Zika Birth Defects Surveillance

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2017 NDBPN Virtual Meeting

First time in history...

"Never before in history has there been a situation where a bite from a mosquito could result in a devastating malformation."
-- Dr. Tom Frieden, former CDC Director
Fortune, April 13, 2016

"...the last time an infectious pathogen (rubella virus) caused an epidemic of congenital defects was more than 50 years ago..."
-- New England Journal of Medicine, April 13, 2016

CDC Emergency Response Levels

Level 1 is highest level
Level 1 Activations
- Hurricane Katrina 2005
- H1N1 Pandemic 2009
- Ebola 2014
- Zika 2016
Zika Virus is A Cause of Microcephaly

Criteria for Proof of Human Teratogenicity

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Criterion Met?</th>
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<tbody>
<tr>
<td>1. Proven exposure to agent at critical time(s) during prenatal development</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Consistent findings by ≥2 high-quality epidemiologic studies</td>
<td>Partially</td>
</tr>
<tr>
<td>3. Careful delineation of clinical cases</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Rare environmental exposure associated with rare defect</td>
<td>Yes</td>
</tr>
<tr>
<td>5. Teratogenicity in experimental animals (important but not essential)</td>
<td>No</td>
</tr>
<tr>
<td>6. Association should make biologic sense</td>
<td>Yes</td>
</tr>
<tr>
<td>7. Proof in an experimental system that the agent acts in an unaltered state</td>
<td>NA</td>
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Birth Defects Surveillance in the United States

- More than 40 states collect birth defects data
- Variations in methods, lag time in data collection, and case inclusion

Surveillance of Birth Defects Potentially Related to Zika Virus Infection

- Rapid surveillance to identify all infants with Zika-related birth defects, with and without Zika virus exposure, in a consistent manner across the United States
- Birth defects of interest
  - Brain abnormalities and/or microcephaly, neural tube defects and other early brain malformations, eye defects, consequences of CNS dysfunction
- Method: active case-finding with standard data collection tool
Collecting Data To Inform Public Health Recommendations

Surveillance of Zika and its Effects on Pregnant Women, Infants, & Children


Pregnancy Registries (USZPR / ZAPSS)
- Pregnant women and infants with laboratory evidence of possible Zika virus infection
- Infant & child follow-up for prenatal Zika exposure
- Referral to services: Infants with birth defects

Active Birth Defects Surveillance
- All infants with Zika-related birth defects, with and without congenital Zika exposure
- Referral to services: Infants with birth defects

These maps show CDC’s best estimate of the potential range of Aedes aegypti and Aedes albopictus mosquitoes in the United States. These maps include areas where these mosquitoes are or have historically been found, and are not intended to represent risk for specific diseases, but rather are an estimate of the potential range of these mosquitoes.
Zika Birth Defects Surveillance (ZBDS) Cooperative Agreements

Active Zika Birth Defects Surveillance
- Developing or enhancing population-based systems using active case-finding
  - Staff perform medical record abstraction to collect infant and maternal information
  - Clinical review/consultation as appropriate
  - Travel history and arboviral disease noted in medical record abstracted/linkage with lab testing
- Standard case definitions for birth defects potentially related to Zika virus
- CDC clinical review of verbatim diagnostic information
ZBDS Case Inclusion Guidance for Medical Record Abstraction

- For each birth defect potentially linked to Zika
  - Description
  - Inclusions and Exclusions
  - Diagnostic Methods
  - Medical Records – what and where to look for information
  - Associated Defects / Conditions
  - Prenatal Diagnoses Not Confirmed Postnatally

ZBDS Case Inclusion Guidance for Medical Record Abstraction – Illustration Examples

- Brain – Exterior View
- Eye Cross-section View

Data Collection Tool

- Access database to capture the information on the USZPR/ZBDS integrated forms
- Includes data validation to improve accuracy
Baseline Prevalence of Birth Defects Potentially Related to Zika Virus Infection

- Provided a reference to help interpret the effect of Zika virus infection on birth defects in the United States
- Estimated about 3 out of every 1,000 births affected with one or more birth defects potentially related to Zika virus
- Highlighted the importance of systems that collect information about birth defects potentially related to Zika virus infection

Active Zika Birth Defects Surveillance

How are we using the data?

- Link with other surveillance efforts, e.g., Zika pregnancy registries
- Perform epidemiologic studies
- Referral to services for affected families
- Address community concerns

Zika Response: Evolving Knowledge

- Identify full range of health effects among infants with congenital Zika exposure
- Determine optimal Zika virus testing to identify infants with congenital Zika virus infection
- Understand how neuroimaging will help identify infants with adverse effects of congenital Zika infection
- Understand implications of Zika RNA persistence in pregnant women and infants
- Assess risk of other adverse outcomes associated with Zika infection during pregnancy
- Use data to inform clinical management of pregnant women with Zika
Maternal Child Health Response to the Next Emerging Threat

- Evaluate the data for emerging threats and prepare guidance
- Establish a universal pregnancy registry framework that can quickly adapt to
  - Monitor all pregnancies with evidence of infection
  - Collect data on miscarriages, stillbirths, and other pregnancy outcomes, including birth defects
  - Use pathology findings
  - Ensure longitudinal follow-up of all infants with congenital exposure or infection
- Maintain rapid birth defects surveillance to
  - Monitor birth defects of interest
  - Ensure infants with birth defects and developmental disabilities receive care
  - Link to other key programs that monitoring infant health

Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-222-6348 www.cdc.gov

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.
Zika Birth Defects Surveillance: The Massachusetts Experience

Integrating Zika Birth Defects Surveillance into an existing active birth defects surveillance system

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1. Starting Out
2. Gearing up & Challenges
3. Going Forward
4. Related Activities

Starting Out

• Active statewide birth defects surveillance system since 1999:
  – Monthly report of range of codes by 50 Massachusetts (MA) hospitals;
  – Initial review/de-duplication
  – Abstraction of eligible cases
  – Case reviews
  – "Case closed" within 2 years
• 2011: Addition of prenatal reports from 10 tertiary facilities and one large independent imaging center.
Starting Out: Advantages

- Experienced, highly qualified staff
  - Birth Defects Surveillance coordinator: with us from the start!
  - Medical abstractors: nursing/medical/health information management degrees; training & experience.
  - Clinical consultant: Clinical geneticist
- Access database and electronic abstraction forms in place.

Gearing Up

1. Add Zika-associated conditions not previously in surveillance
   - Easy: Intracranial/intraocular calcifications, heterotopia, ventriculomegaly beyond mild: codes are in the range of those submitted by hospitals, so we just don’t reject them.
   - More difficult: congenital deafness.
     - Solution: Newborn Hearing Screening modifies their consent form to allow sharing of diagnostic results with Birth Defects Surveillance.

2. Need Zika test results
   - Already collaborating with the State Lab on USZPR, so,
     - Data sharing agreement in place.
     - Birth Defects staff trained on the lab’s MAVEN database.
   - Challenges:
     - Birth Defects Data System (BDDS) can’t communicate directly with MAVEN; need to look up BDSS cases individually to see if they have been tested.
     - MAVEN output not in format desired by CDC.
### Gearing Up

#### 3. Improve timeliness of reporting ZBDS cases
- Prioritize ZBDS cases for abstraction and review;
- Remote electronic access to medical records at additional hospitals:
  - Expanded from 1 (June 2016) to 8 (June 2017); more in progress.

**Preliminary Data:** Average time from delivery date to 1st abstraction for cases with ZBDS-eligible defects:
- Jan 1-Jun 30, 2015: 200 days
- Jan 1-Jun 30, 2016: 145 days

### Gearing Up

#### 4. Data Transmission to CDC
- Automate selection of eligible cases:
  - Some additional programming, e.g., addition of Intergrowth HC%ile in BDDS
- Map to specified formats in CDC Data Dictionary:
  - Not too bad for initial variable list; more challenging for expanded “Integrated Forms” list.
  - Having our own data system already in place is both a blessing and a curse!

### Going Forward

**Continue to Improve:**
- Process for obtaining laboratory data.
- Timeliness of reporting; move beyond low hanging fruit.
- Mapping data for Integrated Forms; still a work in progress.
Related Activities

Educational Materials
• Collaboration with State Lab, MA DPH Communications Office and MORE Advertising.
• Focus-group tested; Gender-specific; Targeted to at-risk populations.

Related Activities

Outreach to Providers
• Established Zika Advisory Group; includes representatives from MA Medical Society, MA Hospital Assoc, MA ACOG, MA AAP, March of Dimes, MA Nurses Assoc, and Assoc of Women’s Health, Obstetric and Neonatal Nurses, as well as MA DPH.

Related Activities

• Webinar for CME credits, with multiple modules hosted online.
• Mailings to parents of infants with Zika-associated defects, with brochures on available services.
Summary

Our experience with ZBDS and collaboration with USZPR has put us in a stronger position for responding to future outbreaks!

- Collaborations and data sharing agreements with other bureaus/programs;
- Improving efficiency of the Surveillance system overall;
- Strengthening relationships with provider organizations.

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Moving (Rapidly) to Active Case Finding

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APORS Manager

9/14/17

ILLINOIS

BIRTH DEFECT REGISTRY PRIOR TO 2016

Data collection
1989 – Passive
2002 – Verification
BIRTH DEFECT REGISTRY PRIOR TO 2016

Data collection
1989 – Passive
2002 – Verification

AND THEN THERE WAS ZIKA...

STRENGTHS
• Authority to collect
• Fairly prompt birth defect reporting mechanism
• Relationships with nursery staffs
• Relationship with Infectious Disease

AUTHORITY TO COLLECT
• All birth defects
• Other adverse outcomes
• Chart review
• Modifiable data base
AND THEN THERE WAS ZIKA...

WEAKNESSES

• Fairly prompt reporting mechanism
• Unused data sources
• Staffing challenges

FAIRLY PROMPT REPORTING

unused Data Sources

• Statewide hospital discharge data
• Genetic clinics
• Genetic labs
STAFFING CHALLENGES

- Staff changes
- Time needed to hire
- Medical leaves

REGISTRY PLANNING

WHY WE COULD MOVE QUICKLY:
- A justifiably broad case definition
- Established relationships
- Build new relationships
- Require prompt reporting
- Chart review
- Great team

THE APORS TEAM

Jodi Snow  Julie Rowden
Latina Iverson-Simmons  Lisa Lingleo
Angela Butler  Theresa Sandidge

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THANK YOU

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ZIKA VIRUS OUTBREAK

The Impact on Population-based Birth Defects Surveillance Systems

Joan Ehrhardt

• Impact of the Zika response on the Michigan Birth Defects Registry (MBDR)
• Birth defects surveillance systems’ experiences per National Birth Defects Prevention Network (NBDPN) Publications and Communications News interviews

Familiar Partners

• Hospitals
• Public Health Programs
• Vital Records
• Maternal Child Health (MCH)
• CDC, NCEDDD
• March of Dimes (MOD), Family-to-Family Health Information Center (FTHIC)
• NBDPN

Cases

• Vital Records and Health Statistics (VRHS):
  • Births
  • Deaths
• Newborn Screening (heart and hearing)
• Children’s Special Health Care Services (Title V)
• WIC
• Early Intervention (Part C)
New Data

- CNS anomalies
- Case Definitions
- Imaging Results
- Follow Up Health and Development - Longitudinal
- Primary and specialty care providers
- Local public health and community agencies
- Local home visiting programs

New Partners

- Notifiable Disease Surveillance System
- PH Bureau of Labs, Commercial Labs
- Local Public Health, Clinical Providers
- U.S. Zika Pregnancy Registry
- Communicable Disease, Arboviral Group
- STI Prevention
- Family Planning (Title X)
- Medicaid (MMA)
- Clinical Providers (Primary and Specialty)
- Mosquito Control
- Federally Qualified Health Centers
- Migrant Health and Resources Council
- Professional Organizations (American Academy of Pediatrics (AAP), American Congress of Obstetricians and Gynecologists (ACOG), Council of State and Territorial Epidemiologists (CSTE))

Future Directions

- Improve MBDR Case Data
- Contribute to the USZPR
- Share information and resources as they become available
- Integrate Zika virus prevention and follow-up messaging into our routine program work
Zika Virus Public Health Response

States which shared their experiences:

- Illinois
- Massachusetts
- Michigan
- New Jersey
- New York
- Ohio
- South Carolina
- Texas
- Utah
- South Carolina
- Texas
- Utah

Overarching Challenges

Communication and Coordination
- Establishing roles and meeting requirements
- Number of meetings, webinars, conference calls, presentations and inquiries
- Variety and number of partners across federal, state and local jurisdictions

Time and Timelines
- Amount of new information: keeping up
- Scope: identifying and getting to know key partners
- Urgency: emerging issue, rapid response

Data Demands
- Staff capacity: state level hiring restrictions
- Training
- Documentation, storage and management
- Increased number of visits/abstractions to collect complete case data

Impact of Zika Birth Defects Surveillance (ZBDS) Funding

Increased infrastructure, data and referral capacity
- Surveillance staff and training
- Data management, data linkages
  - Case reporting and review
  - Disease control, hearing screening
- Service provider training
- Program collaboration
  - Chart review
  - Infant developmental screening
  - Community outreach, awareness, and education
Observations and Surprises

- Work needed to educate healthcare community and get buy-in about importance/relevance of Zika virus infection and response.
- The existing emergency response tools and protocols (e.g., HAN alerts, WH.gov news calls).
- Challenge of identifying roles and responsibilities among state partners.
- The continental U.S. has not been hit in a major way by the Zika epidemic. So far, we have been very fortunate.
- Raised the visibility of birth defects within the department and led to new partners and champions.
- Seeing how many microcephaly cases we had compared to Zika-exposed cases.

Member Tips and Lessons Learned

Regulatory

- 'Our birth defects law is a solid foundation for birth defects surveillance. Getting that...is integral to sustained work.'
- 'Build your registry into act and legislation as broadly as possible to have the flexibility to respond as needs arise.'
- 'Know whether/when you need memoranda of understanding (MOUs) and data use agreements (DUAs) with internal and external partners.'

Sustaining

- 'Maintain relationships with key internal and external partners.'
- 'Increased visits to review records made our staff unpopular. Brownies helped.'
- 'Use such opportunities [as this] to get senior agency managers aware of the registry and what it offers.'
- 'Zika put us on the map; now [public health programs] are coming to us for more than Zika.'

Other

- 'Background training in disease outbreaks would have been beneficial.'
- 'Breathe.'
What can NBDPN do for you and your partners?

• Create a group that meets on an ongoing basis or provide a forum to discuss hot topics, surveillance issues and questions, e.g.:
  • When and how is best to access records for rapid ascertainment?
  • How are data used to make referrals?
  • The next emerging issue.
• Provide information, training, and tools for outbreak investigations and public health response.
• Offer an epi 101 for working with birth defects data.
• Work to facilitate public health access to medical records from the top down.
• Help with interstate data exchange.

NBDPN’s Zika Birth Defects Surveillance Needs Assessment Survey is coming soon!

THANK YOU

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