

FTS CDC ITSO

Moderator: Ulrica Andujar
May 13, 2009
1:00 pm CT

Coordinator: Good afternoon and thank you all for holding. I would like to remind all parties that your lines are in a listen-only mode until the question and answer session of today's conference. Today's conference is being recorded, if you have any objections you may disconnect at this time.

During the question and answer session you can press star 1 on your touchtone phone if you have a question.

I will now turn the call over to Jeanne Tropper, ma'am, you may begin.

Jeanne Tropper: ¹Thanks. Hello everyone. Thank you for joining us. This is the second call that we have had to talk about the tracking for the novel influenza A (H1N1) so we will refer to it as H1N1 moving forward here. ²We will go through a little bit of a background and then we will talk about the vaccine update, get into some of the planning considerations and then open up for question and answer.

And as usual I am joined by colleagues from National Immunization and Respiratory Diseases Center Immunizations Services Division and as well as the CRA Development Team, and they are here to answer questions and to talk in some of the specific areas.

³So moving along with the background, as everybody is very familiar with the National Pandemic Strategy calls for monitoring scarce vaccine - pre-pandemic/pandemic. ⁴As you probably are aware, we have focused the

pandemic efforts to support the H1N1 response. And so we are basically using the same plans that we have for the pandemic to support H1N1.

And so given that we are moving ahead with plans to track the H1N1 vaccine when it becomes available in or around the September timeframe. And to do this we are going to use the Countermeasure and Response Administration system much as we have in our practice exercises in 2008 and 2009. So we hopefully are all fairly well prepared for this.

Basically the intent is to have a subset of data sent to the CDC and one of three different methods; option 1 is if you are collecting the detail information in your local immunization or other system, extracting that and sending it in one of three file layouts to the CDC.

Another way is to use the detail - the CRA detail patient collection capacity and we will extract the count. And then the third way is to enter the counts directly via the CRA web entry form.

So moving on we did expect that the vaccine will be limited in the initial phases of the fall campaign. And as such we will be following the same priorities tracking and need to make sure that the appropriate target groups are actually getting the vaccine in the appropriate time.

And with that I am going to go ahead and turn it over to - is it Toscha that's going to talk about the vaccine update?

Toscha Stanley: Yes, I am on the line Jeanne.

Jeanne Tropper: Okay great.

Toscha Stanley: ⁵Hi, this is Toscha Stanley. I am with the Immunization Services Division and I will give you brief updates on where we are in the vaccine process of this response.

Basically, we are still working with the leadership here in making final decisions on the manufacturing of an H1N1 vaccine. And from there we just go into the distribution of this vaccine; the vaccine would likely be shipped directly from the manufacturer to your selected ship-to sites for administration.

As far as the priority groups, they currently remain the same; in the coming months it will be a little bit clearer if there needs to be any changes made to the listing as it is currently developed. And we do ask that you have great flexibility as needed throughout this process.

As far as when you can expect some vaccine, it will probably be somewhere around the early September timeframe.

And at this point this is pretty much all I have to share with you on vaccine updates.

Jeanne Tropper: Yes and just a reminder we will open up for questions once we go through the presentations so - as well as entertain any online. And with that we will kick it over to Charles Williams to talk about the specifics of the vaccine tracking.

Charles Williams: ⁶Thank you. So to get a little more specific about the vaccine tracking itself, we first want to make you aware that you should be expecting larger volumes of data for the H1N1 vaccinations and tracking compared to what was collected for CRA exercises. So it is a much larger scaled project and we just want to emphasize that before we move forward.

Also, the data will be sent here to CDC on a weekly basis by the following Tuesday of the reporting period by 11:59PM of the respective time zone. This is the same requirement that we had for DAX2008, and it will be implemented as well for the federal campaign for H1N1.

There will be quality control measures employed where we will, on the CDC side, look at the completeness and timeliness of the data that has been submitted.

⁷So for planning considerations, we want to bring to your attention at the Project Area level that in preparation for tracking the H1N1 vaccine doses administered there will be a lot of coordination with clinicians and also the second bullet which is the coordination with the preparedness officers and local health departments in order to prepare for this.

This is going to require clinics from all of your jurisdictions and different areas within Project Areas to administer and collect information. There is a need for coordination between the emergency health preparedness officers and the health department to carefully lay out the plans that you need in order to get all the people needed to administer the vaccines, get the data to its intended areas, and lastly make it to CDC in a timely fashion.

For technical considerations we are suggesting and encouraging you to update your digital certificates; check to see if they have expired or not.

Now we are in the process of exploring different or different alternatives to the digital certificate process and other security measures for access to the application, but to be completely prepared for this we ask that you still have your digital certificate updated and available to use in order to access CRA.

Also consider your IT, computers and things of that nature at the local department and at the Project Area level. Please consider everything that is needed in order to run CRA effectively at the different clinics or at the state level and wherever that may occur.

And then on the operational side it is very necessary to think of what staff you may need to recruit and also the volunteers that may be needed in order to participate in the federal campaign.

Training materials for all those staff and volunteers that will be using CRA will be important. Of course, we will have training materials available from CRA as well, but then there may be some on your side that you would like to also have available for your staff and volunteers.

So we just want to get everyone in the mind frame of preparing for this as we know you are. These are some things that we came up with and wanted to share with you.

⁸On the CDC side we will be making many modifications to the CRA application to support this effort. We will also reconfirm the options that the Project Areas will be using for collecting and sending the data to CDC.

Jeanne Tropper: Excuse me, Charles, if I could interrupt, this is Jeanne. I would not characterize it as many because I want to reassure folks that are on the phone that the CRA application has been set up to collect the current priority groups. And so I think what we mean in terms of the modifications are: as we know more about the priority groups and as they may change, we will need to meet the program modifications.

But there is not going to be any wholesale changes that we are aware of at least at this point; the concepts that we have in place and the priority groups that we have in place have already been established within the CRA application and still apply.

As we know more we may make some adjustments, but there are no wholesale adjustments to the application which we have worked long and hard to make sure we were prepared for this kind of an event.

Charles Williams: Thank you, Jeanne. ⁹And so we are also asking all Project Areas to really confirm with us here at CDC what option you will be using to submit the data to us in order for us to prepare on this side and make sure we have things in order to receive the data in a timely fashion. If there are any changes expected in the data exchange specifications those will be made in a timely fashion.

We will continue to work on training materials and guidance to help everyone through the process throughout the summer. Data presentation is something that we are really working on our side: how we would present this to our executives here at CDC once we receive it, and to keep a tally and keep everyone informed of what is happening in the federal campaign for H1N1.

As I just mentioned, we are exploring the different opportunities or possible changes in security measures for the CRA application access.

Jeanne Tropper: This is Jeanne again - I wanted to mention more about the security measures. We have heard during the exercises and over the last couple of years as we have been working on this, that the digital certificates are rather onerous and there has always been concern if we have an actual response, how will we deal with that.

So that is what we are really looking into as to what we can do to make this less onerous and yet keep it very secure. And so that is what we are looking at. And when we say to go ahead and maintain the certificates, between now and the actual campaign, it would likely be very difficult for us to have any more open method to access CRA.

So we encourage people, particularly the public health administrators and the folks that are responsible for setup and so forth, to continue to maintain those certificates up to date. And as we know more about the possibilities for the response/campaign itself, we will look at what the possibilities are with our security and what we can do to make it less onerous during that response period if you will.

Charles Williams: So in the next step for the Project Areas we are asking that you please inform your CDC CRA point of contact, or in some cases it may be me, who your point of contact is on the Project Area side and then also your option choice. For those that I am not necessarily the point of contact, you may still send that information to me as well.

And this applies even for those Project Areas who have not changed points of contact and have not changed their option choices since the exercises. We just want to make sure we have our data and information up to date so that we can keep track of everything and have everything prepared on the CDC side.

Also, please identify any needs and gaps that you may discover when thinking about the different things you need, such as resources, staff, recruitment and things of that nature.

Also, within the coming months, expect a one on one call from CDC, from your CRA point of contact. This call will be to further understand what you

have planned for H1N1 vaccine tracking. And once we get closer to making those calls, we will notify you.

¹⁰We have been receiving a number of questions regarding the Training Conference that was held last year and whether we were going to have it again this year. We do have it scheduled for August 26-28 here in Atlanta as last year. And we are planning for participants for each of the Project Areas to attend.

Some of the tentative topics may include vaccine updates, training on CRA, safety, priority screening and the distribution of vaccine among other topics.

So we are still in the planning stages of this but we wanted to let you know that we are in the process of planning. And if you have any thoughts on what you think should be shared during this conference please share that information with us. We are about to open the lines for question and answers and so we are taking any feedback and information that you may have in regards to this conference.

Jeanne Tropper: This is Jeanne again. We also wanted to get your sense about whether indeed this is something that people would be able to attend. I think when the response first came out a couple of weeks ago now there was a concern that maybe we needed to reconsider the conference and whether or not people would be able to attend, etcetera.

But since then we have thought that this would be a great opportunity to proceed and focus on a lot of the topics that would help support the campaign in the fall. So we have evolved the thinking but would like to get your feedback on that when we open up for Q&A in a moment.

Charles Williams: ¹¹So before we open the lines I just wanted to share again some of the contact information that you have on hand in case you need to talk to us. We have Jeanne Tropper who is our CDC Science Lead for CRA. Tom Shimabukuro who is with ISD and he is the Pan Flu Task Lead and handles all of our vaccine information and keeps us up to date.

I am Charles Williams, an SRA International contractor and I am the Partner Outreach Liaison. You can also use our CRA Help email address; it's crahelp@cdc.gov and I monitor that as well. So now we would like to open the lines for any questions that you may have.

Coordinator: ¹²Thank you. If you have a question you can press star 1 on your touchtone phone. You will be prompted to record your name. Once again please press star 1 on your touchtone phone. One moment please.

Jeanne Tropper: In the meantime while we are waiting for any calls on the line we have a couple of questions online here. And the first one is: "What is the status of deploying offline CRA?" And the answer to that is that capability is and will be available certainly for the fall campaign.

And in fact I think we would encourage folks to consider it that are interested in it. And that will be for those who may or may not have been involved with some of our user group discussions. We have rethought the release of 1.9 a bit.

Originally, the release of 1.9 was going to come out in June and it was going to have all of the priorities that we had talked about including offline capabilities. We have since rethought that 1.9 would include the offline capability as well as the dispensing component.

Just prior to the campaign in the fall we would have another release that would focus on anything additional that we would need in terms of the campaign and any of the other priorities that were going to be included within the original June date.

So offline will be available not only in June as planned but certainly for the campaign in the fall. And that was probably a long-winded answer to a very simple question.

Jeanne Tropper: Okay so let's see there's another online. "So to make sure that I understand correctly, for now the plan is to move forward using the same export steps from back 2008."

One of the things we need to clarify is that there were very minimal requirements for the exercise. There is a specification that has the full data elements and priority groups that was defined for pan flu and it is that specification that is going to be used.

Warren can you elaborate at all?

Warren Williams: I think I can, yes. I think we are expecting to use that same layout unless there are changes in the priority group classification or assignment. So we may have to make adjustments for label for certain things and so forth if those change. But at this point that is all we know where we think there might be changes. But generally we would be following what we pilot tested in the past.

Jeanne Tropper: However expanding to all priority groups.

Warren Williams: Yes, there is going to be data submitted on more of the categories than just the general population which is what we did last time. But unless the priority

groups change, then I do not think we would expect too much change in that department.

Jeanne Tropper: So people need to look at that specification and look at it through the eyes of the response. The original specification was meant to support the actual response and then there were some addendums or components that were specific to the exercise. And so we just need to revisit it from the broader response perspective.

Warren Williams: And the other thing that we think would probably change would be the vaccine type so we would have a H1N1 code for that which we have codes already in place for it and we just have - once the vaccine got identified we would just assign one of those placeholder codes that label and then that would come in.

That would be different than the normal seasonal flu codes that came in, for example. So that is another possible change that we know of.

Jeanne Tropper: Yes. Okay another question that has come up it says: "I like the idea of a training conference but August 26-28 seems a little late given that we would be expecting vaccine in early September. Any chance to move this up?" I would completely have to defer to Warren on that one.

Warren Williams: I think the issue we are debating with right now is the timing of the conference and whether or not to have it and meet all the needs. I think logistically it may be tough to have it much before that timeframe in August. But that is a great point, earlier the better, but making it earlier would be something to consider but it may be difficult to do.

Toscha Stanley: Warren - is it difficult just to do it this year or to ever do it?

Warren Williams: I would say just this year.

Toscha Stanley: So then maybe you can put that in the response; perhaps we can look at doing this in future years.

Warren Williams: If future conferences it would be better for folks to have them earlier as opposed to later that's great. And one feedback we got from the previous conference was that it was nice that it was tied to other conferences going on in the Atlanta area like the PHIN conference and so people liked hanging out for the CRA training and then heading down to the PHIN conference too.

So that was one of the reasons why, but if people would rather keep it more separated we could consider that for the future. That is a good point, Toscha.

Jeanne Tropper: Okay we show no more online right now.

Yes, so please go ahead - the lines are open. And we are suspecting there must be questions.

Coordinator: Thank you, ma'am. The first question comes from Marcella Bobinsky, your line is open.

Marcella Bobinsky: Thank you, this is Marcella in New Hampshire. I got on just a little bit late so I am not sure if I missed this or not, but again I guess I am back about the release of the vaccine - H1N1. This has definitely been decided that there will be a vaccine completed and ready for distribution in September?

Toscha Stanley: Marcella this is Toscha.

Marcella Bobinsky: Hi Toscha.

Toscha Stanley: Nothing is definite yet. There are some very pretty hard, stern conversations taking place about the production of the vaccine. Now the final release - that has not been made available to us, but if they move along with the production as outlined then the vaccine can be available by September but that doesn't mean we will have it. A final decision will have been made to have it distributed beginning in September.

Marcella Bobinsky: Okay and again I know all this is conjecture, but they are also looking at two different vaccines; one for H1N1 and one for seasonal at this point?

Toscha Stanley: That is correct. No one has ruled out seasonal flu and yes they are in the market of an H1N1 separate vaccine.

Marcella Bobinsky: Okay. And you were talking about already beginning to talk with regional partners and the potential of putting up the clinics, etcetera. So I was also wondering how public we can be about actually beginning to think about this out loud.

Toscha Stanley: Well we do not want you to enter in any type of contract where you are going to have to start spending money. But if you can just perhaps give them heads up that there is likely to be the campaign of this type vaccine, then you can do as much as that.

Marcella Bobinsky: Okay that is fine. Those were the first few words that I heard when I came on so I was a little astounded. So I just wanted to clarify that in terms of our potential planning here at this early date. Thank you.

Toscha Stanley: You are welcome.

Coordinator: Thank you. Ellen Gish, your line is open.

Ellen Gish: Hi. I have one comment and two questions. The first comment is I appreciate the information I was able to get from Charles. I had a quick question and I was not able to participate in the last call so I really appreciate that. And then the first question is on the adverse events reporting in CRA; has that change taken effect? I cannot recall exactly.

And the second question is regarding the private retail sector, is it anticipated that this vaccine - I know at the beginning will be in scarce supply and will be tightly held by public health. But are other Project Areas anticipating that it would be pushed out to the phase three private distribution model?

Warren Williams: Well I do not know about the adverse event piece. Are you referring to reporting an adverse event through the normal VAERS routine?

Ellen Gish: Well we have the normal VAERS routine but if say, a state or Project Area going through the vaccine safety office and kind of what they put us onto at this conference last year was that, heaven forbid, and I know it is not known yet but I am assuming it would be a completely safe vaccine. But if we had a death or something that we needed to report right away, we would use VAERS, but if we had some adverse event following this new immunization, I am not sure how we would convey that through CRA or if that would even be a consideration.

Warren Williams: I - and of course this is still fluid but as far as I know - haven't heard that there be any other different for reporting adverse events other than through the normal VAERS channel.

Toscha Stanley: That's correct, Warren. Ellen, at this point VAERS is the reporting system for an adverse event so we would push the continuance use of the VAERS system. So if you are asking about having like a hotline to a separate desk, I do not think any of that is set up as of yet.

Jeanne Tropper: Yes and just to reinforce, Option 3 level of CRA has the ability to automatically create a VAERS report. So at least as we understand it, VAERS would be the system for reporting. And then depending on if you used Option 3 there is the ability to create the form and get it into the VAERS. Right now it is manual but that is only if you are in Option 3.

Toscha Stanley: Now the second part of your question, Ellen, do you mind repeating that for me?

Ellen Gish: Sure. The second part of the question was related to the phase three distribution model of the vaccine where it goes to the private retail sector. I was the private retail sector is not like I do not know other states they do not particularly CRA.

So I am not sure if there has been thinking that when it is initially in a scarce supply how many months would we anticipate that it would be at the private retail sector and then states would be expected to report on that.

Toscha Stanley: You know, I am not prepared to answer that question, Ellen, but I am going to take note here and get back with you offline about that, okay?

Ellen Gish: Okay great. Thank you.

Coordinator: Thank you. Laurence Burnsed, your line is open.

Laurence Burnsed: Yes, I just wanted a clarification on the options because currently we do not have the tier groups.

And then- does the CRA system include any kind of just aggregate reporting? Are you expecting individual level information on individuals? And then on a follow up to that does that also mean updating when a person has a first dose versus their second dose?

Jeanne Tropper: Laurence, where are you from?

Laurence Burnsed: Oklahoma State Health Department.

Jeanne Tropper: Oklahoma, yes. There are actually three methods and just to go through them, there is an option if you are using an immunization system or you are using another system locally and extracting; another is a Web-based where you are actually just entering the aggregate information.

And the presumption is that you are collecting the detail as you normally would to support good medical practice, state laws, all of those kinds of things.

But you are then aggregating in whatever method whether it is supporting from information from a system or whether it is using a spreadsheet there are many, many different methods. Then you can enter the information directly on an aggregate basis.

And then the third option is where you use CRA to collect the detail and then we just we extract the count from that. And then in all of those, yes, we would be collecting the dose number as well.

Laurence Burnsed: And then to clarify on the aggregate reporting is it just going to be the priority groups then and then first and second dose among the priority groups or do you all have any specific details on that yet?

Jeanne Tropper: Yes, we have the data specification and we can share that with you. Is that on the website Charles?

Charles Williams: Yes.

Jeanne Tropper: Yes, the specs are on there and it goes into detail as to exactly what data elements etcetera. And we are happy to go through that with you.

Warren Williams: Jeanne, this is Warren. You could also – for Option 2 was - just open up a screenshot of that and see what the entry form looks like.

Jeanne Tropper: Yes. Did that answer your question?

Laurence Burnsed: Yes, thank you.

Jeanne Tropper: Okay great.

Coordinator: Thank you. Pat Hays-Moore, your line is open.

Pat Hays-Moore: Yes. I am wondering was there prior discussion about the necessity of getting some kind of letter of encouragement for participation in the August Training Conference? A number of states are really facing some pretty stiff resistance to travel at this time. And we could really use some kind of letter or email to the effect that this is an expected performance measure for the preparedness and the immunization side.

Warren Williams: Yes, this is Warren. I think there were several requests for something like that last year. And so I think we could tweak it to meet some individual needs there and send it off to you. So as we get closer I think we can do that.

Dianne Wylie will be a key point of contact for that and I think she has some templates on that that we can use to get out to whomever needs one.

Pat Hays-Moore: Great. Sooner rather than later is preferable because not only is there resistance, it moves at beyond a snail's pace.

Warren Williams: Yes, I know the feeling. Who was that again?

Pat Hays-Moore: This is New Mexico - Pat Hays-Moore in New Mexico.

Warren Williams: Thanks, Pat

Pat Hays-Moore: Thanks.

Coordinator: Thank you. Regina Irvin, your line is open.

Regina Irvin: Yes. I was trying to make sure - I missed some of the conference call. Did you all go over the minimum data set for data collection requirements?

Jeanne Tropper: You know we did not. It is in the specifications and that is on the website. But it is the same as the specification. I just wanted to clarify we have slightly less for the exercise so it is important to look at the specifications for an actual event.

And expect the same with the caveat that there may be some adjustments, as we talked about earlier; there may be some adjustments to the priority groups.

This certainly is a different vaccine code for H1N1. The specification gives a full list of the data elements.

Regina Irvin: Okay. And my other question is: are we going to be required to track just H1N1 and seasonal flu?

Toscha Stanley: This is Toscha, Regina. The H1N1 is being tracked as you would have in a normal pandemic. And then whatever your normal means of tracking seasonal flu if that is the case then yes you should still be doing that.

Regina Irvin: Okay will we be required to have eight clinics, and one of the other requirements of this upcoming season was going to be a mass clinic. So would that be applicable to just the H1N1 or just the seasonal flu?

Jeanne Tropper: Yes, just wanted to make sure that you are clear that from the seasonal perspective we are not going to do any kind of exercise so you do not need to worry about the eight clinics or anything to do with what you did last year with staff.

As far as the H1N1 we are in the federal campaign mode. I need to kick it over to Warren and Toscha. However you are structuring your clinic to support a federal campaign that is what we will need to be tracking in the early phases when the vaccine is limited.

As we evolve when it is available for everyone then we move into a different method. Warren or Toscha?

Warren Williams: Yes, I mean basically the seasonal flu - we were using seasonal flu as the proxy and a preparedness experience but now that is off the table; we are preparing for the full campaign as Jeanne said. So the part about the eight

clinics and tracking seasonal is not the plan now. We are preparing for the large campaign.

Regina Irvin: Okay. And the reporting, would that be aggregate reporting like we did?

Warren Williams: Yes, well depending on what option is most conducive for you to use but the minimum amount of data is an aggregate set of data that manifests in basically a couple of ways: either the electronic file or the web form.

And you can use either of those methods. And if you cannot use either of those methods you can use the Option 3 technique for collecting the individual information and then it gets aggregated at CDC to come up with those aggregate counts.

But essentially it is a very minimal set of information on certain priority groups and vaccine type and dose number and that is it.

Jeanne Tropper: Yes, and just again just to reiterate so for H1N1 in the early stages when we are tracking, it is all vaccine from all clinics that are part of the federal campaign.

Warren Williams: Right.

Jeanne Tropper: So it's geometrically larger. One of the reasons that we are talking early on is making sure that people understand the scope of that because the pandemic plans are in effect as they relate to the vaccine for H1N1.

Regina Irvin: Okay. And can you all put the contact list back up?

Jeanne Tropper: Sure.

Regina Irvin: Thank you.

Coordinator: Thank you. As a reminder if you have a question please press star 1. Our next question comes from Danielle Reader-Jolly, your line is open.

Danielle Reader-Jolly: Okay. I am going to take us back to the specification one more time. I know that the full pan-flu spec had been pulled for a while or was not available due to like a limited or a revised version for the DAX2008 exercise. So has that full spec been posted? And if not do you have a timeline for when it will be available?

Ulrica Andujar: Yes, this Ulrica Andujar. The specification that is on the web page actually has the two parts; it has the DAX2008 minimum data set requirements and then it also has pan flu minimum data set requirements. So the pan flu codes and all of that data set is in that same specification.

Danielle Reader-Jolly: Okay perfect.

Jeanne Tropper: Yes and I am wondering as we are talking here: maybe we need to just pull the exercise related information just so that there is no confusion on that because it is a challenging mind set to think that we have been in the exercise mode and now we are talking about the real thing.

Danielle Reader-Jolly: Okay and then one last question. The process for the export file - are you going to offer the same review that you have for the past two years so that as we add in the expanded priority groups and such is there still a mechanism in place to run a sample file past you prior to actually implementing?

Jeanne Tropper: Yes and again we are in the beginning stages here so certainly we will get a little more specific on who is supporting what states and the mechanism for you to work with us to get your test data to us and so forth.

Warren Williams: Danielle, this is Warren. You should still think about flexibilities for different priority groups and then a new vaccine code to represent this particular vaccine type. And I think at this point we think that that will be about the most of those changes there.

Danielle Reader-Jolly: Okay sounds good. And I think that we are ready for that as well. I just want to make sure that it lines up with the spec and that we have a chance for you guys to just give us a little thumbs up on it before we do a mass distribution on it.

Warren Williams: Yes, that's a good idea.

Danielle Reader-Jolly: Okay great. Thank you.

Coordinator: Thank you. The next question - Cindy Lessinger, your line is open.

Cindy Lessinger: Yes. I am with Alabama Department of Public Health. And I've already talked with Charles and Ulrica but I did have a general question about the antivirals. I know CRA is set up for multiple countermeasures. And I guess my question is we are looking at potentially using it for some limited distribution right now but is there a reason that we are not looking at that for the fall?

Jeanne Tropper: No the system has capability to do both. So you are an Option 3?

Cindy Lessinger: Yes.

Jeanne Tropper: So you should have capability to do both. So our focus on this call is the federal campaign and that is the priority. But CRA Option 3 is capable of supporting antiviral tracking for those that want to use it.

So in fact I believe that Ulrica and Charles are setting up an event that would allow the tracking of antivirals. And just to clarify, as you know right now there is no requirement to report that to CDC. So this would be a tool for you to use locally.

Cindy Lessinger: Right. I guess my question is why is CDC not requiring information back on antivirals?

Jeanne Tropper: That I cannot comment on.

Cindy Lessinger: Okay well because ventilators also may be sent out in the fall and I guess with all the things that may possibly be scarce during the pandemic I guess we need to know at some point why some are being targeted for CRA and some are not.

Jeanne Tropper: Yes. I am not quite sure what to tell you on that. And maybe I can get back to you on that as far as if there are going to be any changes in the tracking requirements for the fall because that is a very good point. And it has come up in other circumstances. And certainly if there were going to be any change you would want to be prepared.

As since we interact during the response with the folks that are involved with antivirals there was no requirement. And to my knowledge there is not one expected but I certainly can get back to you if that is likely to change...

Cindy Lessinger: Okay thank you.

Coordinator: Thank you. Steve Sakamoto, your line is open.

Steve Sakamoto: Yes. This is Steve. For the Training Conference are the travel expenses something that CDC will fund or are states required to find their own funding to attend that?

Warren Williams: We anticipate being able to fund some state people to come. Obviously it will not be an infinite number, so there will be some kind of limit placed on that. If you want to send people beyond that then the states or whoever would have to be responsible for that travel.

Steve Sakamoto: So each state will have at least one representative able to be funded by CDC then? Is that correct?

Warren Williams: That's the current plan, yes.

Steve Sakamoto: Okay thank you.

Jeanne Tropper: Before we go on to the next question - this is Jeanne again about the antiviral tracking. I do want to clarify one thing: SNS has asked that people report the distribution of antiviral tracking. So what I was referring to is the actual dispensing - there's no requirement there. I know that SNS has asked in the event that you are distributing it that they are interested in that information.

And I believe that they have developed a method to request that. It maybe that they are calling the state preparedness director or representatives on that but I did want to clarify that there is some interest in - and not so much a requirement but in interacting with SNS. But that again is on the distribution

side as opposed to the dispensing side. But, yes, I'll try to get further clarification.

Coordinator: Thank you. Mark Thoburn, your line is open.

Mark Thoburn: Yes, so are the eight clinic minimum no longer a requirement? And are we going to be required to report on all of the clinics?

Jeanne Tropper: Yes, just again to reemphasize, for H1N1 vaccine all clinics are part of the federal campaign. Again, during that time we would be tracking at this level. Okay because there is a point where the presumption is that there would be that there would be enough vaccine at some point for everybody who would want it.

But in the earlier stages there would not be enough and it would have to go to the defined HHS priority groups that we have been talking about. And then there is no eight clinic requirement since that was more of an exercise to prepare for the events that we are actually going to have in effect.

Warren or Toscha, did you want to add?

Toscha Stanley: No I do not have anything else.

Warren Williams: No, that's right.

Jeanne Tropper: Okay.

Mark Thoburn: Thanks.

Coordinator: Thank you. As a reminder if you would like to ask a question please press star 1 on your touchtone phone.

Jeanne Tropper: So there is actually another one online here. It says: "To clarify would we be collecting any seasonal flu administration data for previously formulated TIV where only novel H1N1 vaccine is available?" And I think we have answered that. That it's just the H1N1.

Coordinator: Ma'am, I do have a question from Regina Irvin, your line is open.

Regina Irvin: Hi this is Regina again from Mississippi. You keep mentioning a federal campaign. Can you tell me exactly what that is? Nobody in this conference call that is a part of it here knows.

Warren Williams: It is a generic term in reference to the decision to distribute and administer the vaccine; it becomes a big production for lots of key players here.

Toscha Stanley: Right. This is Toscha. And just to add to that it is being mandated by the federal to offer the vaccine to everyone opposed to it just being in the private setting where you go and get it and pay or whatever. So it's just a mandate of getting people vaccinated.

Jeanne Tropper: Yes, and I am sorry, it is the semantics that we use to refer to something that would be managed through the federal system or federal and state systems and not within the normal free market as it normally is for the flu season.

Regina Irvin: Okay, thank you.

Coordinator: Thank you. I am showing no further questions at this time.

Jeanne Tropper: All right, well with that we appreciate all of your questions. And you have the contact information. And we will certainly be in contact in the coming weeks and months as we move forward with this effort.

Coordinator: Thank you for joining. This concludes today's conference call, you may disconnect at this time.

END