Lessons Learned: U.S. Zika Pregnancy & Infant Registry

Meeting: Challenges in Initiating and Conducting Long-Term Health Monitoring of Populations Following Nuclear and Radiological Emergencies in the United States

Convened by: National Academies of Science, Engineering, and Medicine

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US Zika Pregnancy & Infant Registry

- Established in early 2016 in all US states and territories
- Monitors pregnancy and infant outcomes in pregnancies with laboratory evidence of possible Zika virus infection to inform clinical guidance and public health response
  - Estimate the proportion of fetuses and infants with birth defects
  - Provide information to inform the phenotype of congenital Zika syndrome
  - Facilitate referral to care for infants with possible congenital Zika infection
- Over 7,400 pregnancies with lab evidence of possible Zika virus infection in US states and territories (pregnancies completed Dec. 2015 through March 2018)
- Follows infants to at least 2 years of age
Tracking Zika in Pregnant Women and Infants
How did it work?
US Zika Pregnancy & Infant Registry
US Zika Pregnancy & Infant Registry: How It Works

- **Identification:** Health departments identify pregnant women with Zika virus infection from healthcare providers and/or positive Zika test result.

- **Data Collection:** Health departments abstract key data elements and submit to the US Zika Pregnancy & Infant Registry.

- **Data Analysis & Reporting:** CDC receives data from health departments, aggregates and analyzes, regularly reporting data on CDC’s website during an outbreak.

- **Publication:** Data Use Working Group (consisting of CDC and health department partners) jointly prioritize and publish results.
US Zika Pregnancy & Infant Registry: **Data Collected**

- **Maternal** Health and Pregnancy Data
  - Demographics
  - Zika virus exposure history, including travel
  - Zika virus testing results
  - Health history and pregnancy information
  - Prenatal imaging
  - Prenatal testing
  - Pregnancy outcome
US Zika Pregnancy & Infant Registry: Data Collected

- **Neonatal** Assessment
  - Physical examination
  - Neonatal imaging
  - Zika virus testing
  - Other testing (e.g., infectious diseases, cytogenetics)
  - Hearing screening
  - Eye exam
US Zika Pregnancy & Infant Registry: Data Collected

- **Infant** follow-up at 2, 6, 12, 18, & 24 months of age
  - Physical exam findings
  - Developmental assessment
  - Additional studies
  - Neuroimaging, hearing evaluation, retinal exam, consultations
Reporting Data to the Registry

- **US Zika Pregnancy & Infant Registry data types:**
  - Line Lists
  - USZPR Forms
  - Electronic Data exchange – Access Database, Local REDCap, etc.

- **Accepted secure methods of Registry data transfer:**
  - Phone
  - SAMS
  - FTP
  - Fax
Lessons Learned

US Zika Pregnancy & Infant Registry
Challenges in Zika Pregnancy and Infant Surveillance

- Asymptomatic infection
  - Tension between traditional case-definitions (requiring symptoms) and importance of tracking infected but asymptomatic pregnant women

- Time delay from infection in pregnancy to outcome
  - Early information allowed monitoring of numerator data of infected pregnant women, but risk of infection couldn’t be estimated before pregnancy completion

- Testing/diagnostics
  - Testing capacity at state and local level
  - Transient nature of virus
  - Lack of knowledge about definitive diagnostics in utero
Data Protection via Assurance of Confidentiality

- **Assurance of Confidentiality:**
  - Special protection for identifiable information in the Registry
  - A formal confidentiality protection authorized under Section 308 (d) of the Public Service Act

- **Under this Assurance**
  - CDC cannot share information that could be used to identify patients and providers without their permission
  - Data can only be used to better understand Zika virus infection during pregnancy and its outcomes

- **Data reporting was voluntary**
  - Healthcare providers and health departments felt confident that data were protected, which facilitated collaboration and reporting
Linked Mother-Baby Surveillance: Easy Access System

- Implemented a system that was easy and accessible for all jurisdictions to report data consistently
  - Data accepted in multiple formats
- Functionality to link data from pregnant woman with infant
- Clinical review or reported data by subject matter experts

<table>
<thead>
<tr>
<th>Mother's Zika virus Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>State/Territory ID:</td>
</tr>
<tr>
<td>Maternal Age at Diagnosis:</td>
</tr>
<tr>
<td>State/Territory of residence:</td>
</tr>
<tr>
<td>Ethnicity: Hispanic or Latino</td>
</tr>
<tr>
<td>Asian</td>
</tr>
<tr>
<td>Black or African-American</td>
</tr>
<tr>
<td>Race (check all that apply):</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Indication for maternal Zika virus testing:</td>
</tr>
<tr>
<td>Exposure history, no known fetal concerns</td>
</tr>
<tr>
<td>Exposure history and fetal concerns</td>
</tr>
<tr>
<td>Date of Zika virus symptom onset:</td>
</tr>
<tr>
<td>OR- Asymptomatic:</td>
</tr>
</tbody>
</table>

Pregnancy and Zika Virus Disease Surveillance Form
These data are considered confidential and will be stored in a secure database at the Centers for Disease Control and Prevention.

Please return completed form by sending an encrypted email to ZIKApregnancy@cdc.gov or by fax to the secure number: 404-718-2200. Pregnancy & Birth Defects Task Force phone number: 770-488-7100
Standardized Core Variables

- Moving forward: Developing list of core variables for surveillance of exposures during pregnancy
Modules to Address Specific Health Threats

- Because long-term sequelae of congenital infection unknown, unsure of outcomes for data collection
  - Started with microcephaly, but surveillance cohort approach allowed us to follow-up for any potential outcomes
- Moving forward: Developing modules to address specific health threats
  - Environmental exposures
  - Infectious diseases
Loss to Follow-Up

- Mobility
  - Families move and often seek care from different pediatric providers
  - Hurricanes that hit Caribbean resulted in challenges to follow-up of infants with possible congenital Zika infection

- Moving forward:
  - Working across jurisdictions to find families and follow-up infants, with data sharing between jurisdictions
  - Clinical outreach to pediatric providers to encourage them to ask parents about possible Zika exposure during pregnancy
Data from the US Zika Pregnancy and Infant Registry

About 5-10% of infants born to women with possible Zika infection had Zika-related birth defects and another 8-10% had neurodevelopmental disabilities potentially related to Zika

Identified that Zika infections during all trimesters have been associated with birth defects

 Revealed no discernable differences between symptomatic versus asymptomatic maternal infection in impact to their babies

Recognized pattern of birth defects associated with prenatal Zika virus infection
For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.