DRAFT

Question and Answer Session
during the Webinar on May 09 2007 and the Conference Call on May 30 2007

Q 1.	**Can one state/ jurisdiction have different types of reporting options? For example can a city within a jurisdiction use option 1 while the rest of the jurisdiction uses option 2 or 3?** **Or** **Can jurisdictions choose one reporting option initially and then switch to another reporting option in the future?** **Or** **Can state/ jurisdiction choose multiple options?**
A.	We prefer each Public Health Emergency Preparedness (PHEP) grantee (Project Area) operate with one option to maximize accuracy, consistency, and operational ease. We will be happy to discuss any issues with this approach on a case by case basis. Our intent is to obtain full participation in aggregate reporting of vaccine doses administered data.
Q 2.	**What funding will be available or provided for Project Areas to use either existing IIS or adopt any of the options of CRA system for panflu vaccine doses administering tracking?** **Or** **What funding is available for developing the plan to track doses administered and to support the salary of a planning lead?**
A.	Preparedness funding from the PHEP cooperative agreement is an appropriate source of funding for this work, but as with other preparedness activities, many states will also rely on in-kind participation from other parts of the state health department, including immunization programs. How planning activities will be supported must be worked out at the Project Area level and the approach used is likely to vary across states. We do not envision the planning lead to be a full time position, requiring an FTE. The primary role of this individual is to coordinate appropriate staff within the Project to develop and oversee a team plan for collecting, aggregating, and submitting data on the administration of pandemic influenza vaccine determining how the pan will be operationalized/ implemented, training staff as needed for their roles, and exercising the plan to identify any gaps. As part of the plan, CDC is also requesting that Project Areas make an assessment of the resources needed to carry out the process of collecting; aggregating and submitting doses administered data so that we have a sense of the magnitude of resources needed to carry out this aspect of pandemic response.

Q 3.	**Since CDC is primarily interested in cumulative aggregate data, do our sites still need to collect and record individual patient level data in their own systems such as a paper chart or other electronic system? For example, if my site selects Option 2, do we still need to ensure the other clinical data is captured somewhere?**
A.	Yes, clinic sites still need to be responsible for the collection of this typical clinical information, such as route of administration and lot number, etc. that is needed to document that a vaccine was administered to a patient.
Q 4.	**For the pilot testing, will issues concerning the lag times (timeliness of reporting) between vaccine administration and transmission to CDC be a major consideration?**
A.	Our primary focus for the pilot testing is to test the transfer of data from state/ jurisdiction into CDC-CRA system. Our webinar on June 27th will be dedicated to preparing for pilot testing.
Q 5.	**How is the accuracy of the data going to be addressed during this pilot test? Is there a validation mechanism in place?**
A.	As mentioned earlier, the primary goal of this pilot test is to test the successful flow of data from state/jurisdiction to CDC using the CRA system. Though data accuracy will not be assessed during this exercise we do assume that what will be sent is reasonably accurate.
Q 6.	**Once the data has been aggregated and sent to CDC, will CDC want to validate the sent data with individual level data later on?**
	At this time, we are discussing this issue to develop an appropriate approach for doing this. Once we have determined this, a plan will be developed.
Q 7.	**You mentioned that for the pilot testing the data has to be sent to CDC at least twice. Can this be one clinic sending two times or does it have to be two different clinics sending data one time?**
A.	We want to have data transmission to happen twice during the pilot testing from a jurisdiction (Project Area) to CDC via CRA system. The following scenarios would meet our requirements: one clinic sending data at two different times or two separate clinics sending data one time.
Q 8.	**If our present immunization registry is not robust enough as yet to fully comply as Option 1, can we chose Option 2 or Option 3 initially and then switch over to Option 1 when the registry becomes fully capable.** **If yes, will we be testing the wrong method since we will not be using ultimately what we used for the testing purpose?**

A.	Again, we are encouraging you to utilize a single option for reporting. However, if the above situation occurs you can initiate Option 2 or Option 3 and then switch to the Option 1 when the registry becomes fully capable. A test may need to be performed upon switching from one option to another; particularly if switching to option 1. Detailed plans are being developed and will be disseminated when ready.
Q 9.	**Will CRA be able to collect non-aggregate data?**
A	This depends on the option chosen. If a jurisdiction chooses option 3, more detailed non-aggregated data is collected using the CRA application. The aggregate counts are then calculated from the detail and will need to be validated by the user. However, if the jurisdiction chooses Options 1or 2, only aggregate data is sent or collected within CRA.
Q 10.	**Will adverse events tracking be part of influenza vaccine tracking?**
A.	Multiple constituents within CDC are determining how adverse events will be handled and tied into influenza vaccine tracking.
Q 11.	**When are the core data elements going to be finalized?**
A.	The core data elements that CDC will require are defined and available via the CRA website in the AR specifications document. Within this core data set, the recipient tier groups have not yet been finalized at the national level. What is reflected within the specification now is our "best guess". Once the tier groups are finalized and published, the specifications will be updated.
Q 12.	**Could you give us the status of the recipient tier data element for pandemic influenza vaccine doses administered?** **Or** **In an earlier webinar you mentioned that the recipient tier will be updated? Has this been updated?**
A.	Briefly, the timeframe on the release of the recipient tier has been extended and it could be several months before we will get the final answer.
Q 13.	**Is the current focus of CRA pandemic influenza or does it has other activities as well?**
A.	Pandemic influenza is an integrated project that CRA has prioritized. In addition, we do have regular webinars on CRA in general. The next major CRA system release is in September. We will be demonstrating/presenting this release during the CRA session of the 2007 PHIN conference August 27-29 in Atlanta. The weblink for this conference is:http://www.cdc.gov/phin/phin_conference/index.html
Q. 14	**How many digital certificates are available for each state/jurisdiction partner?**
A.	There is no limit on the number of digital certificates each state and local partner can have.
Q. 15	**During a pandemic, how many digital certificates can be issued in a 24-hr period?**
A.	There is no upper limit to the number of digital certificates that can be issued in 24 hours.

	CDC encourages Project Areas to anticipate in advance who may need access during an event and to proceed with getting digital certificates. We understand that there is a need to have processes in place for mass production of digital certificates during emergencies. We are in discussions with colleagues in the Shared Services Division on what these processes may be and to ensure that they are realistic and effective.
Q. 16	**Have the technical specifications for HL7, XML and pip-delimited data formats been posted on the CRA website?**
A.	Yes, they are on the CRA website at: http://www.cdc.gov/phin/preparedness/cra.html
Q. 17	**Is CDC going to have the same focus for antiviral tracking in the future?**
A.	Currently, CDC is focused on Pandemic Influenza vaccine doses administered only. There is much discussion about antivirals and their role in a pandemic. However, nothing has been finalized regarding tracking their administration. The CRA aggregate reporting capability was designed to support any kind of countermeasure tracking so we are well positioned to support such a requirement if it is needed.
Q. 18	**Is there a disaster recovery plan in place for Aggregate Reporting?**
A.	The CRA application has a disaster recovery plan that is part of CDC's overall business continuity plan. In addition, CRA has an off-line capability that will be further improved for ease of operation and synchronization with the central system. If the disaster is so pervasive and none of these capabilities exist, Project Areas will need to rely on faxes and phones.
Q. 19	**How is the dispensing portion defined? For example, if certain jurisdictions have ship-to-sites, are they considered dispensing points as well?**
A.	This depends on how the jurisdiction has determined their ship-to sites. In some jurisdictions, ship-to sites may also be the sites for dispensing. In others, all dispensing sites may different location than the ship-to sites. In still others, there may be a combination of these two scenarios. Since we are tracking vaccine doses administered and not vaccine doses shipped with CRA, data would be associated with the dispensing sites.
Q. 20	**Some jurisdictions may not be prepared to report aggregate doses during the very peak of the pandemic such the WHO pandemic category 5. Will the CDC still require reporting during category 5 scenarios?**
A.	Yes, collecting information on vaccine doses administered is a critical public health function and must be a high priority during any event. Aggregate reporting is roll up of that activity and will be a requirement during the phases of pandemic when vaccine is scarce.
Q. 21	**Can the state and local partners receive the reports back or have some kind of feedback once they have submitted aggregate data to the CDC?**

A.	Yes, the CRA system will have the functionality for the user to view the submitted information.
Q. 22	**Will CDC provide training or training materials, including 'train the trainer', once the reporting options are finalized?**
A.	Yes, CDC will develop training materials that can be used by Project Areas. What training will be available is still under consideration at this time. Most likely, a "train the trainer" approach will be used. Training materials and approach will differ based on the option chosen.
Q. 23	**What are the transfer vehicles for the reporting options?**
A.	The transfer vehicles are: ebXML transport such as PHINMS; manual upload; and a CRA-developed applet (built using JMS Queue) installed at the sending site.
Q. 24	**What is a Project Area?**
A.	Project Area is the term CDC uses to refer to PHEP (Public Health Emergency Preparedness) grantees. There are 62 Project Areas, which include states, territories and large metropolitan areas.
Q. 25	**Would a one time tie-in with an exercise be sufficient for the aggregate reporting testing phase or are multiple exercises needed?**
A.	The details of the test plan using seasonal influenza vaccine are being developed; Also our webinar on June 27 will be focused on the planning for seasonal influenza pilot test. At minimum, one clinic would be chosen from each Project Area for the test and the test would have to be done at least two times. As the plans are solidified, we will share them.