Collaboration of the Health IT Policy and Standards Committees

Public Health Task Force
Report of the February 8, 2017, Public Hearing

Name of ONC Staff Liaison Present: James Daniel

Purpose: None stated

Opening Remarks

Michelle Consolazio, U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC), welcomed participants to the public hearing. She reminded the group that there will be two opportunities for public comment (limited to 3 minutes per person) and that a transcript will be posted on the ONC website. She told members to identify themselves for the transcript before speaking. Participants introduced themselves.

P. Jon White, Acting National Coordinator, welcomed and thanked everyone. He talked about the importance of a health information structure and interoperability for surveillance.

Daniel reported that the task force is asked to focus on recommendations for standards to capture pregnancy status. Coordination with CDC is on-going. He thanked everyone.

Review of Agenda

Task Force Co-chairperson Larry Wolf reminded the panelists to focus on one or two key messages. Consolazio reminded the panelists of the 5 minute time limit.

Panel 1: Public Health Departments

Aisha Haynie, Harris County Public Health, (no written testimony) reported that her agency has detected 39 Zika infections after evaluating 800 patients. Having a good Zika surveillance system is particularly important in her county due to its geographical location. Other conditions could benefit from the capture of pregnancy data. Pregnancy is routinely captured in public health agencies (PHAs). Paper forms are scanned into EHRs. Haynie said that affordable and robust EHRs would help surveillance efforts. Two-thirds of the county's confirmed cases were of Hispanic ethnicity. Integrated clinical decision support (CDS) would help with health care. Many at-risk patients are missed. Sometimes the wrong test is ordered; patients are not retested, or are tested in another location. Policy and funding are needed to enhance infrastructure.

Shawna Webster, National Association for Public Health Statistics and Information Systems (NAPHSIS), (no written testimony) reported on the vital statistics program, which is based on birth and death certificates, and other vital records. States are responsible for the collection of these records. Thus, the process, and some information, varies across states. Each state is responsible for financing its system. As evidence of the complexity and difficulties inherent in the systems, Webster said that it took 15 years to get states to adopt the 2003 U.S. Standard Certificate of Live Birth. The electronic registries face challenges. Vital records rarely receive funding for new processes or the addition of data elements. Currently, new elements typically require the redesign of systems. Nurses and others who collect the birth data at hospitals need more training for the collection of special indicators. Staff turnover and limited time affect data quality. Furthermore, there are lag times in the guidances. According to

Webster, better coordination across federal agencies is needed. Members of her association cannot fully participate without support.

Oscar Alleyne, National Association of County & City Health Officials (NACCHO), showed slides that described NACCHO's work and membership. He reminded the members that local health agencies (LHAs) are responsible for vector surveillance and control. He explained that this epidemiological work requires good interviewing skills and the ability to inform and explain risks and interventions to the public. Without accurate and timely information, public health workers cannot intervene. Electronic information exchange cannot replace the work of the local epidemiologist. At a minimum, local public health workers need basic demographic information for follow-up. Reference labs do not obtain this information, not even contact information. A minimum data set is needed for every lab test. But the extraction of these data from EHRs is complex. Some PHAs have to deal with many different systems. Most local PHAs do not have EHRs. Alleyne urged the task force to recommend the consideration of needs and resources at the local level.

Emily Petersen, U.S. Centers for Disease Control and Prevention (CDC) (virtual), showed slides and described the U.S. Zika Pregnancy Registry. She had made the same presentation to the task force at a previous meeting. The registry is a supplemental surveillance effort coordinated by CDC and is dependent on the voluntary collaboration of the state, tribal, local, and territorial health departments. Testing locations are expanding. More states are developing capacity for IgM and PRNT testing. Additional testing is being done in commercial laboratories. However, participation in the registry will likely decline without pregnancy status reporting with the result that less data will be available to monitor and understand Zika and pregnancy in the United States. Petersen requested support to enable easy data capture of pregnancy status in EHRs that can be used for clinical care and accompany laboratory orders for Zika virus testing.

Charlie Ishikawa, Joint Public Health Informatics Taskforce (JPHIT), pointed out that pregnancy data are routinely used to protect and improve maternal, prenatal, and infant health. These data are needed by:

- Immunization providers for ensuring that patients receive the right vaccines
- Public health surveillance professionals for identifying, monitoring, and gauging the size, severity and impact of outbreaks
- Maternal and child health professionals for identifying and providing timely health education and social support services
- Public health epidemiologists and researchers for etiological studies and assessing the effectiveness of interventions, medical counter measures, and changes in clinical standards of care.

The minimum data with regard to a pregnancy seems to be gestational age (GA) (trimester), expected delivery date (EDD), and pregnancy end date. These pregnancy-related observations would be made for all women of child bearing age, remain current, persist beyond the end of pregnancy, and be linkable to mother and infant test results and health outcomes. Currently, data on pregnancy status are captured by multiple parties and at multiple times along the continuum of care. Those data may be based on direct clinical and laboratory observations, patient self-reports, or administrative claims. Pregnancy status is also inferred from data such as date of last menses, procedure codes, or a provider's medical or surgical specialty. Pregnancy status information presently appears in standards-based syndromic surveillance data, immunization information systems (IIS) records, and all payer claims databases. Certified EHRs can provision pregnancy status data in chief complaints (OBX segment), diagnoses (DG segment), and as an immunization contraindication. Ishikawa asked for consideration of two contingencies in making recommendations. State and local public health informatics infrastructure

needs modernization and greater human capacity to fully benefit from better and timely pregnancy status data. Public-private partnerships like the Digital Bridge will be critical to working out implementation details in mutually beneficial ways.

Mary Ann Cooney, Association of State and Territorial Health Officials (ASTHO), described three key areas: the critical interest of state and territorial health agencies (S/THAs) in collecting timely pregnancy status data; current availability of pregnancy data; and public health and CDS. Cooney said that real time pregnancy status data are important to PHAs to align resources for infectious disease notification and response in the instance of an outbreak. For prenatal care, especially in areas at greatest risk for Zika, this includes rural and designated provider shortage areas. Rural communities pose additional challenges where access to early prenatal care is critical but difficult. Mobilization of resources must be coordinated with local PHAs. Regarding the availability of data, PHAs develop strong partnerships and foster effective data exchange relationships with health care systems for disease reporting. Zika presents both challenges and opportunities for how to improve these reporting methods and processes. Health care providers and public health workers would greatly benefit from newer technologies for bidirectional electronic case reporting. Currently, surveillance relies on delayed reporting of live births, fetal deaths, and maternal mortality. These data exclude women whose pregnancy did not end in a live birth, reported still birth, or maternal death. For example, maternal mortality case finding is challenging, and women whose cause of death was not related to obstetric causes, who lack a link to the live birth or fetal death record, or whose pregnancy status is unknown, are lost to surveillance. Information from Medicaid claims is limited. Optimally, pregnancy claims should be linked to other data such as laboratory confirmation, ultrasound, and clinical exam details to provide a full picture of risk to both mother and fetus. There are no reliable pregnancy flags, and knowledge is retrospective. It would be useful for both surveillance and intervention practices to be able to identify pregnancy in real time or near real time. However, PHAs are challenged to keep pace with technological advances.

Gillian Haney, Massachusetts Department of Public Health (virtual), submitted written testimony, saying that, in addition to Zika, there are infectious diseases posing serious threats to women and children's health for which public health and clinical intervention are necessary. Rapid identification of pregnancy status prioritizes follow-up activities, improves surveillance and ultimately prevents further spread of disease. These diseases include:

- Hepatitis B and C viruses
- Syphilis
- Chlamydia and gonorrhea
- HIV
- Influenza virus
- TB disease and LTB infection

With regard to what core pregnancy information public health needs to know, Haney said that there must be guided policy that ensures these data are captured via coded and standardized value sets, to the extent possible. This will support more accurate data collection and reporting, and enable public health to automatically triage and respond to the vast amounts of information reported to surveillance and case management systems. At a minimum, public health needs to know whether an infected woman is currently pregnant and if so, her EDD. These variables may be captured as "yes/no/unknown" and "date" fields respectively. Additional important data elements and corresponding coded values may include:

- Current GA (as a number with weeks or months as a unit) and associated date
- # of fetuses (as a number)

- Complications, prenatal diagnosis, and abnormal ultrasounds--this information is particularly relevant for Zika virus, syphilis, and rubella infections. However, these data elements or findings may not be fully portrayed as coded values.
- Whether the pregnancy was terminated (yes, no) or if miscarriage occurred (yes, no, and date)
- Current treatment for the infection of concern (standardized medication and dosage) and corresponding date
- Exposure date

Q&A

Task Force Co-chairperson Anne Fine asked about the capture of possible pregnancy, recent pregnancy, and outcome of pregnancy data. Cooney agreed that all three data elements are essential both for care and surveillance. Haynie reported that Texas has a birth registry. Information on possible pregnancy is important to avoid missed opportunities. Information should be obtained from lab tests for pregnancy, not just in response to Zika tests. The health department can use the pregnancy data in collaboration with mosquito testing. Pregnancy should be a notifiable condition. These data are needed to discover more about Zika, such as any transmission via breast feeding. Haney questioned the value of making pregnancy notifiable, saying that prioritization is required due to limited resources. Another panelist said that data across the life course would mean better quality data for maternal and child health and women's health interventions. Ishikawa also urged caution about the capture of new data. How data are captured is significant, for example, changing from free text to structured data.

Richard Loomis wondered about the opportunity for a reflective pregnancy test after a positive Zika test if pregnancy is unknown. Cooney responded that that would be good practice given limited resources.

Wolf noted that the information flow is mainly from labs to PHAs: What is the status of provider reporting to PHAs? Alleyne said that it varies greatly across jurisdictions, particularly by size. Some PHAs continue to rely on fax and mail. NACCHO's 2016 profile data indicate that only 17% of LHAs engage in electronic exchange. Haynie reported that there is no electronic reporting in Harris County. Follow-up testing is not possible. Providers fail to contact the PHA.

Fine asked another question: What about interim and long-term solutions, such as the Digital Bridge? Several panelists appeared to support the use of the Digital Bridge. A panelist cautioned about the language being used. Lab reporting is the state of art. There are limited resources. Cooney reported that few SHAs have the capability to receive data from EHRs in real time. Wolf concluded that reporting comes primarily from labs, although providers would be expected to have a more complete view of the case.

Noting the time, Consolazio asked members and panelists to be concise. Andy Wiesenthal said that as a pediatric infectious disease doctor, none of these congenial issues are novel. A universal approach for a new emergency is needed. How can Zika be used to design an effective electronic system for reporting and using electronic data? Many conditions cause problems equivalent to or greater than Zika. According to Alleyne, the public health community has been excluded from discussions of health IT. The necessary incentives and infrastructure have not been available. Public health authorities want a comprehensive approach, not just a response to Zika and not just responses to emergencies.

Anjum Khurshid wondered about priorities, given the time line and available resources. Cooney said that, when asked about priorities, SHA officials do not list bidirectional data exchange. But they do say that bidirectional exchange is essential for the future. Medicaid is essential to population health and to address inequities in health services. SHAs do not have the necessary relationships with Medicaid agencies.

Janet Hamilton asked about the criticality of improving lab reports. Should pregnancy status be required with the lab order? Haynie replied that providers would be the best source of information in real time. Having pregnancy status on electronic lab records (ELRs) is essential. By the time a Zika test result is delivered, the woman has been discharged from hospital. Lab results are reliable, but they are not timely. EHRs would be a better source, but they are not designed to submit reports efficiently. Primary care providers do not have systems that can do this efficiently. Alleyne talked about simultaneously EHR and lab reporting. Since it is available in only a few jurisdictions, lab reports became the best available source in current circumstances.

Susan Mcbride asked about missed opportunities: If the capture of pregnancy is standardized, where are the missed opportunities at the point of entry? Haynie responded that in the 800 investigations in Harris County, staff found that cases were missed at all stages. The wrong tests were sometimes administered at the wrong times. Cases were missed in the delivery room. Test results were not communicated from primary care to hospital. Language barriers occurred. Zika guidances and findings change rapidly. Safety net providers do not have the systems to communicate with hospitals and others.

Fine declared that the charge is how to standardize pregnancy status for reporting and to support clinicians to make the best possible decisions. These are different goals. Standardization of pregnancy status is the priority. Pregnancy status is important for pharmacy, immunization and other services. Data collection should be made similar to that of vital statistics.

Panel 2: Labs & Standards

Virginia Sturmfels, Quest Diagnostics (virtual), presented several slides. She noted that PHAs use pregnancy status in prioritizing testing at the public health laboratory and for certain surveillance activities. Currently, pregnancy status is required only for Zika and Hepatitis B Surface Antigen testing, although the addition of other STDs is under discussion. Pregnancy status is not required for most laboratory testing. During the Zika outbreak, commercial laboratories did not prioritize; they were able to perform all tests ordered. Sturmfels compared Zika testing with Hepatitis B Surface Antigen. She spoke about challenges in obtaining pregnancy status from the lab perspective. It requires the ordering provider to supply additional information to the laboratory. Providers have limited time to submit information beyond CLIA requirements, and there is no incentive for the clinician to provide information. For lab staff, follow-up with providers can delay reporting to PHAs, disrupts the flow of automated electronic reporting, and requires laboratories to provide dedicated staff to this task.

Carmen Pugh, LabCorp, (no written testimony) declared that diagnostic labs' responsibilities are to their customers. Data exchange occurs via client vendor interfaces, lab direct interfaces, or non-interface methods. The method of exchange is bounded by what the client can and cannot do. Clients must be willing and able to give the information to the lab. Then, many other processes must take place for storage. All interface processes must be redesigned. Regarding the reporting of potential pregnancies to the PHA, the provider's diagnostic code for a prenatal test can be used. Regarding Zika, although LabCorp reports if the PHA is able to receive the data, it is extremely burdensome to report whether both a pregnancy and a Zika test were done. Labs are being used as a public health repository, which is unfair. The task force should focus on mandated provider reporting.

Julie Luepke and Stephen Julien, Mayo Clinic, showed slides that described the reporting of pregnancy status in their organization. They also submitted written responses to the questions distributed in advance to panelists. In terms of identifying best practices for sharing pregnancy status from the provider to both commercial labs and PHAs, pregnancy status by an Ask on Order Entry (AOE) question can be added to the laboratory test order. The ordering system should be able to send that status to the laboratory information system (LIS) and in such a manner that it will be readily available to downstream

systems for reporting back to the client, provider or PHA. For ordering from the EHR, the pregnancy status should be available when ordering any test, such as laboratory, x-ray or procedure. This information is sent to the LIS or other systems to be available on the final reports. When the client provides pregnancy status when ordering tests, by AOE, the ordering system currently stores and sends this status to the LIS. When the question is not answered, it will not be in the LIS which then cannot pass it to other applications such as the Reportable Disease Application. Unanswered questions delay completion and release of results. Internally, pregnancy status can be entered and stored in the EHR. Pregnancy status is not currently available to the ordering system. Pregnancy status is not passed discretely to the LIS. The ordering clinician must answer AOE questions for tests that require pregnancy status to ensure that this is provided to the lab and LIS. A short-term solution was to add AOE questions to the Zika order. Likewise, questions could be added to other tests. A medium-term solution would be to indicate pregnancy status when the test order is submitted. Long-term, updates to all of the relevant systems to capture and report to all systems will be required. Standardized data are needed, and systems must have the capacity to be updated. Currently, changes require manual addition of data, and not all steps are automated.

Kelly Wroblewski, Association of Public Health Laboratories (APHL), showed slides and described the current pregnancy-related data flow, which varies greatly across labs. From provider to lab, pregnancy status is AOE (HL7 v2 messages use OBX segments for AOEs, with associated LOINC / SNOMED CT codes). From the lab to the PHA, it can be included in ELR (HL7v2) to PHA or in summary documents (CDA) in the social history section or problem list. But not all public health labs report test results using HL7 messaging. She offered several potential solutions. In the short-term, define standard vocabulary for data exchange and standard location for elements (in HL7 v2 and CDA). Medium-term, vocabulary solutions across data exchange standards used (if not already done short-term) can be harmonized and data element representation and associated vocabulary in storage identified. Long-term, standard data element representation across storage and exchange and reasoning against data elements for decision support must be applied.

Mary Wedig, Wisconsin State Laboratory of Hygiene (virtual) (no written testimony), Said that pregnant (yes or no) and EDD are current fields. The lab receives many paper orders. The SHA gets Zika data from providers on paper and sends them to the lab. The SHA puts data into its electronic disease system. The lab can consume electronic orders and send the information to the SHA. Wedig agreed that standards should be developed for pregnancy status. Her lab does not use AOEs.

Q&A

In response to a question from Fine about commercial labs, Sturmfels said that the majority of Zika test orders are received electronically. Pugh explained again that, for Zika, LabCorp obtains pregnancy status from the provider. She emphasized that this information is not needed for the test itself and that labs should not hold off on the test in order to get pregnancy status. Pugh estimated that from 60 to 70% of test orders are electronic. According to Luepke, the majority of Zika tests at Mayo are ordered electronically, and results are immediately reported to the PHA. In order for this to work, providers must have an incentive to report pregnancy status. As a reference lab, Mayo has many clients. Although questions can be added, they should not be unless the information is used.

Hamilton asked for more information on delayed reporting due to the capture of pregnancy status. Luepke replied that although the testing is not delayed, the results are not delivered until all required information is received. When information is missing, staff must contact the providers. Since Mayo supports multiple EMRs, there is always some manual component.

Loomis wondered about the industry's ability to pass through pregnancy status to PHAs with Zika test results. Also, what should be considered beyond Zika? Julien replied that the Zika test is not a solution to obtain pregnancy status. PHAs differ in their capability to order, store and track information. The LIS does not have a place to store information for future use. A surveillance system should be built up from the bottom. Pugh indicated that storage was possible if sufficient resources were available. Labs collect only the information needed to perform and bill for the ordered test. To add pregnancy status, labs are being asked to change hundreds of systems. The demand for changes for this one test must be weighed versus other needs. The addition of pregnancy status would be a hug effort. Sturmfels emphasized the importance of standardized data, not AOEs. Wedig said that her lab can store many data elements and send them to the PHA.

Consolazio asked the members to be concise. Wolf inquired about the success of use of logic for pregnancy status for Hep B tests. A panelist indicated that it is not feasible for most public health labs, although it is done by Quest in its own system, not the provider's EHR. Pugh reported that the majority of orders have the client ID information and are stored in the LIS. That information is used for reporting to PHAs. Orders from non-clients are more difficult. Sturmfels repeated that providers do not want to take the time to supply patient address and demographic information. Julien said that inbound interfaces have not been upgraded to 25.1. A top-down approach makes it difficult. There is no incentive for commercial labs to update.

Mcbride asked Sturmfels about missing data from hospital and ambulatory providers. Sturmfels said that the required information is provided most of the time. However, hospital labs cannot always provide the information to Quest because they do not have the capacity to access other systems in the same hospital.

Julia Gunn wanted more information about not needing pregnancy data for Zika testing: What about HIPAA? Sturmfels reminded her that PHAs are covered entities. It has not been an issue. Pugh reported that race and ethnicity data are mandated for some tests (although the information is not relevant for the test itself), and collection is difficult. Some providers say that collection violates HIPAA. Labs need to be shown why such information must be collected, for instance, that it is mandated by state law. Luepke reported that the collection of race and ethnicity was added to Zita tests because of a CDC guidance. The information is used for surveillance and interventions.

Fine again asked a question. She disclosed that the New York City PHA is dependent on the cooperation of labs even though it is not their primary business. No funding is provided. Federal partners must help. Labs cannot be forced into collecting all data. It may take years for PHAs to build the systems to obtain these data from EHRs. Fine wondered why labs handle diseases differently: Could these tests be called a prenatal test? Pugh said the LabCorp is trying to do this via the diagnostic code. The lab relies on the SHA to define what is needed. She emphasized that providers do not want to see a report that includes pregnancy status. To them, it is superfluous information. Another panelist disputed this, pointing out that providers change over time; the one who views the report is not necessarily the provider who ordered the test. Pugh declared that labs want to provide a user-friendly report to clients. Sturmfels reminded the members that Zika testing calls not only for pregnancy status, but also for location and travel. Another panelist talked about the need for a universal, standardized system of reportable diseases and standardized reporting. The variation across states is the issue. Julien said that there is a difference between a focus on the science or the standards of care. The priority should be agreed to.

In response to a question from Steve Hasley, Pugh said that CLIA prohibits performing any test that is not ordered. To do a pregnancy test on a positive Zika test, the lab needs gender, age and other demographics. Providers do not consistently provide this information. Gathering the information creates

delays and has costs. Sturmfels corrected Hasley's statement that pregnancy is a cheap test. Wroblewski pointed out that public health labs do not routinely do pregnancy tests.

Hamilton said that in her experience public health labs have different responsibilities and authorities. Clinicians often order the incorrect Zika test. The public health lab follows up with the clinician to ensure that the proper test is ordered. Clinicians have a huge amount of information to make the best decisions possible. What can be done by labs to help clinicians make good decisions? Wedig responded that the SHA becomes involved in that situation.

Margaret Lampe asked what data commercial labs mine to determine current pregnancy status. Pugh said that a reflective test must be ordered. The provider can select from the online test menu. Clients can set up specific panels. Prenatal panels are identified. But that does not verify that a patient is pregnant. The system cannot link back to previous orders. Fine interrupted to ask a question about ICD-10 codes. Sturmfels said that the provider sends the code, which is used for billing. Then it is cross-referenced for public health reporting. Diagnostic codes must be included in claims. Mayo does not do it this way. As a reference lab, Mayo does not connect to EHRs. Consolazio issued another warning about running short on time.

In response to a question from Wolf, Sturmfels said that labs are working toward a patient-based longitudinal system. Pugh spoke about the difficulty for a reference laboratory to link patient data over time; there is no unique number for doing so. Patients can request this for a patient portal.

Public Comment

Mari Saivicas, College of Healthcare Information Management Executives (CHIME), commented that a patient identifier for use over time is essential for interoperability. The federal government prohibits the use of HHS resources to establish a unique identifier system. Therefore, CHIME has issued a challenge to address this issue. She can be contacted for more information.

Panel 3: Clinical Decision Support & EHRs

Sasha TerMaat, Epic, presented a slide that depicted two public health emergency broadcast systems, one as it exists today and the other as it could work in the future. In the latter, CDC publishes machine- and human-readable guidelines. EHRs query the CDC API hourly and translate machine-readable guidance into CDS. EHRs increase awareness of and compliance with guidelines. When a guidance is updated, the feedback loop goes into effect. Although the challenges are significant, this approach would have these advantages:

- High visibility CDC-EHR communication channel to front line clinicians for information regarding public health emergencies
- Faster and easier incorporation of CDC guidance and updates
- Consistent implementation of CDC guidance
- Simple, standards-based technical solution for EHR developers

Karen Harris, American Congress of Obstetricians & Gynecologists (ACOG), (no written testimony), spoke about the importance of cooperation across federal, state and local agencies, and professional associations. Which test at which time is critical with Zika. Any algorithm must leave room for the clinician's input. Clinicians must be selective because a sufficient number of tests may not be available as was the case with Zika in Florida.

Carey Eppes, Baylor College of Medicine, showed slides. Eppes said that linking Zika test results and travel screening with pregnancy episodes should result in:

- Improved ascertainment of the population at risk
- Improved uptake of testing of pregnant women
- Easier reporting for PHAs and the CDC

Eppes said that linking travel risk factors to pregnancy will provide a denominator for at-risk pregnant women. Clinical support will help with detection and uptake of the appropriate testing in the right population and improve estimation of rates of congenital Zika virus. Linking lab results will improve reporting of the total number of tests and positive results.

Bill Hanson, CHIME (virtual), showed slides stating that public health emergencies are typically unexpected and require interpretation of governmental publications and announcements. There are emergencies other than infectious diseases. The opiate overdose crisis may be an example. The EHR is now the workflow workspace. Building workflows into the EHR takes time as does making modifications (i.e. updated Ebola geography). EHR workflows need humans; humans need easy. Institutional variability necessitates flexibility. Since CDS works best with closed loop feedback, internal and external reporting is ideal. However, reporting is hard, and real time reporting is harder**.**

Bryn Rhodes, Database Consulting Group (virtual) (no written testimony), said that with regard to automating the CDS for emerging public health threats, one must realize that EHR implementation cycles measure in months and years, not days and weeks. Implementation costs for CDS in each system are significant. Development challenges include:

- Development of effective content
- Change management
- Content delivery

Although a common format exists for content, most content is still in proprietary formats and/or services. Terminologies vary by site, and gaps are encountered with development of new content. Required information is often not available in a structured way and may require questionnaires or modifications to user-interfaces. Rhodes had several recommendations for content standards. Current HL7® V3 Standard is seeing applications in CDS content, as well as public health reporting, but is not broadly implemented. The Virtual Medical Record (vMR) for patient information uses HL7®. HL7® FHIR® Clinical Reasoning is an emerging standard (STU3). Rhodes supports the development of standards.

Q&A

Mcbride said that pregnancy status may be captured in several places in the EHRs. With current certified products, where should pregnancy status be captured? A panelist said that value codes can be used to capture and store variables of interest. Mcbride asked panel 4 participants to provide information to answer her question.

Loomis inquired about relative value of short-term solutions versus more robust long-term efforts. Hanson said that institutions will resist prescribed solutions. There is variation in workforces. Local interpretation will be required. Harris said that light and fast is better and effective to meet patient demand. Installation of a better, long-term solution would have adverse effects on current patients. Systems must be sufficiently nimble to meet new demands.

Wolf asked about the readiness of machine-readable, automatable guidelines to turn into CDS. Rhodes said that the infrastructure for content is being developed. There is a way to quickly deliver content. Hanson wondered about the readiness of vendors. Pregnancy is represented in different ways in EHRs. A

lighter, more flexible approach will work better at this time. Harris suggested that CDS is not well-defined. Provider education is difficult.

Fine referred to variability across jurisdictions and time, saying that total reliance on CDS at this time is not a good idea. Flexibility is required.

Lampe reported that after a year of experience, CDC is considering revising the Zika guidelines. A CDS tool is needed to flag patients for additional attention. Pregnancy status is also important for opiate dependency.

Gunn said that women who are late to prenatal care are the most at risk for Zika: What about ultrasound data to identify problems with the fetus? Harris said that no Zika lab test is available at this time for late pregnancy. No answers are available at this point. An infant who is normal at birth may later develop signs of exposure.

Hamilton wondered about the challenges that the lab representatives reported in panel 2. A panelist said that standardization is important. Hanson reported that lab systems are components of systems. Harris said that the time and workflow requirements are burdensome for providers. The issue is not for the provider, but for populating registries. Panelists agreed that alerts serve purposes, but overloads are counterproductive. Rhodes spoke about the timing of triggers in workflows. Consolazio asked members to respect the time constraints.

Steve Brown asked Rhodes about SMART on FHIR: Who will do this? Who has the infrastructure? How can SMART on FHIR infrastructure be made available? Rhodes said that profiles must be developed. Components are not available across the board, but they are coming.

Mcbride wondered about mid-term solutions and evolving travel history: Would it be helpful to have CDC push out travel history? Is that feasible? According to Rhodes, the idea is sensible and could be distributed as a value set. The goal is a way to dynamically gather and distribute content. Harris talked about a new version of the ACOG record with embedded CDS tools for use in outpatient settings.

Wiesenthal urged an approach to recommendations similar to that of the Presentative Services Task Force, which is based on level of evidence.

Panel 4: Clinical Workflow

Itara Barnes, KPMG, (no written testimony) said that similar data elements and standards have a long history. The Zika use case could drive development forward. Quality measures are only one driver for data capture. Value-based payment is a driver. Maternity care is an opportunity for efficiency in value-based care. Women of child bearing potential must be identified and their risks assessed. The industry must prepare for the next public health use case. If there is no action, each organization will develop its own approach. The level of granularity necessary for all use cases must be identified. Context is important. Data elements should be actionable. The goal is a well-defined data element and structured data.

Stephanie Hoelscher, Texas Tech University Health Sciences Center, (no written testimony) described her organization's approach to Zika data collection and application. She described the design and process developed for Ebola and, later, Zika in her organization. It focused on all points of entry. The lack of health resources in rural areas is a major problem. The question is who will pay for the infrastructure and time. Hoelscher agreed that this is a well-founded effort.

Kimberly Bodine, Tenet Healthcare (virtual), (no written testimony) pointed out that pregnancy status is captured by clinicians in conjunction with many other questions on women's health. Travel status is

explored in clinical consultations and may be captured in free text, which is preferred. The integration of base EHRs and other EHRs, such as NICU EHRs, should be considered for potential solutions.

Vijay Shah, JBS International, began by showing slides that listed challenges for PHAs and registries, and for HIT providers and vendors. A standard that addresses these challenges is needed. Structured Data Capture (SDC) may offer a way to a solution. The SDC Initiative:

- Extends EHR capabilities in using available data and interoperability standards to facilitate reporting
- Explains SDC standards and guidelines in two published Implementation Guides – IHE SDC Profile and FHIR SDC Profile
- Defines a structured form definition model
- Supports both SOAP and RESTful transactions

The SDC value proposition:

- Allows PHAs to define forms for data collection
- Significantly reduces time required for public health reporting
- Minimizes data capture and reporting errors
- Ensures that the PHA receives high quality data that can be immediately analyzed
- Promotes use of common data elements and re-use of forms

Shah proposed a solution: InteropX–Healthcare Interoperability Solution. It is a standards-based health care interoperability solution that gives PHAs a quick and easy way to design and distribute new and updated forms (e.g. Zika Evaluation). It provides direct integration with EHR systems to capture the public health event data and enhances EHRs reporting capabilities for various public health reportable events as they are observed. Moreover, it reduces provider work burden by prepopulating structured data from the EHR to minimize data capture errors and streamline reporting. According to Shah, the underlying design pattern is extensible and can be used to satisfy any number of public health reporting requirements. Proven demonstrations were made at HIMSS 2016 and the Public Health Informatics Conference 2016.

Rhoda Sperling, Mount Sinai Hospital (virtual), described and showed slides of screen shots of testing with EPIC in her hospital. Knowing which test to order is not necessarily easy for clinicians. Mount Sinai used its EHR to give information to clinicians and direct them to which test is appropriate and where to send it. SmarSets within Epic was used. The first question was is the patient pregnant. According to Sperling, pregnancy status should be incorporated as a vital sign.

Q&A

Mcbride asked what would help with CDS. Responses were: standardized guidelines; finalized guidelines, because of the expense involved in making changes in process; a standard for documentation of pregnancy status (possibly similar to smoking status for meaningful use; and building upon existing systems and requirements.

Khurshid asked about challenges with templates. Shah explained that the agency that wants the data is the best one to describe the collection process. SDC was used to create a template. Branching logic and questions can be used. Demographic data can be captured in a similar manner across organizations and providers. A provider may need some changes, but only a one-time change is required.

A member inquired about prioritization of testing after an order was submitted and received: What did you do to indicate which case should be tested first? One panelist talked about prioritization for

targeting public health interventions. Risk-related variables must be known. Another panelist reported that the demand was such that it was not necessary to prioritize. Although it took 2 months to receive results of the first tests, that time period has been considerably reduced.

Fine asked about the collection of data by ancillary staff at the point of encounter. A panelist responded that no pushback was experienced. Female patients routinely respond to questions about the first day of last menstrual period. Regarding how to map data into the correct field, Shah explained that when designing the form, one can designate what kind of data is required. Information from the EHRs can be leveraged.

Gunn observed that some of the design to respond to Ebola is not now relevant: How can processes move from immediate need to a lower level need? Bodine said that her organization is considering this problem. Who is responsibility for keeping up with epidemiology? Sometimes a process for a disease needs to be shut down, but should stay ready. Bodine noted that if destination of travel is left as free text, new epidemics can be tracked. Barnes recommended building for future use cases and to examine current use cases such as influenza, which is turned on and off annually. Communication with patients regarding travel plans is important. Shah said that if PHAs receive structured data, they can notify providers regarding on and off.

Daniel referred to Sperling's slides on the lab ordering system: Is this particular to your vendor? How is it populated? Could the data be supplied automatically? He noted that attempts to use order sets had not worked. Sperling responded that she worked with Epic staff on the design. When SmartSets is opened, it leverages existing functions. Hard stops can be inserted. Nothing special was created. Wiesenthal said that every Epic client has access to SmartSets. Orders must map to the LIS, which makes them non-automatic. The data go into an Epic library for use by any Epic client, but the data are not consumable. Although it is not too difficult to do, a special kind of order set is needed. Bodine said that Cerner has a similar function.

Mcbride inquired about alert fatigue. Bodine said that the CDS absolutely must be kept up to date. If not, patients are affected by unnecessary costs, tests and referrals. She recommended use of SAFER Guides.

Taskforce Discussion and Next Steps

The task force is scheduled to meet February 9 for discussion of the hearing output. Consolazio discussed participants' travel plans in view of impending inclement weather.

Closing Remarks

Wolf thanked everyone. He urged members to think about a simple approach to a complex issue, such as hybrid approaches. He wants to get pregnancy status right. Smoking status collection did not work well. Perhaps travel history should be embedded in EHRs. Fine thanked the panelists. She called for consideration of both short- and long-term solutions.

Public Comment

Rita (name not determined), JBS International, Inc., commented that she was intrigued by the use of patient portals to acquire and use lab test information.

Meeting Materials

- Agenda
- Panelist bios
- Questions
- Written testimonies
- Presentation slides

Attendance

Name	02/08/17	01/25/17	01/18/17	01/12/17	12/20/16
Andrew M. Wiesenthal	X			X	X
Anjum Khurshid	X	X		X	X
Anne Fine	X	X		X	X
Brian Anderson		X		X	X
Chesley Richards					
Floyd Eisenberg		X		X	X
J. Marc Overhage		X		X	X
James Daniel	X	X		X	X
Janet Hamilton	X			X	X
Julia Gunn	X	X		X	X
Larry Wolf	X				X
Margaret Lampe	X	X		X	X
Noam Arzt	X	X		X	X
Richard Loomis	X			X	
Riki Merrick	X	X		X	X
Steve Hasley	X			X	X
Susan Mcbride	X	X		X	X