

FTS-CDC-ITSO

Moderator: Ulrica Andujar
April 29, 2009
1:00 pm CT

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode until the question and answer session. If you would like to ask a question at that time, please press star then 1.

Today's conference is being recorded. If there are any objections, you may disconnect at this time.

Now I would like to turn the meeting over to Miss Jeanne Tropper. You may begin.

Jeanne Tropper: Thank you. Hello everyone. Thank you for joining us today. We wanted to talk to you about the situation with Swine Flu, and about refocusing efforts away from the DAX exercise to preparing to track Swine Flu vaccine when it is available in four to six months.

Before we get started, I just wanted to let you know that on the phone we have Tom Shimabukuro who will be giving you an overview of where we stand right now. And I am also joined here in the room with Warren Williams, Howard Hill and Ed Brink from the Immunization Services Division as well as a number of our Development Team to answer any questions that you might have.

So the expectations at a high level will be that all states will ramp up to send CDC the minimum data set that we have been working on on a daily basis

beginning when the vaccine is available and stopping when indicated from CDC. And the expectation is that all of the Grantees would participate.

And we will open it up for questions later, but with that I am going to turn it over to Tom Shimabukuro to kind of give us the latest update on where we stand with the vaccine. Tom?

Tom Shimabukuro: Hi. Thanks Jeanne. I am not going to run through the epidemiology because if you have been following the news you probably know as much about what is going on as we do. The CDC has been releasing information as it becomes available to them provided they can validate it.

I just want to let you know what is going on with vaccines right now. They are currently working on preparing reference strains here at the CDC lab and other places to send to the manufacturers which they need before they are able to start their work.

Once the manufacturers receive the strains from CDC, they are able to manufacture seed strains, which is the first step in creating a pilot lot of a vaccine. And once there is a pilot lot, we can conduct clinical trials.

And it looks like the same timeline that we have been putting out to have a vaccine available within four to five months (which puts it in late summer) is a possible option.

And there was an HHS press conference a little bit ago where they said that developing and procuring vaccine is one decision. Administering it or how to administer it is another.

So we are going through the preliminary steps that we would normally go through when we detect a novel virus to manufacture a vaccine. No decisions right now have been made on whether we are going to do commercial scale production of a Swine H1N1 containing vaccine, but they are taking all the necessary steps to move towards that.

As Jeanne said, there are certain fairly high level requirements that we have, or expectations that we have and that involves reporting on the minimum data sets through whatever option you choose on a weekly basis beginning when vaccine first becomes available and is distributed for administration and ending when we put out the word that we are effectively shutting down CRA although we probably would not completely shut down CRA. We would continue to accept data.

Some additional steps we would like you to take right now, for the last two seasons, we have conducted a series of exercises. And they have been limited scale functional exercises.

We are really asking you over the next weeks and months to expand your efforts to include all your local jurisdictions and certainly inform them that there are certain steps they have to take such as identifying and coordinating with clinic sites and making sure that the necessary staffing and resources are in place.

Most states have local and county health departments which function independently or semi-autonomously. And so communicating with them and setting expectations with them and giving them guidance on how to ramp up activities for reporting to CRA both strategic and operational are very important right now.

Although we are listing off these sets of requirements, we are also realists. And we understand that you have a lot of things going on right now. You will have a lot of things going on if and when we deploy a vaccine.

And so we just want to emphasize that although we view it as important to monitor utilization of vaccine, we also realize that you have a lot of priorities and your number one priority with a vaccine of course should be to vaccinate as many people as rapidly as possible and maintain vigilance for any adverse events which may result from vaccine.

As Jeanne said, we are placing a hold on planning for DAX2009 indefinitely. If we continue at this pace and if we continue to see disease spread like we expect to, I would anticipate that we could cancel DAX2009.

Now it may be that our planning pause puts us in a position where we cannot reinitiate. But we want you all to really focus with your immunization programs, your preparedness programs, whoever you work with to really work with your local health departments and communicate clear guidance to them and make sure that they realize the guidance is to also work with their communities and their clinic sites to get ready to implement CRA to go live with this.

The soonest we would probably do this is again in late September when a vaccine might become available. Now I just want to say that these discussions about vaccine availability and administration and tracking utilization are somewhat premature.

Right now, the U.S. government is taking the steps to create pilot lots for clinical trials which is the first step in moving to commercial scale production.

But no decisions have been made yet on commercial scale production of a Swine (H1N1) containing vaccine.

An issue which has come up several times on different calls is around anti-viral tracking through CRA. And I think Jeanne is going to want to address this, but our focus right now is on tracking vaccine utilization.

Right now CRA is not at its point in development where we could fairly rapidly implement anti-viral tracking like we could for vaccine. And I guess fairly rapidly is kind of a relative term. But, I mean, CRA is an all hazard, all countermeasure response tracking informatics system.

And again, right now there aren't current plans to track anti-viral utilization. But should that change in the future, this capability will be built up into the system. That might be an option. But like I said, right now we are focused on vaccine.

Jeanne I do not know if you want to address that further. And then if I had missed any key points I will let the other CDC folks chime in and then we can open it up for questions.

Jeanne Tropper: Yes. Just to reiterate what Tom said, there is no policy right now that says that we would be expecting to track the antiviral. And as Tom also said that however if that should become a need we are capable of tracking it through this in a similar manner.

But for now that is not an expectation. And if there is any indication that it would become such, then we will be back in further touch obviously.

But I think that is pretty much it as far as the antiviral. But just again, there is no expectation right now. Warren did you want to add anything?

Warren Williams: This is Warren Williams. The only other point: I would like to also acknowledge and thank everybody for their participation in the past couple years for the exercises that we have done. I think that those efforts have helped us to be in a little bit better position to tackle what we have to tackle right now.

The enthusiasm and participation at the recent NIC conference and various sessions was also good. So I think we are just going to be transitioning this passion and enthusiasm into the reality planning with all these other details that we have to think about now.

And I would just like to thank everybody for their previous participation in the prior exercise and their willingness to participate in the '09 exercise which is now, in all likelihood, not going to happen.

And I think we are aware of a few technical considerations and modifications that we need to be planning for and thinking about. And I am sure there are some others that will come up over the course of the next couple months, and we probably need to figure out some type of communication plan to coordinate some of these activities.

So I think you will probably be hearing some from us, like we were for the exercise planning but more for the reality situations that we have to think about right now.

I think there are lots of details to think about as Tom said about coordination with the preparedness programs and the immunization programs getting the

dispensing sites lined up and really trying to stay on top of where all these reporting units are and making sure that there is appropriate follow up for them and resources at the place for getting this thing ramped up with the scale of magnitude of what we think it might materialize into. And now is the time to start planning for that.

Tom Shimabukuro: Yes this is Tom. I would like to second what Warren said. We really appreciate all the effort you have put forth in the planning for CRA, and a lot of other aspects of vaccine operations.

I know that a lot of you wear multiple hats in your health department. You deal with distribution. You deal with monitoring distribution. You deal with safety. You deal with regulatory issues. And it is pretty amazing that although this scenario is quite different than the one we trained for we trained for an H5N1 originate in Asia, migrating here and having some lead time.

How we are responding, at least at CDC, is largely playing out the way we planned it with the exception of there not being a pre-pandemic vaccine and it is starting in North America which is a huge departure from our planning assumptions.

But how we are actually working through these issues is pretty much playing out like we trained. So we appreciate you participating in our training, in our planning events because I think it is really helping us in this response.

Jeanne Tropper: You want to go ahead and open it up for questions?

Coordinator: Thank you. If you would like to ask a question, please press star then 1. To withdraw your request, press star then 2. Once again if you would like to ask a question, please star then 1 now. One moment please for the first question.

First question comes from Tim Heath. Your line is open.

Tim Heath: Hi this is Tim Heath in South Dakota. Question - we were moving forward with CRA before the Swine Flu hit. We were thinking about switching from a paper base to an electronic base system realizing that we would need some resources on the CDC end to help us with technical specifications. Is this something we should put on hold for now as well?

Jeanne Tropper: What exactly were you expecting to do?

Tim Heath: Well we were using a paper base system and submitting aggregate accounts into CRA. What we wanted to do was use our registry to record those that administered into your groups and use that to upload to the CRA down the line here.

Tom Shimabukuro: How far along is your registry in making those preparations?

Tim Heath: Not very.

Tom Shimabukuro: I would not discourage that, but if you think that is going to be a distraction to other pandemic planning efforts - if you think that those resources and that staffing power would be put to better use, I probably would not do that. And what do you think Warren?

Warren Williams: Yes, I think it just sort of depends how far along you were with that process. It sounds like you might not be very close to it so you might have to consider some of the other options to think about the Option 1 technique or some improvements of other systems there.

Tim Heath: Okay. Thank you.

Warren Williams: Again, we can talk maybe off line to see how far along the maturity there, the registry is for those functions. But typically if you are not very far along it may be too late to start that.

Tim Heath: All right. Well I will talk to my contractor and see how far he has made it.

Warren Williams: Okay.

Tim Heath: Thank you.

Coordinator: Once again if you would like to ask a question please press star 1. Our next question comes from Bob Swanson. Your line is open.

Bob Swanson: Hi. I just had a couple of questions, one maybe having to do with the vaccine. Tom you talked about the vaccine four to six months if in fact they decide to move forward with it. Is it likely to be included in the season vaccine with that or a separate one?

And secondly, on the antiviral, we are getting pushed in our state to keep track to the individual who received each course of antiviral from the SNS program. Do you have any direction? Is SNS's requirement that we track all the antivirals down to the individual?

Jeanne Tropper: This is Jeanne. When you say SNS, a lot of time the states are talking about their own SNS versus the Federal SNS. Which are you talking about?

Bob Swanson: It is our state SNS but they said it was direction given to them by the Federal SNS.

Jeanne Tropper: I am unaware. We will need to touch base with that. We are unaware at this point.

Bob Swanson: Okay.

Tom Shimabukuro: This is Tom. I am sorry, I did not get your name again.

Bob Swanson: Bob Swanson. I am from Michigan.

Tom Shimabukuro: Bob are you the Stockpile Coordinator in addition to a vaccine guy as well?

Bob Swanson: No. I am the Immunization Program Manager, but we work closely with the SNS folks.

Tom Shimabukuro: I think that your state's Stockpile Coordinator probably should contact their SNS regional Coordinator or contact somebody at CDC SNS. I am not aware of any requirements from the Strategic National Stockpile to track administration at the individual level, but I do not know that.

But your SNS Coordinator should be able to contact a CDC Stockpile rep and find that out.

Bob Swanson: Okay.

Tom Shimabukuro: As far as your first question: are we going to make a quadrivalent or some type of multivalent vaccine that includes seasonal strains as well as this new H1N1 strain or are we going to have a monovalent H1N1 vaccine and then a seasonal vaccine. And those are kind of hot topics of discussion here at CDC.

There are advantages of having a separate monovalent vaccine because it gives you more flexibility in your decision making process. If you have a quadrivalent or a multivalent, you are basically linking seasonal to pandemic. They are - you cannot separate the two.

But that decision is - those discussions around that decision are under way and that is a very high level policy decision. When we find out we will certainly let you know although you will probably hear it on the news before we hear it.

But, I would prepare like you are going to - we are still operating under the planning assumption this is going to be a government managed national vaccination campaign which means Federally managed until it gets to the state and then state managed until it gets to the local health department and then pretty much a local health department, local government operation.

We are still operating under that planning assumption. Whether it is going to be a monovalent vaccine, monovalent H1N1 vaccine or some type of quadrivalent or multivalent - for the purpose of the CRA it probably does not matter.

We are going to ask that you report on whatever is the H1N1, the Swine H1N1 containing vaccine. That is kind of a non-answer but that is the best information I can give you.

Bob Swanson: Well I am glad they are all talking about it. They are a lot smarter people than I am so that is good.

Coordinator: Our next question comes from Laura Ann Nicolai. Your line is open.

Laura Ann Nicolai: Hi. I was just checking to see what the progress is for batch processing digital certificates?

Jeanne Tropper: So yes. We have a precedent right now where the SDN has been set up to accept user name and password for a certain length of time and for a certain data collection.

So we will be following up with the security folks to do the same thing once we start this. So we are expecting that we will have a very different set up to accommodate the situation.

On the other hand, if your certificate for routine uses is expiring, you still will have to use it for other CDC systems. And until we can actually set that up with SDN we are still going to be accessing CRA through the digital certificate. But once we are ready to track, our expectation is we will be loosening that up.

Laura Ann Nicolai: Okay thanks.

Jeanne Tropper: And of course we have to work out the details on what that really means.

Coordinator: Our next question comes from Kim Tichy. Your line is open.

Jenny Evans: This is actually Jenny Evans with Kim Tichy in Iowa. My question is regarding the CRA. And if that goes through are we going to be working with tier groups on those?

Tom Shimabukuro: That is what we are planning for. I mean there is a process in place to reassess the guidance by various advisory groups ACIP, NVAC, the NBSD

and possibly make modifications to the recommendations based on the epidemiology.

However, we are building or we have already built the capability for the tier groups and we are moving forward and we would like you to move forward with your plans to create some type of triage protocol and some type of documentation process to slot people into tier groups because we are still using the pandemic planning assumptions in all the Federal guidance and national plans.

Jenny Evans: Okay thank you.

Coordinator: Our next question comes from Eric Dobb. Your line is open.

Jeanne Tropper: Hello.

Coordinator: Mr. Dobb has withdrawn his question. At this time I have no further questions.

Jeanne Tropper: All right. Well great. If there are questions as normally you can funnel them through Charles Williams and the PHIN Help Desk as we normally have. And as we know more, we will continue to share with you. Well thank you everybody.

Tom Shimabukuro: Thanks everybody.

Jeanne Tropper: All right. Bye-bye.

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