The Office of the National Coordinator for Health Information Technology

Supporting Zika Response Through Health IT

October 5, 2016

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Agenda

- Introduction and Overview
- Zika Response: A detailed look at health IT activities to date
- Building an All Hazards Approach

Introduction and Overview

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…"
– S.Rasmussen et al. *New England Journal of Medicine, April 13, 2016*

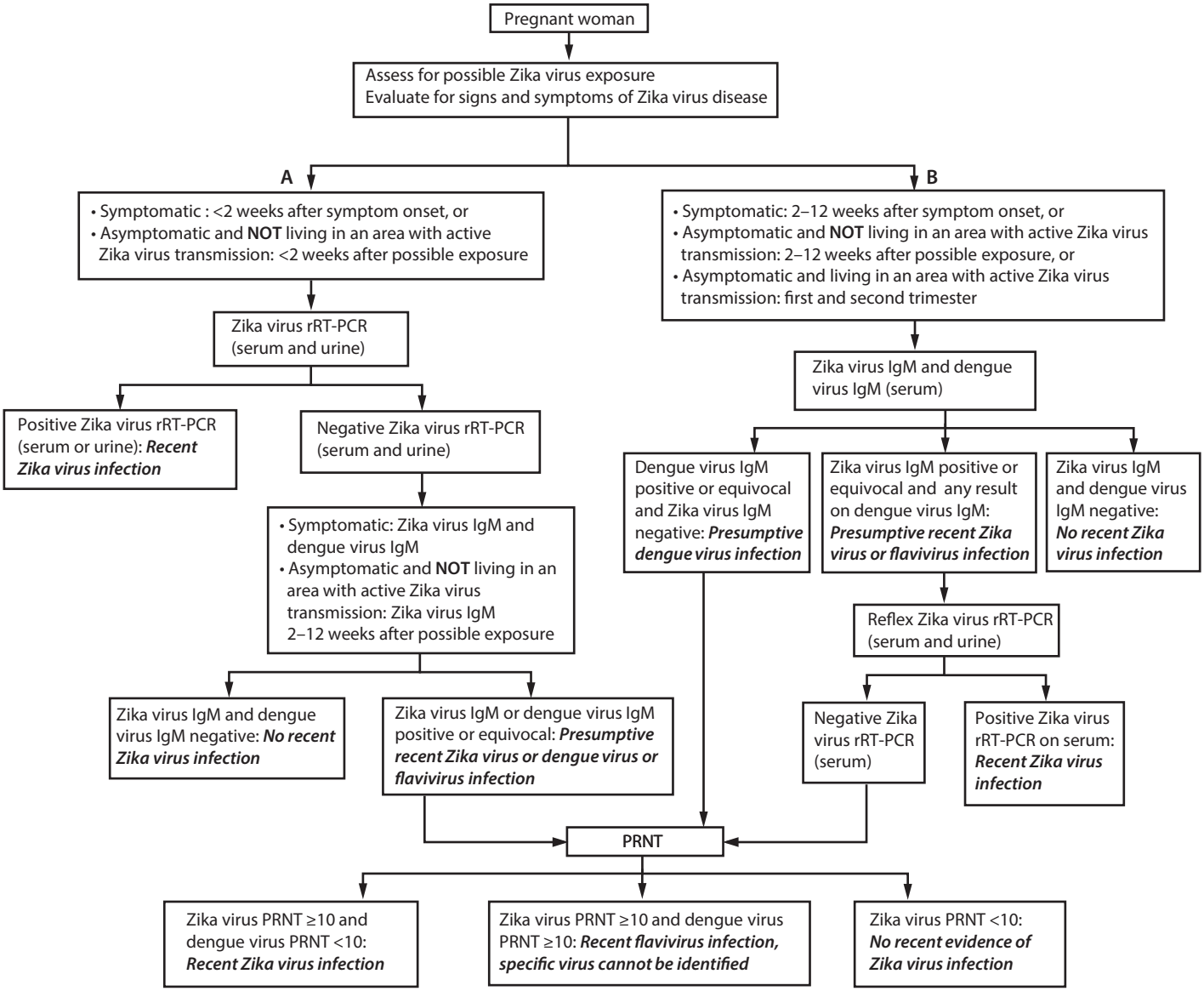
"[Zika] became the first major infectious disease linked to human birth defects to be discovered in more than half a century and created such global alarm that the World Health Organization (WHO) would declare a Public Health Emergency of International Concern."
– Petersen et al. New England Journal of Medicine, March 30, 2016

Current Activities Underway to Support Zika Response

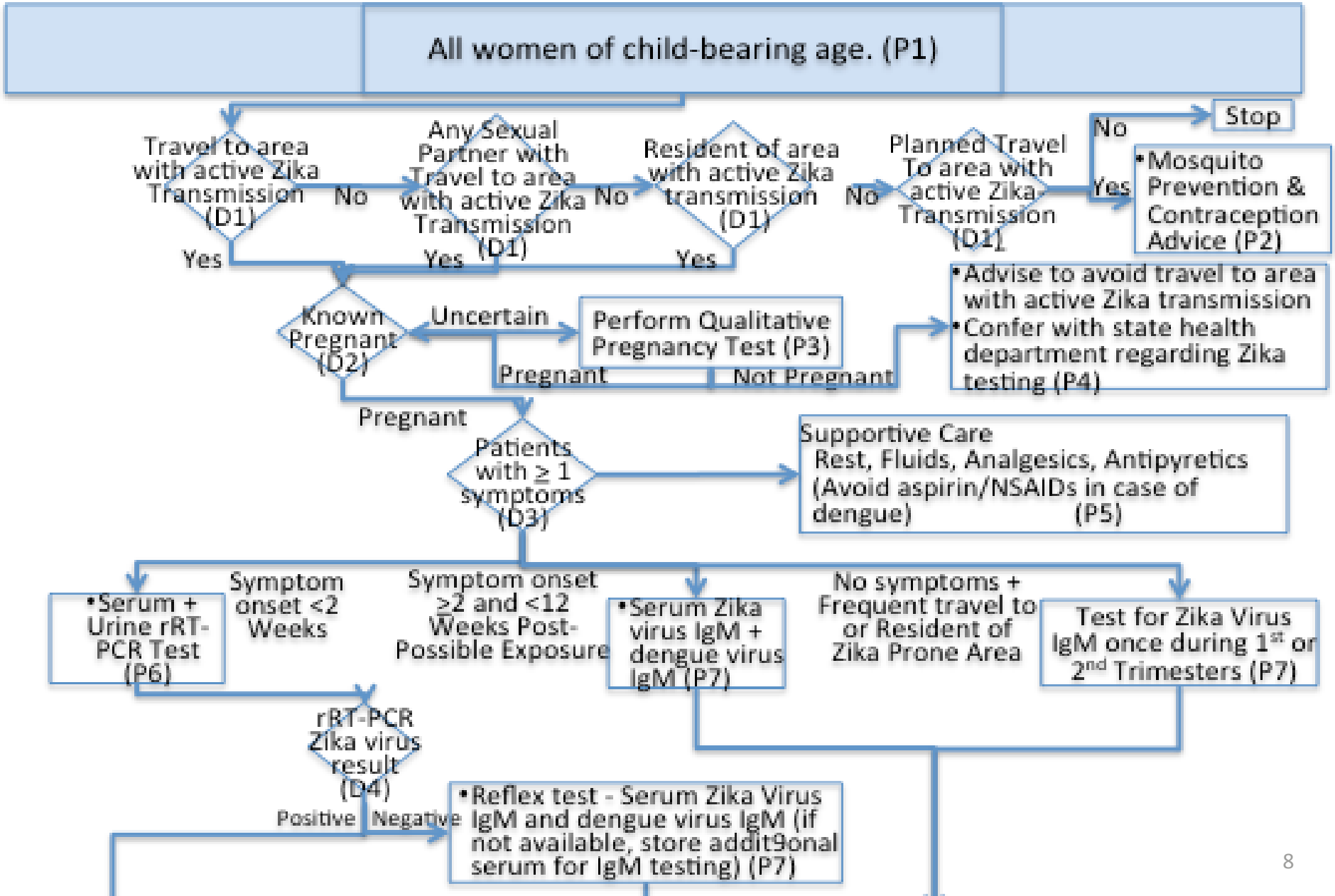
Activities Underway

- Building on lessons learned from Ebola Response and the MERS Response
- Algorithm Development
- Vocabulary Sets
- Order Sets
- Vendor Outreach

MMWR – Guidance for Clinicians



Algorithms for Developers



Algorithms for developers (Information)

1. Areas with active Zika transmission	Areas of known Zika virus transmission. http://www.cdc.gov/zika/geo/index.html
2. Travel and Mosquito Prevention Advice	a. Advice for patients about how to avoid Mosquito bites. http://www.cdc.gov/zika/prevention/index.html
	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/zika/transmission/index.html 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. http://www.cdc.gov/zika/symptoms/index.html
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. http://www.cdc.gov/zika/hc-providers/diagnostic.html

Algorithms for developers (Value Sets)

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.

Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS)

Value Set Information

Value Set Code	PHVS_ZikaAffectedAreas_CDC
Value Set Name	Zika-affected areas
Value Set OID	2.16.840.1.114222.4.11.7457
Value Set Description	Zika-affected areas value set has been created based upon Jan 26th, 2016 travel notice from CDC Zika virus disease website. For more information, please visit http://www.cdc.gov/zika/geo/index.html

Download Value Set
Subscribe

Version History

Version 7 (Current)

Value Set Concepts | Value Set Details

45 Value Set Concepts found 1 2 3

Select All | Clear All | Download All | Download Selected

Concept Code	Concept Name	Preferred Concept Name	Code System	Value Set	
VIR	U.S. VIRGIN ISLANDS	VIRGIN ISLANDS, U.S.	Country (ISO 3166-1)	Zika-affected areas	Details
ASM	AMERICAN SAMOA	AMERICAN SAMOA	Country (ISO 3166-1)	Zika-affected areas	Details
ABW	ARUBA	ARUBA	Country (ISO 3166-1)	Zika-affected areas	Details
BRB	BARBADOS	BARBADOS	Country (ISO 3166-1)	Zika-affected areas	Details

Order Sets

- How can Zika related order sets be incorporated into health IT products?
- The local variation challenge introduced complexity-mapping variations may prohibit an automated push of orders sets
- Current documentation (i.e., vocabulary standards, etc.) on order sets as related to the clinical guidance documents remain useful

Next Steps: Addressing Ongoing Challenges

- Clinical Decision Support modules on the Zika workflow are still built at the local level (i.e., practice/hospital)
- Capture of Pregnancy Status and other data related to case management of Zika cases
  - » Pregnancy status/outcomes
  - » Infant status/outcomes
  - » Linkage to US Zika Pregnancy Registry

Capture of Pregnancy Status in EHRs

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

- **Participation in the US Zika Pregnancy Registry supports Zika response efforts**
  - More data would be available to monitor and understand Zika and pregnancy in the United States
  - Pregnancy reporting supports a coordinated public health response

Building an All-Hazards Approach

Building an All Hazards Approach

- Consider
  - » Best practices from Ebola and MERS response to aid Zika response efforts (day to day)
  - » Standards Use, e.g.,
    - – Clinical Quality Framework/Clinical Decision Support
    - – Structured Data Capture

All Hazards Approach: Collecting the Right Information: The Patient Profile

Patient Characteristics

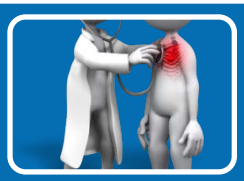
- Gender
- Age
- Pregnancy Status, sexual activity

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, eg. Patient appears sensitive to light

Assessment and Plans

- Tests
- Orders (pregnancy)
- Results

All Hazards Approach: Workflow/Moving the Right Information Across the Care Continuum

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

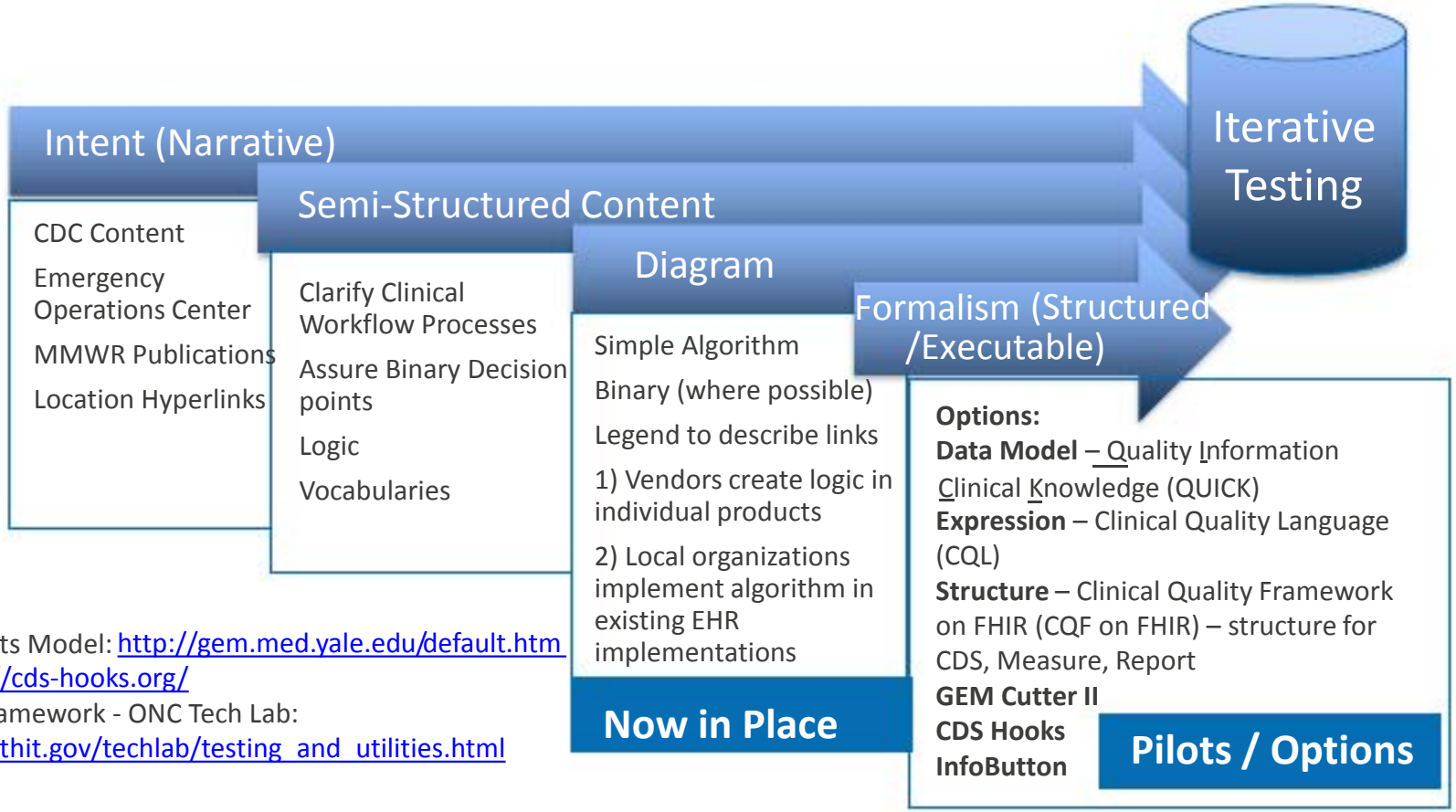
Recommendations regarding how to manage
a) The patient
b) Healthcare workers
c) The patient's exposures

All Hazards Approach: Building Blocks

Establishing the right building blocks must consider the hazard:

- For a given situation, the order of the building blocks may change and certain blocks may be of less importance. The objective is to determine the right blocks and where they belong.
- Other considerations may include order and workflow optimization (i.e. move individuals out of the queue, drive reflective questioning)

All Hazards Approach: As Applied to Zika Response Efforts



Guideline Elements Model: http://gem.med.yale.edu/default.htm
CDS Hooks: http://cds-hooks.org/
Clinical Quality Framework - ONC Tech Lab:
https://www.healthit.gov/techlab/testing_and_utilities.html

All Hazards Approach: As Applied to Zika Response Efforts

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)

Acknowledgements

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  Zika Emergency Operations Center, CDC
- **Margaret lampe, MD**
  Zika Emergency Operations Center, CDC

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Questions

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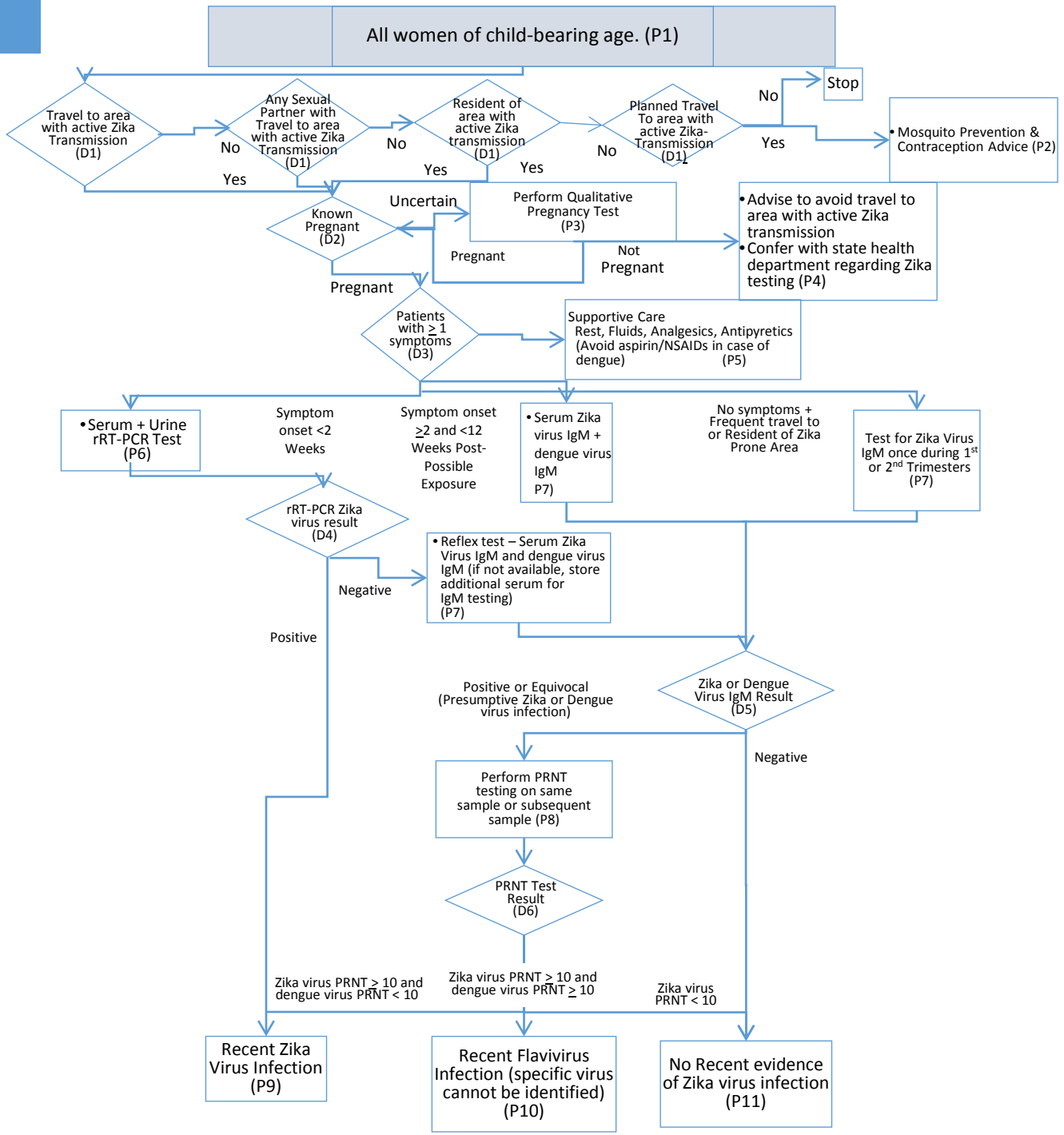
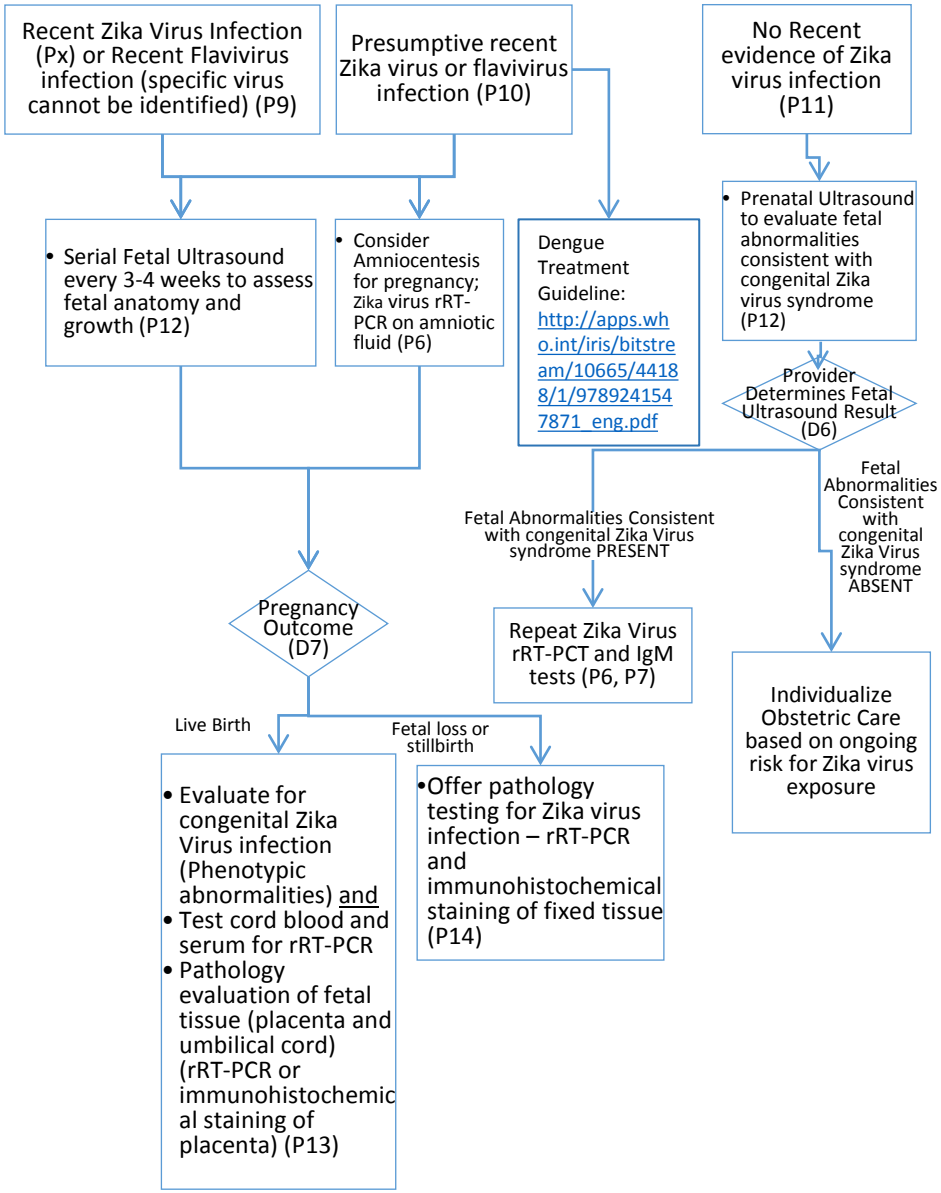
Appendix: Full Algorithm

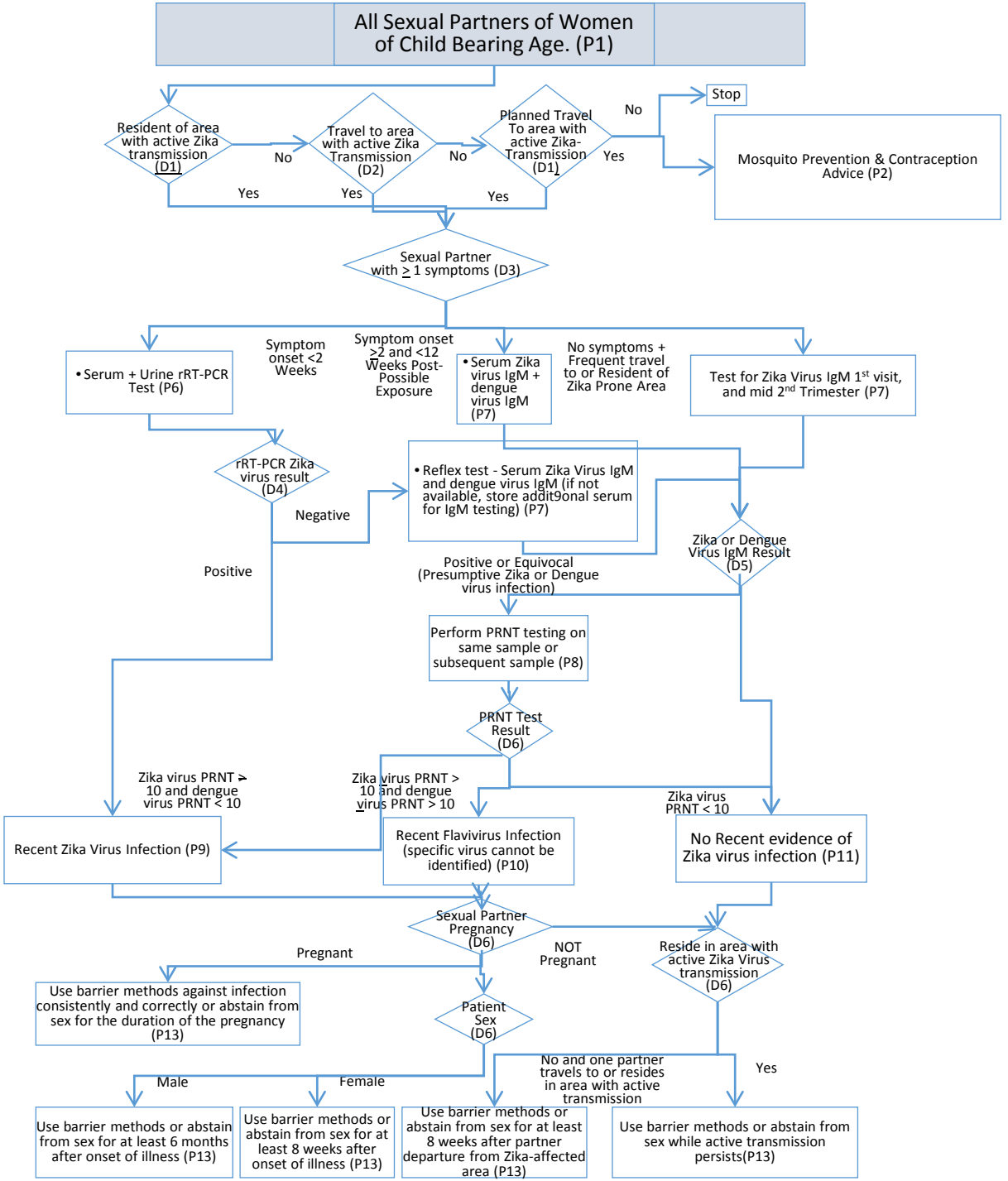
Algorithm


All women of child-bearing age. (P1)
Travel to area with active Zika Transmission (D1)
No
Yes
Any Sexual Partner with Travel to area with active Zika Transmission (D1)
No
Yes
Resident of area with active Zika transmission (D1)
No
Yes
Planned Travel To area with active Zika-Transmission (D1)
No
Stop
Yes
• Mosquito Prevention & Contraception Advice (P2)
Known Pregnant (D2)
Uncertain
Perform Qualitative Pregnancy Test (P3)
Pregnant
Not Pregnant
• Advise to avoid travel to area with active Zika transmission
• Confer with state health department regarding Zika testing (P4)
Pregnant
Patients with ≥ 1 symptoms (D3)
Supportive Care
Rest, Fluids, Analgesics, Antipyretics
(Avoid aspirin/NSAIDs in case of dengue) (P5)
• Serum + Urine rRT-PCR Test (P6)
Symptom onset <2 Weeks
Symptom onset ≥2 and <12 Weeks Post-Possible Exposure
• Serum Zika virus IgM + dengue virus IgM P7)
No symptoms + Frequent travel to or Resident of Zika Prone Area
Test for Zika Virus IgM once during 1st or 2nd Trimesters (P7)
rRT-PCR Zika virus result (D4)
Negative
• Reflex test – Serum Zika Virus IgM and dengue virus IgM (if not available, store additional serum for IgM testing) (P7)
Positive
Positive or Equivocal (Presumptive Zika or Dengue virus infection)
Zika or Dengue Virus IgM Result (D5)
Negative
Perform PRNT testing on same sample or subsequent sample (P8)
PRNT Test Result (D6)
Zika virus PRNT ≥ 10 and dengue virus PRNT < 10
Zika virus PRNT ≥ 10 and dengue virus PRNT ≥ 10
Zika virus PRNT < 10
Recent Zika Virus Infection (P9)
Recent Flavivirus Infection (specific virus cannot be identified) (P10)
No Recent evidence of Zika virus infection (P11)

Algorithm


Recent Zika Virus Infection (Px) or Recent Flavivirus infection (specific virus cannot be identified) (P9)
Presumptive recent Zika virus or flavivirus infection (P10)
No Recent evidence of Zika virus infection (P11)
• Serial Fetal Ultrasound every 3-4 weeks to assess fetal anatomy and growth (P12)
• Consider Amniocentesis for pregnancy; Zika virus rRT-PCR on amniotic fluid (P6)
Dengue Treatment Guideline: http://apps.who.int/iris/bitstream/10665/44188/1/9789241547871_eng.pdf
• Prenatal Ultrasound to evaluate fetal abnormalities consistent with congenital Zika virus syndrome (P12)
Provider Determines Fetal Ultrasound Result (D6)
Fetal Abnormalities Consistent with congenital Zika Virus syndrome PRESENT
Fetal Abnormalities Consistent with congenital Zika Virus syndrome ABSENT
Pregnancy Outcome (D7)
Repeat Zika Virus rRT-PCT and IgM tests (P6, P7)
Individualize Obstetric Care based on ongoing risk for Zika virus exposure
Live Birth
Fetal loss or stillbirth
• Evaluate for congenital Zika Virus infection (Phenotypic abnormalities) and
• Test cord blood and serum for rRT-PCR
• Pathology evaluation of fetal tissue (placenta and umbilical cord) (rRT-PCR or immunohistochemical staining of placenta) (P13)
•Offer pathology testing for Zika virus infection – rRT-PCR and immunohistochemical staining of fixed tissue (P14)

Algorithm


All Sexual Partners of Women of Child Bearing Age. (P1)
Resident of area with active Zika transmission (D1)
No
Travel to area with active Zika Transmission (D2)
No
Planned Travel To area with active Zika-Transmission (D1)
No
Stop
Yes
Mosquito Prevention & Contraception Advice (P2)
Yes
Yes
Yes
Sexual Partner with ≥ 1 symptoms (D3)
• Serum + Urine rRT-PCR Test (P6)
Symptom onset <2 Weeks
Symptom onset >2 and <12 Weeks Post-Possible Exposure
• Serum Zika virus IgM + dengue virus IgM (P7)
No symptoms + Frequent travel to or Resident of Zika Prone Area
Test for Zika Virus IgM 1st visit, and mid 2nd Trimester (P7)
rRT-PCR Zika virus result (D4)
Negative
• Reflex test - Serum Zika Virus IgM and dengue virus IgM (if not available, store addit9onal serum for IgM testing) (P7)
Zika or Dengue Virus IgM Result (D5)
Positive
Positive or Equivocal (Presumptive Zika or Dengue virus infection)
Perform PRNT testing on same sample or subsequent sample (P8)
PRNT Test Result (D6)
Zika virus PRNT ≥ 10 and dengue virus PRNT < 10
Zika virus PRNT > 10 and dengue virus PRNT > 10
Zika virus PRNT < 10
Recent Zika Virus Infection (P9)
Recent Flavivirus Infection (specific virus cannot be identified) (P10)
No Recent evidence of Zika virus infection (P11)
Sexual Partner Pregnancy (D6)
Pregnant
NOT Pregnant
Reside in area with active Zika Virus transmission (D6)
Use barrier methods against infection consistently and correctly or abstain from sex for the duration of the pregnancy (P13)
Patient Sex (D6)
Male
Female
No and one partner travels to or resides in area with active transmission
Yes
Use barrier methods or abstain from sex for at least 6 months after onset of illness (P13)
Use barrier methods or abstain from sex for at least 8 weeks after onset of illness (P13)
Use barrier methods or abstain from sex for at least 8 weeks after partner departure from Zika-affected area (P13)
Use barrier methods or abstain from sex while active transmission persists(P13)