
- Specific data
- common form

AACD
- Forms DIP & neuro
- Identification
- Specific data
- common form

FAV
- Form ophthalmology
- Identification
- Specific data
- common form

HAM-SES
- Form hearing and dysphagia
- Identification
- Specific data
- common form

Children flow for evaluation and follow-up in the cohort and dynamic data collection and management on the platform.

Multiple cohorts? Partial data sharing?
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I - Towards Data sharing - Harmonization of Protocols

Protocol harmonization meeting of Brazilian and Latin American researchers with the support of OPAS/WHO was held in Recife, Brazil, March 2016

Activities:
Harmonization: cohort of pregnant women with exanthema, cohort of newborns with microcephaly
Discussion of a protocol of sexual transmission, discussion of protocol of neurological changes

Participants:
• MERG, Fiocruz- Rio de Janeiro, Fiocruz - Bahia
• Mexico, El Salvador, Equador, Colombia
II - Towards Data Sharing - Harmonization of Protocols

PAHO/WHO

Harmonization, Implementation and Technical support meeting on Zika virus research PAHO/WHO, **Mexico City**, 14-16 June 2016

Harmonisation of 4 protocols:

- 1- Cohort of **pregnant women** with and without Zika virus infection to evaluate the risk of adverse pregnancy outcomes
- 2- Cohort of **newborns and infants** born to mothers infected with Zika virus with “congenital Zika syndrome”
- 3- **Case control** studies to estimate risk factor for microcephaly
- 4- Case control studies of **Guillain-Barré syndrome**

IPD - Individual Participant Data meta-analysis
Harmonization of the protocol of three consortia: ZIKAction, ZIKAlliance and ZikaPlan

- Harmonization of study protocols to the greatest extent possible
- Standardization: (1) the core **clinical** data collected, (2) the core **biological** samples collected, (3) the testing **algorithms**, (4) inclusion/exclusion criteria & endpoint definitions.
- Standardization data **capture tools** including data dictionaries, data collection and case report forms, and clinical as well as laboratory SOPs.
- Review and adaptation of existing documents (e.g. from IDAMS, ISARIC, the NICHD ZIP Study and the MERG group).
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Data Sharing - Zika Image Sharing Platform

Online data-sharing platform for images of fetal and newborn heads

- Administered and hosted by the University of Oxford
- "Data contributors" are the institutions and their designates who submit individual patient data (3D images) to the platform.
- Contributors will have the opportunity to discuss the proposal of analysis (planning stage) and contribute in the data analysis process (phenotypic characterization e craniofacial dimorphism and imaging results).
- Publications of analysis using platform data will be developed collaboratively with data
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Data Sharing – International Prospective Observational Cohort Study of Zika in Infants and Pregnancy (ZIP study)

Sponsored by NIH and Fiocruz

- Multi-site, multi-country study
  Nicaragua, Porto Rico, Colombia, Guatemala
  Brasil: Rio de Janeiro, São Paulo, Bahia and Pernambuco
- Standardization of all instruments and procedures
- Central data management system
- ZIP Scientific Advisory Committee
Data Sharing - Challenges

• Standardization of forms and procedures: partial or total?
• One or several platforms and databases (dialoging)?
• Data agreement
• Governance
• Balance between collaboration and competition
Thank you

MERG Team

Celina M Tucchi Marteli
Ricardo Arraes de Alencar Ximenes*
Demócrito de Barros Miranda Filho
Thália Velho Barreto de Araújo
Laura Cunha Rodrigues

Wayner Vieira de Souza
Maria de Fátima P.M. de Albuquerque
Maria Cynthia Braga
Rafael Dhalia
Ernesto Torres Marques
And the rest of the MERG Team

*raaximenes@uol.com.br
MERG
Grupo de Pesquisa da Epidemia de Microcefalia

www.cpqam.fiocruz.br/merg/