Emerging Infectious Diseases, Clinical Decision Support, and Electronic Health Records Meaningful Use

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Agenda

• Introduction and History
• EHRs and Zika – A detailed look
• Challenges
• Thoughts on an All-Hazards approach to Public Health Responses and EHRs
Introduction and History
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, 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...”

“[Zika] became the first major infectious disease linked to human birth defects to be discovered in more than half a century and created such global alarm that the World Health Organization (WHO) would declare a Public Health Emergency of International Concern.”
Case counts

Pregnant Women with Any Lab Evidence of Zika Virus Infection*

- US States and DC: 1,292
- US Territories: 2,842

*Source: Pregnancy Registries as of December 27, 2016

Zika Virus Disease Cases Reported to ArboNET*

- US States and DC: 4,835
- US Territories: 35,152

*Source: ArboNET as of January 4, 2017
Zika

- Office of the National Coordinator for Health Information Technology (ONC) saw an opportunity to leverage the Clinical Decision Support (CDS) tools in Electronic Health Records (EHRs).

- ONC collaborated with CDC’s Incident Management (IM) leadership to establish a CDC Zika Health Information Technology (HIT) team with the goal of-
  - Translating the published CDC Zika guidance for diagnosis, laboratory orders and travel history into requirement artifacts intended for developers of electronic health records
Facilitate the development of CDS Tools to Implement CDC Zika guidelines

- CDC and ONC collaborated to create CDS guidance artifacts.
- CDC Zika HIT team worked with ONC, and the IM Zika team to establish a process and to streamline communications.
- ONC and CDC jointly hosted 7+ national webinars for EHR vendors to present and discuss CDS guidance artifacts and made these products publicly available at-

(http://www.cdc.gov/ehrmeaningfuluse/public-health-ehr-vendors-collaboration-initiative.html)
Proposed: CDS Tools to Implement CDC Zika guidelines
(An Open Info-Button Approach)
Current activities
Activities Underway

- Building on lessons learned from Ebola, MERS
- An algorithm for developers
- Vocabulary sets
- Order sets
- Current challenges
- Vendor discussions
MMWR – Guidance for Clinicians

Pregnant woman

Assess for possible Zika virus exposure
Evaluate for signs and symptoms of Zika virus disease

A

- Symptomatic: <2 weeks after symptom onset, or
- Asymptomatic and NOT living in an area with active Zika virus transmission: <2 weeks after possible exposure

Zika virus rRT-PCR (serum and urine)

Positive Zika virus rRT-PCR (serum or urine): Recent Zika virus infection

Negative Zika virus rRT-PCR (serum and urine)

- Symptomatic: Zika virus IgM and dengue virus IgM
- Asymptomatic and NOT living in an area with active Zika virus transmission: Zika virus IgM 2–12 weeks after possible exposure

Zika virus IgM and dengue virus IgM negative: No recent Zika virus infection

Zika virus IgM or dengue virus IgM positive or equivocal: Presumptive recent Zika virus infection or flavivirus infection

PRNT

Zika virus PRNT ≥10 and dengue virus PRNT <10: Recent Zika virus infection

B

- Symptomatic: 2–12 weeks after symptom onset, or
- Asymptomatic and NOT living in an area with active Zika virus transmission: 2–12 weeks after possible exposure, or
- Asymptomatic and living in an area with active Zika virus transmission: first and second trimester

Zika virus IgM and dengue virus IgM (serum)

Dengue virus IgM positive or equivocal and Zika virus IgM negative: Presumptive dengue virus infection

Zika virus IgM positive or equivocal and any result on dengue virus IgM: Presumptive recent Zika virus or flavivirus infection

Zika virus IgM and dengue virus IgM negative: No recent Zika virus infection

Reflex Zika virus rRT-PCR (serum and urine)

Negative Zika virus rRT-PCR (serum)

Positive Zika virus rRT-PCR on serum: Recent Zika virus infection
Algorithms for developers

All women of child-bearing age. (P1)

- Travel to area with active Zika Transmission (D1)
  - Yes
  - Known Pregnant (D2)
    - Yes
      - Patients with ≥ 1 symptoms (D3)
        - Serum + Urine rRT-PCR Test (P6)
          - Symptom onset < 2 Weeks
            - rRT-PCR Zika virus result (D4)
              - Positive
                - Reflex test - Serum Zika Virus IgM and dengue virus IgM (if not available, store additional serum for IgM testing) (P7)
              - Negative
                - Symptom onset ≥ 2 and < 12 Weeks Post-Possible Exposure
                  - Serum Zika virus IgM + dengue virus IgM (P7)
          - Symptom onset ≥ 2 and > 12 Weeks Post-Possible Exposure
            - Test for Zika Virus IgM once during 1st or 2nd Trimesters (P7)
    - No
      - Uncertain
        - Perform Qualitative Pregnancy Test (P3)
          - Pregnant
            - Supportive Care
              - Rest, Fluids, Analgesics, Antipyretics
              - (Avoid aspirin/NSAIDs in case of dengue) (P5)
          - Not Pregnant
            - Planned Travel To area with active Zika Transmission (D1)
              - Yes
                - Advise to avoid travel to area with active Zika transmission
                - Confer with state health department regarding Zika testing (P4)
              - No
                - Stop
            - Any Sexual Partner with Travel to area with active Zika Transmission (D1)
              - Yes
                - Accompany for consultation (P2)
              - No
                - Stop

- Resident of area with active Zika transmission (D1)
  - Yes
    - Accompany for consultation (P2)
  - No
    - Stop

- No
  - Stop
# Algorithms for developers (Information)

| 1. Areas with active Zika transmission | Areas of known Zika virus transmission.  
|----------------------------------------|-------------------------------------------------------------------------------------|
| 2. Travel and Mosquito Prevention Advice | a. Advice for patients about how to avoid Mosquito bites.  
|                                         | b. Advice for patients about which mosquito repellents are effective and safe to use in pregnancy. [DEET, IF3535 and Picardin are safe during]  
https://www.epa.gov/insect-repellents/find-insect-repellent-right-you |
| 3. Prevention of Sexual Transmission    | The most current interim guidelines for prevention of sexual transmission of Zika virus.  
http://www.cdc.gov/mmwr/volumes/65/wr/mm6512e3.htm |
| 4. Signs and Symptoms                  | Signs and Symptoms of Zika virus disease and information about how a clinician might differentiate Zika virus infection from other similar infections.  
| 5. Possible microcephaly association    | Known information about association between Zika virus infection and microcephaly and other known complications.  
http://www.cdc.gov/ncbddd/birthdefects/microcephaly.html |
| 6. Zika Virus Diagnostic Testing       | Explanation of diagnostic tests for Zika virus and which to use based on the patient’s clinical and exposure history.  
Public Health Information Network Vocabulary Access Distribution System (PHIN-VADS)  
https://phinvads.cdc.gov/vads/SearchVocab.action

PHIN VADS Hot Topics

Zika virus disease associated Lab Vocabulary (ELR) - Includes value sets associated with lab testing algorithm for Zika, Chikungunya and Dengue  
FILE: Zika_Lab_Test_Information_20160517.pdf - Testing algorithm information for Epidemiologist and Lab experts using standard vocabulary  
FILE: Zika_virus_codes_for_ELR_20160517.xlsx - Technical information for ELR IT staff - LOINC and SNOMED codes  
LINK: Information for State Public Health labs from CDC

Zika vocabulary for EHR and Health IT vendors - Includes value sets for implementing the CDC's interim guidelines which could be used by EHR community for decision support or pick list.  
LINK: Zika affected areas  
FILE: Zika Virus Vocabulary for EHR - 02_01_2016.pdf - Includes value sets associated with Zika, Dengue, Chikungunya, Arboviral diseases, Pregnancy, Newborn and Infant.  
FILE: Zika related CPT procedure codes_04152016.pdf - CPT procedure codes associated with Zika lab tests and imaging.
Order Sets

- How order sets may be incorporated into products
- The local variation challenge; mapping variations may prohibit an automated push of orders sets
- Current documentation on order sets as related to the clinical guidance documents remain useful
Current Challenges

- Clinical Decision Support modules still must be built at the local level at each practice/hospital

- Capture of Pregnancy Status and other data related to case management
  - Pregnancy status/outcomes
  - Infant status/outcomes
  - Linkage to US Zika Pregnancy Registry
Capture of Pregnancy Status in EHRs is Essential for an effective Response to Zika Virus

- Locations of testing is expanding:
  - More states are developing capacity for IgM and plaque reduction neutralization antibody testing (PRNT)
  - Additional testing in commercial laboratories

- Participation in the US Zika Pregnancy Registry will likely decline without pregnancy status reporting
  - Less data available to monitor and understand Zika and pregnancy in the United States
  - A potentially less informed public health response
Potential Standards to address challenges

• Clinical Quality Framework
  » Clinical Decision Support

• Structured Data Capture

• Ask on Order Entry
Ask on Order Entry

- As more commercial labs are starting to process Zika tests, Ask on Order Entry potential solution to collecting current pregnancy status
- Published best practice guidelines to collect pregnancy status as part of Ask on Order Entry
- Allows commercial labs to collect information and pass through to Public Health through existing Electronic Lab Reporting standards
Ask on Order Entry Challenges

- Most public health labs not capable or receiving electronic lab orders nor can they send back electronic lab results
  - Most Zika tests currently done by Public Health labs
- Working with Puerto Rico using HITECH funding to implement electronic order entry/results delivery
- Working with CDC and American Public Health Laboratories (APHL) to document requirements for all public health labs to have capacity for electronic order entry/results delivery
Collaborations

- Public Health/Health IT Developer Community of Practice
- Special meeting with professional societies (CHIME and others) scheduled for December 8
- Potential FACA task force
Emergency Preparedness:

All hazards planning

ICS
Thoughts on an All-Hazard approach to Public Health Responses/EHRs

- All-hazard planning
- National Incident Management System (NIMS)
- Incident Command System (ICS)
The patient profile – in general

**Patient Characteristics**
- Gender
- Age
- Pregnancy Status, sexual activity

**Exposure**
- Where were you? When were you there?
- Examples: travel history, lived in Flint MI, known down wind of a radiation incident

**Symptoms**
- What the patient says
- E.g. chief complaint – “I have the worst headache ever”

**Physical findings**
- What the provider measures, e.g. temperature
- What the provider observes, e.g. Patient appears sensitive to light

**Assessment and Plans**
- Tests
- Orders (pregnancy)
- Results
The patient profile – Workflow

TRIGGER
Identify patients with risk, e.g.,
• All patients presenting to clinic
• All pregnant female patients

EXPOSURE
Patients who have traveled to areas at risk (e.g., known Zika Virus transmission, lead exposure or radiation)

SYMPTOMS
Patient history / symptoms based on the suspected exposure

FINDINGS - EXAMINATION
Findings on examination consistent with the condition or exposure

TESTING
Studies appropriate to help define if the condition is present

TREATMENT ISOLATION REFERRAL
Recommendations regarding how to manage
a) The patient
b) Healthcare workers
c) The patient’s exposures
Building blocks

• For a given situation, the order of the building blocks may change, or be of no importance. Just capture all the factors you will need.

• Later you may be concerned about order, optimizing workflow (i.e. move individuals out of the queue, drive reflective questioning)
Guideline Elements Model: [http://gem.med.yale.edu/default.htm](http://gem.med.yale.edu/default.htm)


Clinical Quality Framework - ONC Tech Lab: [https://www.healthit.gov/techlab/testing_and_utilities.html](https://www.healthit.gov/techlab/testing_and_utilities.html)
All Hazards Approach – Zika Virus Approach
HL7 Connectathon, September 2016

• **Structured Data Capture**
  » Zika virus reporting using FHIR questionnaires

• **CDS Hooks**
  » Zika virus questionnaire using CDC links for travel history and testing recommendations

• **Clinical Quality Framework / FHIR Clinical Reasoning**
  » Data extraction based on FHIR resources with standard terminology for measures, measure reports, clinical decision support (consideration for Zika Virus pilot)
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