

Collaboration of the Health IT Policy and Standards Committees

Policy and Standards Federal Advisory Committees on Health Information Technology to the National Coordinator

Public Health Task Force

Anne Fine, co-chair Larry Wolf, co-chair

March 8, 2017



Public Health Task Force Membership

Member	Organization	Role	
Larry Wolf	Strategic Health Network	Co-Chair	
Anne Fine	New York City Department of Health and Mental Hygiene	Co-Chair	
Andrew Wiesenthal	Deloitte Consulting, LLP	Member	
Floyd Eisenberg	iParsimony, LLC	Member	
J. Marc Overhage	Cerner Health Servcies	Member	
Noam Arzt	HLN Consulting, LLC	Member	
Susan Mcbride	Texas Tech University Health Sciences Center	Member	
Richard Loomis	Practice Fusion	Member	
Anjum Khurshid	Dell Medical School, University of Texas at Austin	Member	
Janet Hamilton	Florida Department of Health	Member	
Julia Gunn	Boston Public Health Commission	Member	
Steve Hasley	American College of Obstetricians and Gynecologists	Member	
Brian Anderson	athenahealth	Member	
Riki Merrick	Association of Public Health Laboratories	Member	
Chesley Richards	Centers for Disease Control and Prevention	Federal Ex Officio	
Margaret Lampe	Centers for Disease Control and Prevention	Federal Ex Officio	
James Daniel	ONC/HHS	ONC Lead	

Health IT Policy Committee and Health IT Standards Committee Work Product

Agenda

- Welcome
- Membership
- Background
- Charge
- Summary of Recommendations
- Detailed Discussion of Recommendations
 - » Process for Developing Recommendations
 - » Deliberations around each charge question
 - » Recommendations
- Discussion and Next Steps

Background

- Zika Response History
- October 2016 HITPC/HITSC Meeting Presentation on Zika Response
 - » Health IT Developer Calls
 - » Algorithms
 - » Vocabularies
- Development of a Task Force Charge

Public Health Task Force Charge

- **Overarching charge:** The Public Health Task Force will make recommendations to help inform public health issues and challenges related to health IT.
- **Detailed charge:** Make specific recommendations to better assist in the standardization of pregnancy status data, clinical decision support in health IT systems, and case management in public health settings—which are important components to addressing many public health challenges. Zika will be used as the use case for these recommendations.
 - 1. Capture Pregnancy Status: Identify the current challenges associated with the collection of pregnancy status when a Zika test is ordered. How could standardization help to resolve these challenges?
 - 2. Send and Share Pregnancy Status: Identify best practices for sharing pregnancy status from the provider to both commercial labs and public health entities.
 - 3. Use of Clinical Decision Support: Is there a need to automate the clinical decision support (CDS) process in order to identify risk and report timely information to public health? If so, what existing standards-based approaches for automating the CDS process are available as part of Zika response (i.e., Structure Data Capture (SDC), Clinical Quality Framework (CQF)) be used?)
 - 4. Electronic Initial Case Reporting: Identify mechanisms for how to move electronic case reporting forward.

Public Health Task Force Principles

- Clarity of purpose Understand the charge and ensure that it is addressed.
- Bright spots Learn from examples of success.
- Build on existing capabilities Build on the large installed base of working systems and current regulations. Use those systems and their data to inform our work.
- Parsimony Recommend the minimum necessary and sufficient to accomplish the goals.
- Generality Recommendations should support the specific issue being addressed, in this case Zika, and should more broadly be applicable to a range of issues.
- Agile Any experiments should be conducted in a rapid-learning environment.
- Flexible –New risks and better knowledge of known risks that will require flexibility in regulations, standards, software and organizations.
- Pragmatic Recommendations should be actionable and efficient, especially in the use of clinician time and effort.
- National Scale Address the complexities of a nation-wide implementation.
- Balance Priorities Stakeholders have many competing priorities and regulatory requirements. As much as possible, we should align and coordinate our efforts with other requirements.
- Sufficient Time– Allow time for regulations, software and implementation of recommendations.

Health IT Policy Committee and Health IT Standards Committee Work Product

Overview of Information Flow



Health IT Policy Committee and Health IT Standards Committee Work Product

Who is considered a provider?

- A provider encompasses:
 - » Hospital
 - » Physician
 - » Clinician
 - » And more

Summary of Recommendations

Charge Question 1: Capturing Pregnancy Status

- » Challenges:
 - There is no standard to capture pregnancy status and associated data in an EHR
 - There is no existing consensus on the minimum Public Heath data elements for pregnancy. Our goal was to identify those priority elements.
- » Recommendation:
 - Disseminate the Task Force identified and prioritized data elements related to pregnancy status (being vetted through public health and EHR vendors)
 - Publish pregnancy data standards in ONC's Interoperability Standards Advisory (ISA)

• Charge Question 2: Sending and Sharing Pregnancy Status

- » Challenges
 - Public Health does not consistently obtain pregnancy status electronically
 - Electronic Laboratory Reporting (ELR) Inconsistently provides pregnancy status information and, at times, only for certain diseases
 - Electronic Case Reporting from EHRs is not currently in place
 - Pregnancy status is needed not only for follow-up, but also is needed at the time a test is ordered for prioritization and to ensure pregnant women are being tested appropriately
- » Recommendation
 - Promote "Ask on Order Entry" for Zika tests using the same pregnancy data elements identified in Charge 1
 - Publish the pregnancy data standards for transmission in the ONC Interoperability Standards Advisory (being vetted through public health and EHR vendors)
 - Note: The Structured Data Capture standard is already listed in the ISA for public health reporting

Charge Question 3: Clinical Decision Support

- » Challenges
 - Guidelines for identification of patients at risk for emerging infectious disease can be complex and often change
 - State and local agencies may have variations on the guidelines
 - Guidelines for choosing the appropriate laboratory tests are complex (e.g., as noted in the hearing, over 300 of the wrong Zika lab tests were ordered in Texas) leading to missed or erroneous diagnoses
 - Guidelines for follow up and case management change during the course of an epidemic
 - CDS implementation in the EHR happens at the provider level
- » Recommendations
 - Demonstration projects have shown how CDS from Public Health can be incorporated into EHRs; Follow these projects to identify best practices for future recommendations
 - Encourage sharing of CDS implementations across provider locations
 - Explore and define the concept of CDS Light

Summary of Recommendations for Electronic Initial Case Reporting

Charge Question 4: Electronic Initial Case Reporting (eICR)

- » Challenges
 - Public health does not currently collect electronic case reporting information from EHRs
 - Digital Bridge and other eICR projects are in their infancy
- » Recommendations
 - Incorporate Charge 1 & 2 recommendation for collection and sharing of pregnancy status into Digital Bridge and other eICR projects
 - Leverage work from pubic health on the development of standards and best practices for eICR through the Digital Bridge and other eICR projects
 - Leverage Digital Bridge and other eICR projects for the purpose of receiving follow up and case management information required for public health investigation

Process for Developing Recommendations

Process for Developing Recommendations

- In-person hearing on February 8
 - » Panel 1: Public Health Departments
 - » Panel 2: Laboratory Organizations
 - » Panel 3: Clinical Decision Support (CDS) & Electronic Health Records (EHRs)
 - » Panel 4: Clinical Workflow
- Additional task force deliberations and follow-up
 - » Case Reporting Digital Bridge
 - » U.S. Zika Pregnancy Registry
 - » Data Elements for Capturing Pregnancy Status
 - » Clinical Decision Support

Deliberations Related to Each Charge: Capturing and Sharing Pregnancy Status (Charge 1 and 2)

Charge 1: Background from Hearing

- Pregnancy status is critical for multiple infectious diseases of Public Health Importance (Zika, Perinatal Hep B, Syphilis, HIV, Varicella, Others e.g. Listeria)
- Lab-diagnosed cases for investigation should be prioritized (especially necessary for higher volume diseases or diseases where timely intervention is needed)
 - » Currently most cases are reported via ELR
- Testing of vulnerable pregnant women is critical
 - » All pregnant women at risk should be tested
 - » All pregnant women should be tested with appropriate diagnostic tests
 - » Issues include access to care, provider understanding of complex diagnostic algorithms, failure to screen pregnant women for risk
- Follow-up on potentially exposed or infected infants is critical
 - » Hepatitis vaccination for infants given in a timely manner
 - » US Zika Pregnancy registry assess for birth defects and follow through the first year of life
 - » Having Estimated Date of Delivery enables public health to conduct outreach regarding status
- Appropriate guidance to providers regarding test interpretation and case management is needed

Charge 1: Pregnancy Priority Data Elements

- Develop key priority data element specifications for Public Health (i.e., standards for collecting this information)
 - » Completed: Key pregnancy data elements and associated vocabulary proposed and mapped to data elements already represented in interoperability standards (e.g., where in a C-CDA or HL7 message do you find this?)
- Confirm specifications with the Public Health community and determine any gaps
 - » Awaiting final feedback from Council of State and Territorial Epidemiologists and other key public health stakeholders
- Vet recommendations concurrently through the Health IT developer community including EHRA and appropriate HL7 working groups
 - » Awaiting final recommendations
- Recommend that the list of pregnancy data elements should be included in ONC's Interoperability Standards Advisory

Priority Data Elements

- 1. Pregnancy status* (yes, no, possible, unknown)
- 2. Certainty status of pregnancy (i.e., ultrasound, lab test evidence)
- **3.** Pregnancy status date recorded*
- **4.** Estimated Delivery Date*
- 5. EDD determination method
- 6. Gestational Age (alternate to EDD)*
- 7. Date Gestational Age determined (alternate to EDD)*
- 8. Method of Gestational Age determination (alternate to EDD)
- 9. LMP (alternate to EDD)
- **10.** Pregnancy Outcome*
- **11.** Pregnancy Outcome date*
- **12.** Postpartum status*

*Green items – Identified as critical at hearing

Charge Question 2: Background

Public Health Authority for Receipt of Pregnancy Data

- Health and Sanitary Codes authorize receipt and investigation of reportable disease data
 - » Electronic Laboratory Reporting
 - » Case Reporting
 - » Case and Contact Investigation and Management
 - » Outbreaks and "Unusual Manifestations of Disease"
- HIPAA allows for PHI disclosure
- Pregnancy status may be required to be submitted when relevant
- See ONC's new fact sheet: <u>Permitted Uses and Disclosures</u>: <u>Exchange for</u> <u>Public Health Activities</u>

Charge 2: Send and Share Pregnancy Status

- Recommended Short Term Approach
 - » Ask on Order Entry
 - Through infrastructure already created, ELR enables Ask on Order Entry data elements to flow to public health
 - ONC's 2015 Edition supports Ask on Order Entry
 - Continue to advance infrastructure for public health labs to support Ask on Order Entry
 - Consider resources required for commercial labs to reconfigure systems
- Recommended Mid Term Approach
 - » Exploration of Structured Data Capture standard
- Recommended Long Term Approach
 - » Initial Electronic Case Reporting enables Public Health to receive pregnancy status

Deliberations Related to Each Charge: Charge 3: Clinical Decision Support (CDS)

CDS provides value because guidelines are complicated



Charge 3: Background on Clinical Decision Support (CDS)

Intent (Narrative)				
	Semi-Structured Content			
Public Health and Clinical guidelines				
produced by CDC and state/local jurisdictions	Clarify Clinical Workflow Processes	Diagram		Iterative
MMWR Publications	Assure Binary Decision points	Simple Algorithm	Formalism (Structured / Executable	Testing
Location Hyperlinks	Logic	Legend to describe links	Pilots /Options:	
	Vocabularies	BRIGHT SPOTS	(HL7 Connectathon = pilots are helping to harmonize the method)	
	-	1) Vendors create logic in individual products and or	Data Model – <u>Qu</u> ality Information <u>C</u> linical <u>K</u> nowledge	
		2) Local clinicians/hospitals implement algorithm in existing EHR implementations	(QUICK) Expression – Clinical Quality Language (CQL)	
		3) Leverage innovative activities already in place (Utah, NYC, TX)	Structure – Clinical Quality Framework on FHIR (CQF on FHIR) – structure for CDS, Measure, Report	
			GEM Cutter II	
			CDS Hooks	
			InfoButton	
			RCKMS - Distributed management of CDS based knowledge	

Health IT Policy Committee and Health IT Standards Committee Work Product



Public Health: Supplier of Guidelines

- » CDC, State, and Local Public Health Agencies develop and disseminate guidelines
- Developers: Technology Platform
 - » EHR developers, CDS developers, guideline producers, large healthcare institutions, and clinical content vendors
- Providers: Workflow Integration

Charge 3: Background from Hearing

- CDS for Public Health and emerging risks:
 - » Identification of at risk individuals
 - » Appropriate tests ordered
 - Trigger points for particular actions (tests ordered for infant at time of delivery)
 - » Clinical management and patient education provided
 - » Guidelines of when to report to Public Health
 - » CDS 5 Rights
 - Right channel /Right Information/ Right intervention format / Right person / Right time = Where / What /How/ Whom / When (Osheroff, 2012)
- Public Health agencies provide stable URL that can be embedded in an EHR which allows access to guidance from CDC and other public health sites (currently "pull")
- Use clinical literature lookups within the EHR which monitor the literature for current guidelines

Charge 3: Clinical Decision Support

Recommendations

- » Demonstration projects have shown how CDS from Public Health can be incorporated into EHRs; Follow these projects to identify best practices for future recommendations
- » Encourage sharing of CDS implementations across provider locations
- » Explore and define the concept of CDS "Light"

Deliberations Related to Each Charge: Charge 4: Electronic Initial Case Reporting (eICR)

- More complete, accurate data in real time for action
- Early detection of cases allows earlier intervention and diminished transmission of disease
- Improves detection of outbreaks
- Responds directly to local and state partner needs
- Diminishes burden on healthcare provider to report
- Directly links health care to population health

Charge 4: Electronic Initial Case Reporting (eICR)

- **Recommended Mid Term Approach:** Follow Digital Bridge, other eICR projects, and the use of RCKMS* for Zika case reporting
 - » RCKMS currently has Zika as a reportable condition
 - » ONC's 2015 Edition case reporting included as optional criteria
- **Recommended Long Term Approach:** Move towards bi-directional data exchange with eICR , case management, and integrated CDS
 - » Use embedded Structured Data Capture standard to access and complete public health forms from within the EHR

*Reportable Condition Knowledge Management System (RCKMS)

Recommendations

Charge 1 Recommendations

- » Disseminate the Task Force identified and prioritized data elements related to pregnancy status (being vetted through public health and EHR vendors)
- » Publish pregnancy data standards in ONC's Interoperability Standards Advisory (ISA)

Charge 2 Recommendations

- » Promote "Ask on Order Entry" for Zika tests using the same pregnancy data elements identified in Charge 1
- » Publish the pregnancy data standards for transmission in the ONC Interoperability Standards Advisory (being vetted through public health and EHR vendors)
- » Note: The Structured Data Capture standard is already listed in the ISA for public health reporting

Charge 3 Recommendations

- » Demonstration projects have shown how CDS from Public Health can be incorporated into EHRs; Follow these projects to identify best practices for future recommendations
- » Encourage sharing of CDS implementations across provider locations
- » Explore and define the concept of CDS Light

Charge 4 Recommendations

- » Incorporate Charge 1 & 2 recommendation for collection and sharing of pregnancy status into Digital Bridge and other eICR projects
- » Leverage work from public health on the development of standards and best practices for eICR through the Digital Bridge and other eICR projects
- » Leverage Digital Bridge and other eICR projects for the purpose of receiving follow up and case management information required for public health investigation

Meeting Dates		Task			
Tuesday, December 20 th 9:30am-11:00am	•	Kickoff Meeting			
Thursday, January 12 th 11:00am-12:30pm	• (Case Reporting, Workflow Issues and hearing overview			
Wednesday, January 18 th 11:00am-12:30pm	• /	Administrative call to discuss upcoming hearing			
Wednesday, January 25 th 11:00am-12:30pm	• (Overview of the US Zika Pregnancy Registry			
Wednesday, February 8 th -9:30am-4:15pm	•	In-Person Hearing			
Thursday, February 9 th 9:30am-12:30pm	• +	Hearing summary and recommendations strawman			
Monday, February 13 th 11:00am-12:30pm	• F	Formulate and review draft recommendations			
Wednesday, March 1 st -11:00am-12:30pm	• F	Prepare draft recommendations for review			
Wednesday, March 8 th – Joint Committee Meeting	• [Draft Recommendations Presented			
Wednesday, March 15 th 11:00am-12:30pm	•	Integrate feedback and update recommendations			
Wednesday, March 22 nd 11:00am-12:30pm	• (Update recommendations			
Wednesday, March 29 th 11:00am-12:30pm	• F	Finalize recommendations			
Thursday, March 30 th – Joint Committee Meeting	• 1	Final Recommendations Presented			



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Public Health Task Force

Anne Fine, co-chair Larry Wolf, co-chair

Appendix

MMWR – Guidance for Clinicians



Pregnancy status required for CDS as well as reporting to Public Health

CDS complicated and changes





Algorithms for developers (Information)

1. Areas with	Areas of known Zika virus transmission.
transmission	
2. Travel and Mosquito	a. Advice for patients about how to avoid Mosquito bites. http://www.cdc.gov/zika/prevention/index.html
Prevention Advice	b. Advice for patients about which mosquito repellents are effective and safe to use in pregnancy. [DEET, IF3535 and Picardin are safe during] <u>https://www.epa.gov/insect-repellents/find-insect-repellent-right-you</u>
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)
 - <u>https://phinvads.cdc.gov/vads/SearchVocab.action</u>
 - 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.
 - o 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.

Vocabulary Sets

CDC Centers for Disease Control and Prevention CDC 24/7: Saving Lives, Protecting People™

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

ion Version: 4.0.1 t Version: 2016.02.18	-12	RCMT	Quick Search			
Notes [PDF-80KB]	Value Set Informat	ion			Version Histo	ory
bscribe	Value Set Code	PHVS_ZikaAffectedAreas	CDC	🛓 Download Value Set		_
	Value Set Name	Zika-affected areas			Versi (Cur	on 7
nks	Value Set OID	2.16.840.1.114222.4.11.7	457		(Cui	ent)
Services	Value Set Descri	ption Zika-affected areas values 26th, 2016 travel notice fro	set has been created based upon Jar om CDC Zika virus disease website.	Subscribe)	
happing tools		For more information, plea	ise visit			
actice	L	nttp://www.cdc.gov/zika/g	eo/index.ntml			
		Value Set Concepts Value Set Details				
ards						
s						
e	Select All Clea	rAll			Downk	Download All
	Concept Coo	le Concept Name	Preferred Concept Name	Code System	Value Set	
205	UR	U.S. VIRGIN ISLANDS	VIRGIN ISLANDS, U.S.	Country (ISO 3166-1)	Zika-affected areas	⊡ <u>Details</u>
DF-	ASM	AMERICAN SAMOA	AMERICAN SAMOA	Country (ISO 3166-1)	Zika-affected areas	⊡ <u>Details</u>
Suide w [ZIP]	ABW	ARUBA	ARUBA	Country (ISO 3166-1)	Zika-affected areas	⊡ <u>Details</u>
	BRB	BARBADOS	BARBADOS	Country (ISO	Zika-affected	□ <u>Details</u>

Morbidity and Mortality Weekly Report (MMWR): https://www.cdc.gov/mmwr/zika_reports.html

Guideline Elements Model: <u>http://gem.med.yale.edu/default.htm</u>

CDS Hooks: http://cds-hooks.org/

Clinical Quality Framework - ONC Tech Lab: <u>https://www.healthit.gov/techlab/testing_and_utilities.html</u>

Reportable Condition Knowledge Management System (RCKMS): http://www.cste.org/group/RCKMS

- Utah: Automated Surveillance
- NYC: Structured Data Capture (Federal Health Architecture demo)
- <u>Health Alert Network (HAN)</u> CDC's Health Alert Network (HAN) is CDC's primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories.
- <u>Clinical Outreach and Communication Activity (COCA)</u>—COCA, via CDC, prepares clinicians to respond to emerging health threats and public health emergencies by communicating relevant, timely information related to disease outbreaks, disasters, terrorism events, and other health alerts.

Improving Outcomes with Clinical Decision Support: An Implementer's Guide

By Jerome A. Osheroff, MD, FACP, FACMI

This is an example of a tool we can leverage as a framework for Public Health. It provides expanded and updated guidance on using CDS interventions to improve care delivery and outcomes in diverse care settings.

Figure 6-2: Using Core Actions to Identify Suitable CDS Interventions to Achieve Objective

Core Action Areas	Your Details	Likely Workflows	Likely CDS Types
RECOGNIZE PATTERNS: Is there need for help to recog- nize promptly that a particular situation, diagnosis, or presenta- tion exists? What data are needed to recog- nize this?	Yes – quickly recognize pre- sentations that are managed differently Data: EKG, past medical history, symptoms (early); troponin markers (kater)	☐ A. Pre-encounter Ø B. RN & MD History/assessment	Data-triggered alerts Troponin Smart documentation forms, calculators, clinical scores MI risk score Relevant data summaries Predictive analytics Expert system
FORMULATE PLAN: Is there need for help in choos- ing the best therapies and/or diagnostic studies for this condi- tion, symptom or diagnosis?	Yes – advise re criteria for different primary treatment options (such as thromboly- sis, percutaneous coronary intervention, glycoprotein IIb-IIIa inhibitors), and contra- indications for each	☐ B. RN & MD History/assessment ☑ C. Formulate plan of care	 ☑ Filtered reference Tables as per col. 2 ☑ Reference info in order sets/ care plans Contain tabular info as in item directly above □ Expert workup advisors
EXECUTE PLAN: Is there need for specific help: - to create orders or care plans correctly, completely and without errors? - in performing relevant procedures? - in carrying out orders or administering meds?	Yes — dosing help for primary drug treatments; full therapy protocol induding IV nitroglycerin, beta-blocker, ACE/ARB-inhibitor options Drug dilution guidance	□ D. Documenta- tion ☑ E. Orders/Rx □ F. Order handling/med dispensing □ G. Therapies/ Procedures	 Order sets/care plans (suggested doses, protocols) Anticoagulation and thrombolysis protocols Parameter guidance Dosing help for thrombolysis, renal doses (ritiques/warnings ("immediate alerts") Maybe warfarin drug-drug Smart documentation forms/checklists Filtered reference info Drug dilution calculator

continued on next page

Potential Solution for Public Health Labs/Ask on Order Entry



Health IT Policy Commi

eCR Digital Bridge High Level Architecture



Health IT Policy Committee and Health IT Standards Committee Work Product