INDIVIDUAL RESPONSES

Testimony of Charles Ishikawa on behalf of JPHIT

Contents

The testimony delivered by Charles Ishikawa is based on perspectives gathered from the associations and organizations of the Joint Public Health Informatics Taskforce (JPHIT). This document presents the individual responses submitted to JPHIT's Secretary by February 7, 2017. Responses are provided in near raw form. Responses are grouped by either a general professional category or by association name.

Charles Ishikawa
cishikawa@jphit.org

Question 1 - Relative to pregnancy status, what at a minimum, and optimally, does public health need to know?

i. Local Public Health Officials:
   - What public health needs to know and how can we automate CDS might be answered by lining up the CDC Zika guidance next to the typical content of an EHR.
   - PH needs to know week of gestation. This tells the public health practitioner what actions should be taken immediately versus which have more time and can be prioritized later. For example, with Zika, someone early in the pregnancy could still potentially seek a medical abortion and may be inquiring about such services. Someone might be looking for social support. A patient reported later in the pregnancy and closer to the delivery date will prompt the PH person to coordinate the required CDC collection procedures with the hospital where the patient will deliver.
      - Note: Week of gestation is more important that a pregnancy test date since some patients can be far along in the pregnancy before ever being tested and this does not give a sense of gestation. Gestation is really key. Since week of gestation is not always a field captured in the EHR, the EDD (estimated delivery date) would also give this same info but this is not a defined field and is often found by reading doctor's notes.

ii. State Public Health Surveillance Professional:
   - Basic: Currently pregnant – Y/N/Maybe/U
   - Ideal: Ideal if the field could be required for all women of childbearing age. Gestational age (preferred over delivery date – can be used to infer delivery date and would better account for pregnancy loss)—win-win-for both clinical care and pharmacists Anticipated delivery date
   - As a start, it would simply be helpful to know if a woman was pregnant or not. Currently our surveillance relies on live births, fetal deaths and maternal mortality, which misses women whose pregnancy didn't 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 wasn't 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. We can get some information from Medicaid claims, but that is limited. There is no reliable pregnancy flag and our knowledge is retrospective. It would be useful for both surveillance and intervention to be able to identify pregnancy in real time or near real time.

iii. American Immunization Registry Association (AIRA):
   - An immunization provider needs to know pregnancy status prior to vaccinating a patient. **This information is needed for routinely recommended vaccines.**
   - While the current disease up for discussion is Zika, this issue has broad applicability to other public health emergencies, including the not-so-long-ago H1N1 pandemic, when pregnancy was considered as a condition for receiving prioritized vaccine.
   - Definitively knowing the patient's pregnancy status will allow clinical decision support engines to provide more accurate patient forecasts. Pregnancy status is an indicator that certain vaccines should be administered (Tdap, influenza) and a contraindication for other vaccines (e.g., live virus vaccines including Measles, Mumps, Rubella (MMR), Varicella (chicken pox)).

- Gestational age, or some other field that would indicate the trimester is needed to forecast the optimal time to receive certain vaccines for best results for both mother and infant (e.g., Tdap -- recommended administration in the third trimester).

Question 2 – How is pregnancy status captured across the continuum? Where is pregnancy information captured electronically and what elements in the EHR would be best for public health to leverage?

i. Local Public Health Officials:
   - How well developed the tools for such communication need to be, and how far we need to go with automation of CDS depends on something we do not know—the future burden of Zika. If it is going to be bad we'd better build it. Again, this leads us back to something like structured data capture where we can respond quickly to novel diseases and we haven't burned a lot of resources if an outbreak turns out not to be like the Spanish Flu.
   - Pregnancy status is not captured in the EHR (at least not for EPIC). The nurses in Marion County have access to the county hospital's records and I'm told the nurse can gather the scope of the pregnancy (tests, EDD, etc.) by looking at labs ordered, lab results, doctor's notes, fields indicating last menses, etc. Pregnancy status per se is not captured. Sometimes the nurses recognize the doctors' names to be OB/Gyn's and this tells them to check that note to look for info about the pregnancy.

ii. State Public Health Surveillance Professional:
   - Syndromic surveillance (SyS) data are provisioned in near real-time. Since the national SyS messaging guidance includes diagnosis as a required element, pregnancy data data captured in these data. For example, there is an ICD-10 code for weeks of gestation. In exploring just the data we have for January 2017, there are many cases that may be pregnant. SyS data are a place where public health agencies may find pregnancy data.
   - There are data from which inferences can be made regarding a patient's pregnancy status. For example:
     - Is a pregnancy test ordered? Could indicate suspicion of pregnancy n If an ultra sound is performed is the gestational age recorded or required to be recorded on the
     - Has an ultrasound been conducted? How is that data stored in the EHR so it can be accessed and shared?
     - Women who are determined to have higher risk pregnancies (age etc.) have an additional set of tests performed during pregnancy. Are there any of those tests that are unique to pregnant women or largely unique that could be used to inferred pregnancy?
   - With regard to the epidemiology side, people with reportable conditions in Michigan, such as Zika, are entered into the Michigan Disease Surveillance System electronic database. There are disease specific case report forms that are completed as the local health departments investigate these reports. Pregnancy status is included as a data field.

iii. Public Health Information Technology Service Provider:
   - EHRs and pregnancy status has become more complicated because sexuality has become more complicated because of transgender, etc. It's hard for doctors to talk to patients about this and even record about it. The British Medical Association has released a guide for effective communication in this regard, since sometimes gender is a social construct. Throw that into the mix, how do you know data is capturing things correctly when gender can be fluid?

Question 2 - Continued

iv. AIRA:

- The HL7 Immunization Implementation Guide references how to send pregnancy status as a patient contraindication using the SNOMED code 77386006 in OBX-5. The HL7 implementation guide also defines how to exchange the contraindication effective (estimated date of conception) and expiration (estimated date of delivery) dates. However, we must also consider how to message the actual end of a pregnancy as it is likely to differ from the estimated date of delivery. The HL7 implementation guide does not currently provide guidance on how to indicate that an observation definitively no longer applies to a patient or was entered in error.

Q2 | Part A – Is it currently possible to know what is needed based on calculations from an EHR system or do new processes need to be put in place to capture that information?

v. Local Public Health Official:

- A possible win/win data collection process could be setting triggers in the EHR that could combine the info related to patient's pregnancy into a 'pregnancy sheet' or summary. I could see the benefit in this sheet them being applied to the infant's EHR once born so that the baby's provider can have a better understanding of any issues the mother faced during the pregnancy.
- Obviously including travel history into the intake process would help (as they did with Ebola) but since Zika has spread to so many countries, there is really more pressure on the provider to know what countries are affected and when a flag should be raised when the patient confirms a travel history. There could be benefit if there was an automated way for the EHR to connect with an update CDC list to create flags to consider testing. That would probably require some collaborations and programming we haven't seen yet but could be done.

vi. State Public Health Surveillance Professional:

- Often we have systems like syndromic surveillance that are meant to lessen the burden on providers, while skill providing valuable information to public health. These systems are to skim data already collected as they are collected. Sometimes we devise ways to get the information we need using those "dirty" data. And that works just fine. Then other players in the space (other federal agencies, big vendors, whoever) will step in and say, we don't get 'x' or we don't get 'y' (like zika pregnancy or Ebola travel). They may create a new drop down or they may call people together and change the systems to collect 'x' or 'y'. Those adjustments o9en don't work for the provider's work flow. So now you have a situation where the systems we use like syndromic surveillance systems had discovered where to get 'x' or 'y' around 60% or 70 % of the time. Then the changes are put into place, the clinic workers are told to change where and/or how they record 'x' or 'y'. Then that doesn't work for their workflow. Many clinicians just give up, while others continue as they used to do, and still others follow the instructions despite the difficulties to their workflow. Now the systems that were giving 'x' or 'y' 60% to 70% of the time drop to 10% or 30% of the time (or worse). The programs expecting to get "quality data" for 'x' or 'y' only get 10% to 30% of the data they expected. Now EVERYONE is unhappy, the vendors, the clinicians, the programs, and the good old

Q2 | Part A - Continued

syndromic surveillance epi. While I agree these systems need to be flexible and adjust to change, we also need to be thoughtful in how we collect information like this.

- With regard to IT issues, this has several layers: lab reporting, birth/stillbirth reporting and birth defects reporting. Zika status and pregnancy status are of interest in all these areas. We are working to add Zika exposure information to the HL7 birth and birth defects reporting standards (in Michigan and nationally) but they are not there now.
- ICD and SNOMED have added codes for Zika infection but not for Zika exposure. Zika exposure needs to be tracked as well.

vii. AIRA:

- Anecdotally, there is significant variation to how pregnancy status is stored within an EHR, and there is also likely variability to how data (both pregnancy status and dates) are stored in IIS as well. This variation may create a risk and need for standards development prior to encouraging interoperability and broad adoption.

Q2| Part B – Are there win-win data collection processes and standards that could be useful to BOTH public health and clinical providers/pharmacists?

i. Local Public Health Official

- The Digital Bridge is a win-win process for developing such standards – See Attachment 3 (Digital Bridge Fact Sheet)

ii. State Public Health Surveillance Professional

- The other issue is the translation of EMR to EHR at the hospital level, will impact the output to the Health Information Network.

iii. National Association of Health Data Organizations (NAHDO):

- As we know no one source will be sufficient for population health needs, a win-win would be to use a combination of data sources. A growing number of states and others are using episodes of care methodology to analyze conditions/illnesses of interest, such as pregnancy, using computerized algorithms from claims and encounter data, which are a under-utilized data source in public health (in my observations). These data sources, in combination with public health reporting, could fill in important gaps in information, especially as health care is expected to shift to decentralized care settings with variable data reporting infrastructures.
- With All Payer Claims Databases (APCD) one can link together the claims data to create a framework for the care and any interventions received and then the outcome of the event with the delivery. From first confirmation with a health care provider/clinic/etc. to delivery there will be records that can be linked together.
- The APCD provides an opportunity to look at a single case longitudinally as well as by episode at various settings of care[1]. Key to all of this will be linking the person key indicators together to link episodes and interventions. As someone can switch health plans during a pregnancy, the key is the patient identifiers that are common across plans.

[1] See Attachment 1 - A Process for structuring bundled Payment in Maternity Care. By: François de Brante, MS, MBA & Karen Love, MHA. Health Care Incentive Improvement Institute, Community Health Choice. Case Study, October 18, 2016.

- There are several examples of episodes for conditions/procedures now: joint replacement is a model in which the index claim (surgery) is identified and then all claims pre and post to that index are linked for that patient to calculate the episode costs: professional, PT/rehab, Rx, lab, imaging to identify efficiency for value-based purchasing by employers etc.
- Pregnancy, with its global billing, may be a bit different and may not be as clear. In states with hospital discharge databases (most), the delivery from the facility is reported. States often link hospital discharge with vital records for more clinical information (also PRAMS)----but more for outcomes.
- In some APCD states, it would be possible to link that index (delivery) to the APCD claims to identify non-facility claims related to that patient (or group of patients) to derive a sense of outpatient services billed.
- As anything in public health, it requires a series of data points and a detective approach to connect the dots, but that's the point I repeatedly make: no one data point or data source or type will be sufficient. Public health must take a big data and data mining approach and get beyond building a perfect registry, survey, or clinical feed and be creative. Medicaid. Medicare. Commercial claims. hospital data. Vitals. Surveys. and more.
- Health systems and plans are moving to this big data model and so should public health (which traditionally has shied away from claims).

iv. AIRA:

- Question 1 above underscores the value/benefit of tracking pregnancy status; working across Public Health, EHR and pharmacy systems to establish standards for uniformity of data collected and consensus on timeline of adoption would increase each industry's ability to exchange these data seamlessly.

Q3 | Part A - Continued

i. Local Public Health Official:
   - Automating the CDS could be difficult since the exposures for Zika could be sexually related (partner travelled to affected area), travel related (patient travelled to affected area), and local transmission (no travel needed) and the countries affected were changing rapidly over the summer.

ii. State Public Health Surveillance Professionals:
   - We are seeing a lot of incorrect testing (ordering PCR, and no IgM) in the provider community; lack of understanding what is the right test to order and when; still have large numbers of women we estimate were not tested according to our guidelines; we have also seen a slow up take on review of travel history information and clinical symptoms; in FL we have had 10 cases that presented to EDs for care and were never identified by the clinical community – they were only identified by review our syndromic data and there was a high degree of suspicion from review of the patient chief complaint that Zika was of suspicion. One could imagine CDS could also help to identify these types of missed cases.
   - If we want to provide the highest standard of care the answer is simple – yes –
     i. We do need a better, simplified way to manage rapidly changing events – send out printed 1 page or many page guidance sheets and testing algorithms don't get absorbed only by the most astute and in tune; educating hundreds of thousands of providers in a manner that transfers knowledge is a challenge and likely a larger challenge than implementing algorithms into EHRs once initial recognition that this really is a path to lives saved and improved quality of life.
     ii. Potential criteria for CDS – amount of potential morbidity, mortality, rapidly changing event previously unrecognized where guidance and knowledge about management of the illness are rapidly changing; if social media can do it why can't we?
   - It would be useful for these systems to determine if someone should get a Zika test.

Q3 | Part A – What are the options for vendors, EHRs and public health to manage rapidly changing content?

i. AIRA:
   - This issue has arisen several times within the IIS community, quite frankly anytime there is a change to the ACIP immunization recommendations, there is a need to quickly update CDS. Some of the barriers to implementing changes within an IIS to manage rapidly changing content are the modifications required to the system to allow it to be modified quickly and where it falls in the spectrum of priorities. Without funding to update systems to capture this information, this becomes a much lower priority.
   - In responding to this question about rapidly changing content, it seems important to separate what would require one-time system modifications (i.e., adding the agreed-upon fields for tracking pregnancy to databases and interfaces), from the triggers that would message this information (i.e., when submitting an immunization, when new pregnancy is entered, when pregnancy has ended following birth, etc.).

ii. State Public Health Surveillance Professional:

- It is important that vendors and public health be in communication. Council of State and Territorial Epidemiologists, in conjunction with CDC and other agencies, develops case definitions. They also annually survey state health departments to understand what is reportable under what conditions in different states and territories. This information is meant to be useful to vendors.

Question 4: Is there a need to automate the CDS for emerging public health threats?

i. ARIA:
   - In short, there is a strong case to be made for this functionality. From the immunization perspective, changes to the routine immunization schedule (e.g., HPV change from 3 doses to 2 doses for certain age groups), when a new vaccine (e.g., H1N1) is rolled out quickly, has new priority groups, or requires multiple doses, or even fewer/booster/additional doses, there is a need for expedient and efficient modification of CDS.

Q4 – Part A – In which situations should CDS from public health be available and implemented? What are the criteria?

ii. ARIA:
   - Every time someone asks us for data we should offer up CDS about the patient in question. That doesn't imply that it should show up on every screen and workflow, but if we offer it up every time, then the users of our data can have it readily available to display when they want to. If we try to determine this ahead of time, we are going to run into way too many variations and use cases. Send it. They can use it or filter it out.

Q4 – Part B – What are the standards and when is it appropriate to push out CDS?

iii. AIRA:
   - Before we can use patient pregnancy status in the IIS we must first define the pregnancy related data needed (status, conception date, estimated delivery date, actual delivery date, etc.) and the triggering events which would initiate an exchange of data between systems. See comments in question 2.

iv. See AMIA response to CDC Request for Information – Clinical Decision Support (Solicitation Number: 2017-RFI-CDS-0001) – Attachment 4

General comments related to the Joint Public Health Task Force's charge re: Zika

i. Local public health monitors returned travelers for the States. So Zika response must include some form of two-way communication between States and Locals.

ii. Pregnancy information is crucial to public health and our ability to help protect our populations health and our national health security

- Public health will be able to respond more quickly, and provided better targeted follow up to an important population that is at higher risk for some adverse health outcomes
- Zika is the reason for convening this Hearing, but many more diseases – hep b, hep c, HIV, chlamydia, syphilis, pertussis, influenza, listeria – many of these are very high volume diseases (100,000s++++)
- Many of these are very high volume diseases (In FL we had ~38 perinatal hep c in 2015) – need info as earlier as possible as it can assist to prioritize follow-up and investigations ; timely vs complete will always be in a tug of war – choose timely rather than complete; want data as early as possible – Pregnancy info should come with the lab test ORDER and that information carried on with the test result – key for Zika while Zika diagnostic testing can still occur without the information, testing will be improved if the information is present = better patient safety