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Advisory Commission on Childhood Vaccines

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The National Vaccine Injury Compensation Program (VICP)

Division of Vaccine Injury Compensation Update

Advisory Commission on Childhood Vaccines
March 6, 2014
Vito Caserta, M.D., M.P.H.

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Attendees

1. Captioner
2. Jonathan Salaveria
3. Andrea Herzog
4. Captioner
5. Theresa Wrangham
6. Jocelyn McIntosh
7. Caption Colorado
8. Allison Durham
9. Jocelyn McIntosh

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Polls

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Q&A

Q/A Done Over the Phone

Transcript

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Welcome to the 91st quarterly meeting of the advisory commission on childhood vaccines. All participants are in listen only mode until he public comment session of today's call. At that time if you like to make a comment, please press Star One on your touch tone phone, on May going and record your first a lasting clearly when prompted. Today's conference is being recorded. If you have objections, please disconnect at this time. Of an election the call over to Mr. David King, you may begin.

Good morning and welcome to all who are on the line and welcome to everyone who's in our room here today. But I think we would do first is due rollcall of the commissioners to make sure that we have everybody here needs to be here. David King, parent of an injured vaccine child.

-- pediatric nurse practitioner healthcare provider.

Showing -- general public.

[Indiscernible--Low volume]

Ed Crouse, 24 vaccine.

You guys can go ahead.

Tom -- center for disease control. [Indiscernible--Low volume]

And we gave it, HHS OGC.

Melissa Houston, division [Indiscernible--Low volume]

Aveda Pacific, division of -- designated Federal federal officer.

Commissioners who are on the phone lines, if you would identify yourselves please?

-- pediatrician.

Jason Smith, attorney with Pfizer.

Anyone else? Okay. We have seven commissioners present. Theothers are unavailable to be here. We will proceed with the days business. For a couple things again just as a reminder, one, before we speak it is helpful to identify ourselves for those who are on the phone and for those who are listening. When we speak we say David King speaking and then we move on. The second item is again just as I said yesterday, let us keep in mind that the purpose of why we are here and keep in mind that when we have her conversations when we make our decisions that if we have two error on any side let us air for those who are the injured and need the most help. And those around them I guess as well. Second, the first item on the business is the unfinished business from day one. I'm not sure that there is any, but since this but let me pull everyone and find out if there are any unfinished business from day one?

Actually I do have a piece of business.

Unfinished from yesterday?

This is Charlene Douglas. I was speaking about our discussion on buses through the various agencies to get to the Secretary and to extend the statute of limitations. Did we give a time?

Extended to what? Because of we didn't give a time,, it is going to take forever series of meetings for people in the agency to determine what time they met, they felt we meant yeah that would probably hold us up the year.

I'm just working on main memory right now. David King speaking, but I do believe we identified a period of time in that. Ibelieve we did.

We did, we recommended eight years and at a minimum, six, but eight years we thought was most reasonable

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Appeared of time that would not solve every problem with timeliness, but at least capture the majority.

Just for the commission to understand, I'm sure if we set 628 years, this going to have to be a whole because you cannot have a rig that's six to eight years, it is got to be a time. Am I correct? That's going to be six months to year of internal discussion. Is it going to be six or is it going to be eight? What ever you choose, choose.

I think --

Vito speaking.

This is Vito speaking. I think the way we were did it was that it was eight and that the commission would accept six is how I think it was worded. But I don't remember for sure.

David King. Myrecollection and we don't have it directly front of us right now so that's what are we are working recollection if I'm not mistaken that the reason that we selected the eight was to maintain consistency across other requests and other things that we had in terms of documentation or people were asking for an extension on the statute of limitations. Go we also felt that even six was better than none so I think it was worded in such a way that the recommendation was for the eight, but that six would be certainly acceptable if people felt eight was way too long.

It may not be as pretty as you might suggest that we have done it, Charlene.

I just want to cut down on the time of internal deliberation.

Understood. We did a boat on it as a commission -- when we revisit that maybe the maybe there's a note or two that we can apply in their to do that.

Good, thank you. Is there any other unfinished business from day one?

Who is speaking?

This is Tom Zernek CDC. Reinforce support -- that you collect some data so if you say I want eight years and this is why. Otherwise it seems kind of arbitrary just to come up with the number.

Okay. Thank you.

Annie. I was looking it was eight years.

There was no six.

No space maybe our conversation around six or eight and we ended up settling on eight years. Nicely done. Thank you.

[Laughter]

We've got there even though we for forgot we've got there.

Ann? Melissa? Dave King. Identify yourself.

[Indiscernible--Low volume] speaking and just to add to Tom's comments I was just whenever something is put forth for consideration that note the positive and the potential negative [Indiscernible] and to have a negative would be addressed so that people considering the

request or recommendation can be more assured that all issues have been discussed and that we address so if there's something that can be considered a negative how that was discussed with certain stakeholders and how that could be mitigated.

Okay. Thank you. Ann?

[Indiscernible] I just have a comment. I don't leave anyone addressed the table yesterday repaired 4.2 on the -- categories of vaccines [Indiscernible--Background noise] seven year period and wanted to [Indiscernible--Background noise] it kind of puts the perspective I know it is -- distributed that by the vaccine then all the different adjudication categories, I'm assuming then with different techniques in the future for monitoring vaccine administration to the barcodes and whatever that this table could even extend more into categories of adult children.

We did that

This is data. We did that in order to provide respect is because not knowing him he does is disputed say that there's all these adverse reactions to the vaccine makes food vaccine look like a bad player when in fact it is not because so many [Overlapping/Multiple speakers]

I wanted to commend you.

David King. Is this on the website this table?

Thank you.

All right.

And it is updated. With operation with the CDC CDC provides us with the dose is disputed data on annual basis and we updated monthly with the adverse event reporting and NOA with the dose to stupider.

Great, thank you.

Is there any other unfinished business before we move onto the next item on the agenda?

This is solely. We're going to be losing six commissioners with their end of term and I note you are a family representative, child representative so it may be towards the end of we can talk about how we are going to replace members and what numbers fill what no caps granny.

We are fine for having that conversation, David King speaking, so lets us make sure that that is an item that we address under the future agenda items and new business. But let us make sure that we have a conversation around that.

I him making a note, one second. Okay. Thank you,Sylvia, any other unfinished business?

Then we will move right into it. The review of the vaccine information systems Skip Wolfe from the CDC, Skip, are you on the line?

I am, good morning.

Good morning to you.

You have the floor, Skip, go ahead.

Okay, thank you. We've been to Disney time so let's just proceed like we usually do. We've got two to review this morning. Let's start with the hepatitis B and go through it beginning with the Section 1.

This is Vito. This letter a.

Let's do have a map first. A before we take, Skip.

Sorry, I keep forgetting my Outlook that. Before we start recently we had another eDAN in the process for developing VAS is what they called consultation meeting where we meet with a group of parent groups and professional groups and discuss them but the same way we discuss them here at ACCV so we had one of those meetings recently and the VAS as we discussed they were not these two but some general comments came up, during that meeting and now I will introduce those, they are things that might be interested for us to discuss also. When those are relevant I will introduce those as well. So for hepatitis A yeah let's get started with Section 1, why get vaccinated? And I will entertain all your comments.

Skip, this is Vito. Underwear says high potatoes a can cause -- I think the second bullet where you have John this and yellow skin or eyes, that's fine, I have no problem with that but then you have it, and then dark urine. I think that may confuse people. Anyone who has a dark urine maybe they have John this so I was just taking dark urine out.

Okay.

If there's nothing else there are a couple comments I came up during the consultation meeting that might be relevant here. One, somebody there were several good brought up the issue of whether one were talking about disease burden with their absolute numbers or percentages or more persuasive when we are talking about how vaccines have been able to reduce the disease burden. In the -- in Hep A we use numbers we see the cases and you cases dropped from 22 to 36,000 down to under 2000. And that hepatitis B when coming up with drop -- 95% in children certify% and other age groups. This thecommission have an opinion on which is a better way to state the vaccines affect on the burden of disease?

It all depends on what those numbers are. This is Charlene Douglas. It all depends on what those numbers are. For example, if you are talking about something like to stick the cancer we only have so the 500 cases year and the rate of that disease is so small that doesn't make sense so when you talk about it you only talk about the numbers. The numbers for this Hep A are so dramatic they carry the date. It we have the numbers for Hep B?

We can probably get them if we don't.

You see what I'm saying? It all depends on the strength of the numbers.

Yes, to me either sounds persuasive, but I've heard other people say that the percentages and times don't connect with people. I'mnot sure why, but --

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David King year. This but I guess it is hard about what we are trying to do to get the information out and what the message is and maybe we don't have the room to put this, but is there any way that we can actually include both on it?

Sure.

It because the only thing is if you have two people and you improve something by two you have 100% ratio and that's -- what does that really mean? When you go back and forth, whenever I see a percent when I'm working with -- in the business environment, I usually want to know what the actual numbers are because they% doesn't really tell the story. It doesn't -- it is only one part part of the course and we need to understand more that in order to really understand what it is.t it is. Does that make sense to you, Skip?

Yes, I think the consensus among the participants in that meeting was that numbers might be credible to percentages. Then general -- just a general other we could use both it we thought it was useful.

I think probably if you use both -- Charlene speaking, if you use both it gets pretty long. And now when you talk about the focus group in terms of health literacy, the numbers would be better than the percentage. Because not everybody can do the percentages.

Yes. This comment that in come out of that meeting but Kevin Malone, our legal counsel, measured in relation to that pediatrics article that just came out about messages effective messages and vaccine promotion that suggested that the ways we've been describing risks of not really been effective. Andsometimes discussing the risks to the disease can actually increase readers concerned about adverse events so Kevin suggested that we might instead try to find a different way, he didn't say with that we would be of talking about the benefits of vaccines during Section 1. Perhaps focusing more on the fact that vaccines have saved many lives during the last century when they become -- became more prominently used. Another issue that came up about -- that would apply to Section 1 is that at least one person suggested that we should be more explicit about saying that vaccines aren't 100% effective. What we currently do is say

that vaccines can prevent disease incident say they do prevent disease. Do believe that we should be more exquisite about that about say that vaccines aren't -- don't protect everyone?

This is Charlene. There is a take rate, if you will, for every vaccines, a percentage and we are getting to that percentage business again. And what percentage takes of any vaccine -- you get into the health literacy percentage issue again.

This is Ed Crouse. Firstof all,, I really appreciate your bringing and -- the fact that you are for the first time that I can recall providing us with input from other consumer groups and audiences, it is helping me take a step back and think about what's really the underlying purpose of the vaccine information statements. So I guess if I could ask what it be Vito or Melissa if we could get some just brief historical understanding of what the vaccine information statement is supposed to be doing.

Vito speaking. With thevaccine information of statement is part of the Act. The national childvaccine injury act. And it is designed to inform patients, the public, when they receive vaccines about different aspects namely the composition program that there may be adverse events and the reason why it was put in place is they was concern amongst parents that were voiced both to Congress and during our early meetings that doctors didn't talk about those things. And this was a way of communicating that information that was mandated rest before it just didn't happen.

Was it -- this is Ed again. Was this as much out of China people weren't aware of the risks?

Yes.

And the ability to pursue a vaccine injury claim? As it was to persuade people of the benefits and of the -- let me rephrase. When I read these it always struck me this way and it is persuasive. There's a clear attempt to persuade people to get whatever vaccine it is that is at issue and I understand the reason behind that.

This is Skip. The loss, the positions of the law states that with the VIS should do is to inform patients or the patient's parents about vaccines benefits and the vaccines risks and then the third item is to make them aware of the composition program. So they are not really made to persuade but they are designed to make people aware of both the benefits and risks of the vaccine.

Okay, thank you, Skip. That helps -- that's helpful for me at least when I think about it so when we talk about providing how we provide information we are talking about a concern both the people understand the benefits and the risks.

If you approach it like that I would think it makes sense to specifically say whatever language we choose that you don't have 100% effectiveness with vaccination. We need -- if it is true then we should provide it and I think the other -- I have going on is that article that was sent around

about why vaccine information statements are not necessarily dating people to get more vaccines or not vaccine information statements but information about vaccines is oddly not resulting in people getting vaccinated. That gets back to an issue that we've talked about before which I think is one -- there are different reasons for that., somebody product could be that people here about the disease and they get confused, concerned about I don't want anything to do with hepatitis so I'm not going to take the vaccine. But I think there's also an issue of trust and I'm not sure what we can do about that or how we respond to that, but I suspect from my perspective and talking to lots of parents and families there's a sense that they are not necessarily -- depicted being pushed and persuaded every which way they turned to get vaccinated. In those rare situations where somebody is injured by a vaccine, there's almost -- in my again limited personal anecdotal experience, there's almost always a sense but I had no idea that a vaccine could cause this. I don't know for what it is worth, those comments, but I think that the most effective vaccine in the mission statement going to be the ones that set out the benefits, set out the risks and then inform people that there is a program and the program and maybe a little more information about the vaccine composition program. For example you need to file a claim within 36 months of the onset of the symptom. We don't provide -- if that's by statue one of the main purposes of the vaccine information system or statement, then we can do more than just -- at the very end that says there's a program. And it like it almost fills like it is it in at the end, don't say to loudly that there's a program where people can get compensated if they are injured by vaccines. It is like if you prompted and disclose it, that's consistent with informed consent. I'm done with my [Indiscernible]. I don'thave a specific comment about any of the language that with comment so far but I think it is helpful to take a step back and think about that.

Okay, thank you.

This is Ann. I guess as a healthcare provider I've used these statements with the VIS -- I say something about and then I'm able to hand it to a parent and I frequently like to give it especially with newborns to them at the visit before they are going to get shots so that you take it home and read it because of fact if you set everything that was on this -- these pages you would it be able to do anything else with your health visit so it is to augment anything that you say out loud and to give them something to read at home and see if they have concerns about. I appreciate the issue about having the vaccine injury compensation program at the end, but almost every parent has some hesitation about this two month shots because they are such a young baby and they are getting immunizations and whatnot. Not the hepatitis A is given at that age but that's when they start the whole idea of vaccinated a tiny baby so that's all I have to say.

Luisita.

The issue of [Indiscernible] one for every 100 is 1% but you don't have to say that so -- one for every 1000, one for every Millicom at this is sometimes easier to understand. Like looking at this number one -- one in 160 -- what's going on in those numbers, doesn't seem to make sense right away.

In Section 4 talking about the risks?

[Overlapping/Multiple speakers]

Section 1.

It is where it says up to one person and a David King speaking and five with hepatitis A has to be hospitalized it is a between about one in 350 and one in 160 died so we are actually putting the ratios. Doesnot regular D&D percent.

The ratios, the reason and I think this grew out of an ACCV meeting a number of years ago where we discussed the best way to present -- maybe talking about adverse event information at the time but would apply here as well that when we make the numerator one I think that's helpful because it makes the patient say I'm that one person and then the denominator is out of how many this is likely to happen to me so twosie to make the numerator one would we use ratios is a decision we made Tivoli is a go for that reason.

As opposed to an adverse event information comes out is often how many out of 100,000 which is hard for somebody to picture on your stinky .5 out of 100,000 or whatever with the numerator is one I think it makes it easier for people to envision the risk to themselves personally.

This is Charlene Douglas. I'm reflecting back on the beginning of my term with ACCV and just looking at this section if there's a serious problem in the vaccine injury program and from ads, immediately went to the back of the sheet and I said that looks really abbreviated and then I looked at the front of the other side of the sheet and if you put all that information together it is a full page. So it is not as if the vaccine injury program is a little corner of the back, it is a full page of information. What if there's a serious problem at a discussion of those problems and what you can do about those problems. As I look at the sheet from the very first sheet I ever saw, this is expanded. This is more information. This is bigger and it is a full page. If you put thesetogether it is a full page. Somebody listen to something because this might reflect from then to now, this is much bigger and it is a full page of information.

One of the dilemmas we always face with these is that it is often that when you talk about the risks we almost have to be specific about the numbers and the ratios and so on. Where as when you talk about the benefits you can state them in a couple words if you want to. It is given anunbalanced my opinion aspect to that EIS because I did admission we have to spend so much more time talking about risks than we do benefits.

Understood. David King. I'd like to first off I think that Charlene is correct. We have seen enter improvements in motion on these statements. By like to talk about Ed Kraus a suggestion where we actually put in the three is a specific time to file underneath that somehow in there. I actually think that is about that idea because it is highly informative to the public, to those who

are injured or to the parent of children to do it. Doesn't mean that they'll always read it, it doesn't, but the piece of information there is just another way for us to be able to provide a point that actually we are talking about expanding the statute of limitations, part of the reason we are trying to do that is because people missed the deadline. If there's a way for us to be able to inform people of the deadline because it is going to take a while before anybody extends any deadline. But it doesn't take that long for us to be a lot to put into the statements that you have 36 months. If there's an issue.

That's in suggestion was made during the meeting I was telling you about. You and they had the same concern. I don't think it would be difficult to add that to the section on the composition program. [Indiscernible] great. Thank you.

This is Vito. It can get a bit complex because there's a different time period in death claims. It would be difficult to work it so it is not too voluminous -- I guess we can find a way.

Suppose we told people without saying what is that there is the statute of limitations and tell them to check the composition program website to learn more?

Ann, I think the general public wouldn't understand that meaning of those words exactly.

Filing deadline I guess would be a better way.

Without talking about specific language but that idea rather than telling people what the time limit was to just telling them that was a limited and they can find out by checking the website.

Tom.

This is Tom. You can just put in there file as soon as -- I don't know how to or do but they'll soon, there's a filing deadline.

Yeah.

Okay. Vito, do you have something much is a?

I will get to later.

Okay. To get back to the VIS itself, there's nothing else in section want to comment, do people have, it is on Section 2, hepatitis A vaccine?

[Indiscernible] I agree with Ann completely as a pediatrician that we had this out of a two-week visit and of course this is not appropriate for the little babies, but one of the things you may want to look at with adults with hepatitis A on that section one can be too old to work. You may want to put, especially restaurant or food service or something because I think this is one of the

major problems that people have about street vendors or food vendors or restaurants that they may not be able to work if they get hepatitis A during their illness.

When they go to Section 2 hepatitis A vaccine, I'm on the first paragraph or first bullet, two doses are needed for lasting and I always have trouble with that. What does lasting mean me? Doesn't mean until I'm 60 or 80 or until next year? I just needed a clarification of that word lasting. I have two points, too ill to work and you may want to stick a late especially food services or restaurants and did in the Seth's in section is a Cliff Tatian of what lasting means.

I'm not sure whether we have another limit on the protection. I guess the issue is that the first those most people [Indiscernible] after one dose but since this is recommended for travelers among other things, that if you want long-term protection you need to get that second dose but I can check with our hepatitis A people and as if we have an idea of what we mean by that.

This is [Indiscernible] if it is a lifelong protection we should say that.

If we know that, yes, but I don't know if we do. Iwill see if I can find out.

This is Ann. Was Sylvia just said about the adults since this vaccine is given for adults and only adults are also covered it is important to start including more information about adults with the diseases that we are covering.

In the statements.

Okay. This is Tom. Twodoses, is that the schedule for everybody?

Yeah. With the six-month interval.

I don't you just say two doses?

Except for -- even for travelers?

Yes.

Can you say two doses are required period? [Indiscernible--Low volume]

That's true. Good point. Yeah.

Silt -- this is healthy again. Skip if I go to the third bullet -- just for historical perspectives, -- pushed by strongly by Dr. Fernando Guerra and a lot of folks with these been a community and also the Native American community and I know you sort of make a comment about it, older children and adolescents living in areas with high rates of hepatitis A, I assume that's what you mean. Was the focus of the Southwest, focus of children living on reservations so is that what you mean living in areas?

At one time and I think I'm correct on this, that once we started vaccinating that some of those Native American and other areas that were really prime risk factors at one time of become more into the mainstream and are not high risk anymore so originally -- there are still certain areas with high risk -- I rates of hepatitis A but it is not the same as it was 20 years ago.

Some of those areas I think have become -- the risk has declined.

It says Vito. When I worked with the Indian health service we would always be concerned in the summertime during when they would have their large powwows that hepatitis A which is run rapid to the community because there would be a lot of folks that would be coming in from other areas and would essentially came out camp out and they would eat food that was prepared and open fires and not very sanitary because of the wasn't running water or adequate toileting facilities. Itwas a major problem every year that we dealt with. Since the vaccination program got going I think that's pretty much diminished.

Yeah, I think so. I will double check but I don't believe that the Native American population as a group is a risk factor anymore. But I will check.

This is Sylvia again. Travelers to certain countries and Tom is there and you can speak more to this but you may want to put to [Indiscernible].gov travel, that we people can look to see with the CDC website says as far as what

One of the reasons we are intentionally vague in some of the areas on the VIS so for example the recommendation -- lab workers that was post judgment need to get the vaccine we would have a change the VIS to magic. On the things we are hoping to do so many of the VIS is are now in an interim form, we want to be able to go through the multi- month process to get them finalized so they won't be interims anymore. From a legal standpoint we need to do that and would've the things that has prevented us from doing that in the past is that when the recommendations change even if it is a change in an indication or something if we list that specifically on the VIS we wouldn't have to change the VIS again to match that. We are try to simple five to the extent that we can to avoid having to change VIS every time there's a small change in the recommendations.

This is one of the Ares I areas I think we can do that because if it is a change in adverse events or changing contraindications obviously we need to make a change but if it is a change in who needs to get the vaccine, that doesn't necessarily need to be stated explicitly on the VIS, we don't think.

Auro we ready to move onto Section 3?

[Indiscernible--Low volume]

This is Sylvia again. On the [Indiscernible] part before Section 3, people treated with the [Indiscernible] clotting factor concentrates, do we have any -- of a plasma derived now? Most of our kids are all we comment.

I couldn't say.

I guess you have folks that they are still getting [Overlapping/Multiple speakers] I assume that's what that means.

I'm not sure. I can check into that. It may not be everyone maybe some people treated with clotting factor concentrates, I'm not sure. I will check with our subject matter experts.

Thank you.

Skip, this is Vito. Just below that we use a anyone who wants to be protected from hepatitis A may be vaccinated. That statement is and direct contradiction to number three.

You image section number three?

Yeah.

I think it should be phrased slightly differently to make it clear that except if you have contraindications, I know that's too high level of language but when he to find a way of saying that.

[Indiscernible--Low volume] if you would like to be vaccinated [Indiscernible--Low volume] healthcare provider.

Okay, we will find a way to exclude without actually saying less is contraindicated, find a way to get that point across.

This is [Indiscernible--Low volume]

It.

Anyone who's ever had a severe allergic reaction -- any part of this vaccine -- how would people know what part of the vaccine that might have had a severe allergy to?

They probably won't. That's why we say the best I think we can do is the follicle at where we see a tell your doctor if you have any severe allergies because we do tell the providers to either check the package insert or took a table that we have under website to find out what's in each vaccine. One suggestion that's been made that was made at the consultation meeting that is to list -- any ingredient of a vaccine that it is likely that the patient would recognize and would possibly be -- know if they are allergic to. Even though should be able to get that information

from their provider to for example eggs or antibiotics or something they might know that the analogy to to actually list those explicitly on the VIS. Otherwise it can be very unlikely they are going to know whether they are allergic to some obscure ingredient in the vaccine.

This is Ann. Are we on Section 3? Can I make my comments?

Hospital I don't know how much longer I will be on the -- replacement rate, but I'm going to make another plea for tell your doctor or nurse or healthcare provider, that's the second section under the first three bullets. I'm petitioning so that again although you may have more data from your group because many times the doctor will not see them on the day they come for vaccines. They may come just for vaccine visit and public health clinic, and pharmacies and in many places that they are going to receive the vaccines. We may not be there Dr. So I think that needs to be generalized and now the idea that pharmacistsarmacists are giving vaccinescines maybe not hepatitis A, I don't know but they have the potential to give all the vaccines from want I understood, that's not included -- inclusive enough and could be detrimental if someone -- my doctors by here so I shouldn't tell this person that I have this problem. It is true that also there are some settings that you provide full-service healthcare but there's never a Dr. On-site. -- many of whom are federally qualified centers centers so I petition to its and abusing or doctor to use healthcare provider really us a more inclusive and if you don't like that then Dr. Or nurse.

This is a perennial issue that keeps coming up. The reason we use a doctor is we kept being told by communications people that even if the person seen Dr. - - Dr. Is a term that people will respond best to even if they know it is not a doctor. How much -- I don't know.

If it is a nurse or pharmacist? Benack we can but then we also have to say physician -- the history is we started out saying Dr. That we decided to change it to Dr. Orner's and we started hearing from nurse practitionersrse practitioners who said if you say using your you say nurse you is a nurse practitioner as well. So either we've got on the slippery slope where we have to either list every possible profession who can give a vaccine or is a more general term but I think the one that seems to be most acceptable is healthcare provider.

That would be great.

We've used the word provider for local focus group turned out to people when they saw the word provide would think of their insurance provider and their medical provider. If we see healthcare provider, it is longer and we get so many comments about this we might have to do that.

All right, Tom and then Steve.

This is Tom. We have been told if you are not going to use Dr. Use healthcare professional because people will usewill use provider with their insurance. However, I will say that from what I hear from the professional community is that CDC whether it is a nurse or met tack or a

doctor, people -- people consider that there doctor. Regardless of what type of healthcare professional they are. I think that's why [Indiscernible--Low volume]

That's what we've been told and that the simpler term and people we've been told that people went to the typical pseudo- term doctor the generalize it themselves.

Steve.

One avoid and adjusted person administering vaccine?

Because that's a lot of words. [Indiscernible--Low volume] A this is Vito. It seems you have the space to because you have a whole line that's empty.

This is Ed. You can say tell you Dr. When the person giving you the vaccine vaccine if you have any severe allergies. It is a very important -- understand the communication angle, but just from of full disclosure perspective we should tell as clearly as possible since we know that the majority of vaccines aren't given by doctors we should spend the extra few words. I think that's an important point.

David King. I support those comments. I think they make a lot of sense.

Okay.

If we use that phrase a number of times in a VIS maybe if we made that specification once and not every time -- tell people to ask their Dr. Or have their provider -- we will look at ways of dealing with that.

This is Ann. I would of course want to change everywhere on the work doctors use but particular though I think that if you're talking to people about before they get the vaccine, do you have these problems, tell your doctor your doctor is not there, you may feel he's not here, she's not here so I will go ahead and get it. It is a safety issue.

Okay.

This is Sylvia. I'm trying to put this in my head to say it without coming across cavalier. We really have to change, this has a thing to do you Skip, we really have to change these PAS pops that some families I talk to say they are trying to hide something, Ann is point is really critical. It is probably not the doctor that's giving the shot, it is probably not going to be in the future anybody that is going to have that kind of power anymore so we've got to help people understand that the doctor is not forcing this or pushing this, but it is really your part of this team and stop if your sick, tell me something. We are really moving away from this medicine where I'm the doctor and you guys don't know this but I'm -- six. I'm talking to a 6-foot four guy. You've got to stop and say wait a minute, I'm not feeling good, I'm allergic to eggs, give me the information. And point is very valid. It may not be the doctor but just I'm offering this vaccine,

please I need you educated, read all of the cap stop if you have any questions or you are not feeling good. Tell your nurse, tell your school nurse, we call it the sugar, tell your shooter --

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We are not going to shooter, I can tell you that right now.

[Laughter]

I think the focus of this whole meeting for the past two days is something is going on and we really have to help the government understand that some families and some people are really opposed to vaccines and we have to have them be able to say, no, I don't want anything to do with this and let's have a discussion. This may be the discussion point, tell your injector, tell whoever is giving you the shot if you're opposed, if you are sick, if you are allergic, a what ever it is and I can put it in my EMR the family refuses the vaccine for this reason. -- code, I know I'm going on a -- but I think it is point was very valid but the reason we are given these forms out is to make sure families understand that there part of this equation. If they don't want it to say so, if they are injured, to say so, if they are allergic, to say so and we are making a change you're and I'm not sure I've heard of language to how to say that, toward of Montney -- image like this point. You guys get that sense or am I just smoking okay because I'm by Colorado?

[Laughter]

Sylvia, I think that you are spot on.

It sounds like and I agreed that if nothing else saying using the term the person who's giving the injection or something like that is going to reduce confusion.

Maybe it will be time to make that change again.

Anything else in Section 3? Section 4, the risk section. There were couple -- there were some comments from the consultation meeting and also another comment from our vehicle total that are appropriate here. -- from our legal counsel that are appropriate here. We havethis new section that we talked about last time where we talked about adverse events and occur after any vaccine. Right now we are putting it at the end of the section. Somebody suggested they would prefer to see that at the beginning of the section instead of the end. This the commission have any opinion on that?

The beginning of Section 4.

Other than starting out with the specific risks or faxing start out with the general risks that can occur after any injectable vaccine. Which is anaphylaxis, deltoid Cocytus and [Indiscernible].

This is Vito, shouldn't you say injectable vaccine?

Publish it, yeah. --probably should, yeah. Thatmakes it a little more complicated because anaphylaxis could occur after the deltoid for site is is only after an injectable vaccine -- [Indiscernible] is per Donnelly after injectable vaccine but anaphylaxis can occur after any.

Right.

What your saying is that is can happen after intranasal flu.

Which is not true. Although we wouldn't have -- we wouldn't put that on the LIV VIS.

We only put it on a VIS where it is appropriate. In the sense just to find it by saying any vaccine, but the person reading it they would not be reading it on MMR or I like the or another -- not MMR but another oral vaccine. The only people who will see it will be the ones getting the vaccine where it is appropriate. This is Ed. I think that make sense, moving that general problems with any vaccine to the beginning of that section.

Okay.

Personally. And then getting into the specific for hep.

Okay, we've got one boat for moving it.

Dave King here. I'm notsure on them movement of it or whatever but the Third World point, someone refresh my memory, I don't have the injury compensation table memorized, but if I'm not mistaken where we have if one were to records we have severe allergic reaction from a vaccine are very rare and that we have one were to occur could be within a few minutes to a few hours after the vaccination. But does the table extended beyond that in some cases or is it only -- four hours is the maximum hasn't spaced out?

For the table, yes.

But do we have -- we ever know people have been compensated for longer durations?

This is Ed.

Within the four hours?

Committing it to severe allergic reaction [Indiscernible--Low volume]

Right now is this would be, you can easily change that to could got no, I don't know.

Keep it as is. We open up something else if we change that.

This is Vito. On this point this may be a bit too technical, but the IOM and the reports on anaphylaxis does talk about the late anaphylaxis where the symptomatology me occur longer than two are hours after. The statement is not at total conformity with the way the IOM discusses anaphylaxis.

That I would change it. It is technical but it's something to consider, Skip.

As a matter of fact I do remember if this was about the last ACCV meeting where in Section 5 and we don't do it on this one we added the word usually go I think that might cover us, usually.

That would work. Thatwould do it.

Okay. All right. Someone at the consultation meeting brought up the issue of unknown risk suggested that we say something that there might be risks that we don't even know about. Personally, I don't know what we could or should do with that, it is something -- it was an issue that was raised.

This is Ed. I was just thinking that pop into my head with mention of the IOM report that the IOM report basically looks at lots of different potential adverse reactions and for the majority of them, 85%, it says we don't have enough scientific information to draw from to conclude whether or not there's a cause or relationship between the vaccine and the alleged injury. Maybe it would make sense to include something along those lines that getting back to what Sylvia was saying and what I mentioned earlier just by way of full disclosure, by way of not feeling as though were trying to avoid people thinking that you're hiding the ball say -- site the IOM or report. I know IOM maybe in terms of health literacy maybe that's not the way to go, but there's other -- there's a lack -- I don't know the best way to word it, but I do think that's a really good point in something we should think about.

One way to deal with this without eating people over the head with that is when we start out we say that vaccines this a chance of side effects, usually mild and go away on their own. Series of facts are possible and before we -- as an introduction to the mild, moderate and severe problems we could say known adverse events associated with this vaccine include suggested maybe some we don't know about.

This is Tom. I would be careful about doing that because I think if you put the person giving, providing the service into somewhat of a difficult position if you say there's an unknown things out there and they can ask what you mean unknown and if it is a Meditech giving the vaccine they may have an awfully tough time explaining what that means in getting into lack of scientific evidence to draw. I think if his stuff is worded in a way that is just opens us up to unknown that the person giving the vaccine could be put in awfully tough position if the person actually reads this where they get the vaccine.

This is Ann. Can go on and on about that, but there are many -- and additives that are in foods that we have no idea are going to cause a problem. It is [Indiscernible] in a way and I don't know whether -- I agree I think it is opening a can of worms.

Okay. Just making notes. [Laughter]. The other thing that can among our legal counsel brought up is that we don't -- and I hate to do this, but maybe we should, we don't mention the fact that you don't use the word death anymore when we talk about vaccine risks. We used to say vaccines could directly caused serious problems including death or the problem I have at that is once a patient sees the word death that's about the only thing they see. On the other side of the coin is that if it is a hypothetical possibility we are disingenuous by not mentioning it.

Luisita.

You mentioned that in part one [Indiscernible--Low volume].

From diseases.

So what Kevin was adjusting we also use death as a potential outcome of the vaccination.

This is Ed. Isn't there a correct answer to that question? Can death be a potential cause or reaction? The doctors in the room are not in their head, I would think it would be important to disclose that in a listen to her legal counsel.

The question is how do we say it in a way that lets people know that it is an extremely unlikely outcome?

Is a Charlene speaking. So we are not talking about readability or public consumption at the second, but the rates of death from chronic liver disease versus the rate of death from vaccine are Polar opposites. Those are so far apart they are not in the same neighborhood, country or hemisphere. That is important -- as well

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It yes, but once we use the word death that difference disappears [Indiscernible] Dave King here. Maybe it only does peers up we don't mention the component that Charlene mentions there which is that the risk of death is higher than if you have the vaccine. Is that a true statement?

I would say so, definitely. [Indiscernible--Audio cutting out]. I always whether the fact that we don't seem to have any -- maybe they exist and I don't know about them, any real figures of how many people have actually died over the years took the general to vaccines.

This is Tom. I think the only data they have is from [Indiscernible] I don't know if anyone else -- I think it is 76 [Indiscernible] [Indiscernible--Low volume] I do have some data but other than that it is hypothetical. A that's what's hard to get across.

You can die from [Indiscernible] reaction. Hypothetically you can die from [Indiscernible] but this quite a bit of data that risk of death following vaccines is the same or lower is a cause of death of the [Indiscernible] unvaccinated people. But there's no epidemiological evidence outside of maybe 76 that there's an increase risk for death but certainly hypothetically, if you can [Indiscernible--Low volume]

We will try to find a way to word that in and make it sounds scarier than it has to.

This is Ed. This is an important point. If the risk to any individual has a contracting and dying from some infectious disease is a risk that they might choose whether they have no choice is this a risk to receive a vaccination that has the potential to kill them is something that they are by law supposed to be consenting to. Now, it is no way to take away from Charlene's point but you provide the information that says it is possible for people or whatever, one extremely rare adverse reaction to vaccine can be very serious illness including death. We can say however, the risk of serious reaction or die, vaccine -- dying from a vaccine is extremely whatever language you use, it is infinitely smaller than the possibility of contracting and having serious problems or dying from the disease. That's keeping with what we are saying. You cannot hide the ball. It is okay. People have to be confronted with that. If they then decide I didn't realize the vaccine could kill me and they choose not to do that, and we need to do more by way of education. On why it is important to get vaccinated, not provide them with less information about the potential remote adverse reactions.

Steve and then Ann.

[Indiscernible--Low volume] is previous meetings -- there's a large vaccine -- effort [Indiscernible--Low volume] so a lot of these assumptions we are making about how stuff is communicated or not about anything having to do with [Indiscernible--Low volume] let alone vaccine stuff, is obviously, located for a subset of the general public. The rest of the general public it still public data but most of them like yourselves [Indiscernible--Low volume] them to use and make a big financial commitment. But [Indiscernible--Low volume] one thing to have all the information that one of the things that keeps coming out of these discussions about hesitancy is most people we have to remember the folks around this table and the folks involved in the faxing enterprise -- small percentage of the general population very specialized knowledge and for us it is hard to even contemplate that somebody wouldn't understand what one in a million means or one in 1000 mentor one in 5000 and that actually is a lot of discussion should we show pictures with one little pixel and the rest so even just saying you might die from this will make be absolutely exquisitely correct comments notwithstanding, the way people interpret that is going to have some impact on what they do or don't do and I guess [Indiscernible--Low volume] even though legally you might [Indiscernible--Low volume] requirements, it is going to have an impact that most folks might not be equipped the way other folks are that -- to be able to -- are but that's the issue. The Mac [Indiscernible--Low volume] so [Indiscernible--Low volume] I'm not going to do this deal. If I remember who are target audiences. It is not us and it is not people that deal with complex information on a day-to-day basis.

Ann, I concur with that to some extent. I think -- this is Ann. It is 20 center vaccine considered to be the biggest help improve -- the thing that is most improvement of student health and I'm sure that's going to continue into the wafer century. To think that my parents me read that of a two -week-old there's no way anyone is going to want any shots [Indiscernible] that's my feeling down in the trenches that -- but you know it is true, some may not read it because [Indiscernible] they come across our iPhones in whatever -- you can get to the next slide if you don't push I agree that I can be you deal -- usually deleted all but I appreciate the issue of full disclosure but I just feel we'd be that's just a little going to far.

It is a communication issue of what we say is actually true but I still believe once a parent sees the word death they are going to not say that is a very rare occurrence, they are going to say this vaccine could kill my baby. Regardless of what it actually says, that's what they are going to read.

I agree with Kevin and those that say it the issue of disclosure we need to mention it but we have to be very careful how we do it.

That's our job.

Dave King. The data that we don't have is how many people get their children vaccinated knowing that it is one of the risks? We simply don't know that answer. And it might be that most ignore that component because they understand what the benefit is. We don't really know.

Right.

This is Tom. Just get what's on here, [Indiscernible--Low volume] these are all things that we either known side effects or in the package insert so they've been detect it [Indiscernible--Low volume] that give you start putting hypotheticals in there, you start us but right now you've got out problems that we know happened [Indiscernible--Low volume] most of them, probably can happen after any vaccine, this is things I one says -- I one says, there's a strong evidence [Indiscernible--Low volume] I would just worry about turning to throw in things that are theoretically possible but we don't really have a lot of evidence that there's a risk for.

This is Ed. I don't -- it is not -- I don't agree with the characterization that it is hypothetical.

[Indiscernible--Low volume]

Allergic reaction, that's possible, biological [Indiscernible--Low volume]

The IOM report discusses epidemiology is only one tool to tease out and determine whether a particular injury has been caused by vaccine. The other is you look closely at the mechanistic evidence. I don't think it is a stretch, that it is hypothetical. I understand all the other concerns

about health literacy and the sophistication of the audience and I think it is a tough issue. It needs to be wrestled with by HHS.

Dave King here. Severe allergic reactions, so as of your religion -- allergic reaction that can cause death or is one of the severe allergic reactions, death.

No. This is Vito. Generally what happens when that occurs is it secondary to an anaphylaxis.

Got it, okay.

Death can occur through other mechanisms. Withinhave a [Indiscernible] they can faint, here to there had, have a serious plate and I very quickly. The other -- these things are all theoretically possible.

Okay. VeriTime, would you be willing to meet with Kevin and us to discuss the best way to deal with this?

Sure.

Okay.

This is Dave. It the way we might want to do this [Indiscernible--Low volume] the way Vito articulated it is probably a good start to say severe anaphylaxis can result from this or whatever [Indiscernible--Low volume] and severe anaphylaxis [Indiscernible--Low volume] can lead to death to go separate them because that's the truth, first of all. Second of all it doesn't say paint back you're going to bid and anaphylaxis reaction [Indiscernible--Low volume] that causes death. That I think it is accurate and they soften a luncheon up so that it is not so report so that I probably [Indiscernible--Low volume]

Good point.

Severe allergic reaction it can be life-threatening? Your life can be threatened by it? A caveat that severe logic reaction [Indiscernible--Low volume] they can be life-threatening.

Ed, that strikes me as a really good way to communicate it without overstating the concern or fear.

This is Vito. Or we could enter it it is under number four, or side effects are also possible call we could say life-threatening side effects are also possible that are very rare.

That we do not actually use the term cap, that's nice.

Okay. That's another possibility. Thank you. Okay. Anything else in Section 4?

Mexico, this is Sylvia. Very minor detail, this hepatitis A cause temperature spikes or fevers in patients do know? Because you don't match in any of that and I've always had the folks that is A doesn't cause fever.

It is not under mild and it is not under stomach maybe it doesn't, I will check no.

Okay, thanks.

Which made it is not listed as a problem and the recommendations.

Correct.

I will check anyway.

Thanks.

Okay, Section 5, 6 and 7 are as always the same across all VISNs we've discussed those before. And we discussed a while ago adding a section to the Section 6 under competition program talking about the time limit. And that would be a change and of in of course will appear on all the VISN. Unless there are any sections, any other comments on the remainder of the VIS we can move onto appetite is B.

This is Vito. I'm sorry, I did have some thoughts. One thought under what should I do, the way it is worded it is talking about a severe allergic reaction and call 911 and then afterwards when you finally have think stabilize, contact layers. Telling you to contact -- is not talking to contact join any Sears adverse event that occurs. I think that's an important distinction in point that needs to be made. Anything serious that occurs, VAERS should be considered.

Okay.

The other thing that I think is important is we need to make clear that reporting to VAERS does not constitute filing with see ICP. I'm sorry, with the ICD. And because some people I know it confused they think that they filed with the government they felt they VAERS before and they think they filed with the program and they learned that there are outside the statute of limitations when they finally the data they haven't.

[Overlapping/Multiple speakers]

We do do that with VAERS when someone reports to VAERS a letter that's sent the reporter makes that point but sometimes that doesn't get communicated to the patient and I think it is important to have a tier.

Okay.

Thomas DCDC. Can you -- the last sentence -- VAERS does not provide medical advice.

That's the way it was originally stated and then we changed it, I'm not sure why.

If there's reason they changed it, there's a good reason. Typically do we tried to depersonalize it a little bit. [Indiscernible--Low volume]

I guess we added that little bit just to say to reinforce what VAERS does do as opposed and then say what they do not do but we can -- if we want to justify it by saying VAERS does not give medical device, advice, that's fine.

Typically they will send anything to CDC to answer.

All right.

Skip, this is Sylvia Villarreal. To get back to that point we will have to fix that were Dr. Mike file -- Dr. Mike file provider, you are -- will file this report. I don't know about Mike file, I really want people to file these reports, I I have a case right now I don't want to talk about it but I have a case now the question is who is going to file this VAERS and it got lost. I think that we have to strengthen that's a little bit. VAERScan be reported by your doctor, your health provider, your school nurse ago.

We made -- this gets to parts of your point. We could make a change after this VIS was drafted where we change the word might to should because it is a legal requirement. We wanted to make it stronger that the doctor or provider if we decide to use the provider, should follow this report instead of might file this report to make that stronger.

This is Ann. Actuallythat raised a question in my mind, does that mean that VAERS should only be for serious allergic reactions another serious emergencies? Isn't it for any?

Theoretically, Tom, correct me if I'm wrong, any reaction can be reported to VAERS?

This is Tom. There are certain adverse events that by law should a lot the provider should report and then there's different laws that apply to manufacturers, but VAERS will accept any report from anybody for any reason without judging the report except for [Indiscernible] this indicates really

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Maybe --

It reinforces probably some serious adverse events or ones that are in the label should be reported and that's probably covered in the law but also I think just for surveillance, CDC wants to get this year's reports. We would -- those are more important than forearms or read arms.

Which we know are associated with vaccines. One singles of one event that are not certain we associated with vaccines.

Skip, this is Ed. But if in Section 5 it says what should I look for then what should I do and after otherwise call your doctor or healthcare professional, then in bold what else should I do? Or who else should I tell? Then say any severe reaction should be reported to the P1, UN, you're doctor should follow this report, but you can also do it yourself.

All out -- because honestly, there's a serious problem the first thing you've got to do is contact your doctor, that's of the utmost importance. But then when you is that after you dealt with the acute medical situation, it is a separate think you should report this to VAERS for for for surveillance purposes.

This is Ann, maybe it is okay to wages.

Thompson you could also say reporting a serious reaction

As a separate header under incentive who else should I tell. I think --

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[Indiscernible--Low volume]

Problem.

Thank you.

[Captioners Transitioning]

Ready to move on to hepatitis B?

This should go quickly because we hit have dealt with a lot of the problems. Okay, section one.

Sylvia. We have any more recent data than 209?

We did not at the time that we added this, I can check?

We just look really dated. A lot of folks can get on their social media and look quickly. On it now, do we have a 10 or 11 or 12?

I think it would be better if we could just say annually about so many. If it's consistent enough from year to year if we could say annually so many people become infected and it would be better if we didn't have to specify a year. This is a veto. We should also say what population we are talking about if are talking about the United States we should say the United States.

Definitely.

This is Sylvia. This is one of the vaccines we have trouble with with family. Hepatitis B. In here, where do you mentioned that if the mother has hepatitis be can go to the baby. So that as a baby who's mother is infected. Is that what you're saying that?

The last bullet under number two.

That one is really critical because a lot of families sake I am not infected so they don't want their kid to get hepatitis B shot.

I know that the controversial area. I just saw something from it immunization action coalition where they mention and they are defending the need for the birth dose to one of the ways they are sake -- doing it is there saying that a woman -- if the mother is positive it might be undetected and not only women that know but women don't know is one of the reasons for the birth dose.

[Pause]

I you saying that we might need to strengthen that statement a little bit.

This is Sylvia. The hepatitis B is point to be and easier one. Hepatitis E is the easier one and hepatitis -- hepatitis B and again I'm a pediatrician, we are dealing only with 20 to 25% out of childhood vaccine problems. For me that one bullet you have under two with chronic a baby who's mother is infected can be infected because of the birth process. That's what I talk to families about. The rest, it is completely irrelevant to children except you get it on the playground or whatever. For me, I have to drill down and say okay if the mother is infected then the baby could be potentially infected. For me that's a much more important part than having to go all the way down to talking about it. This for me is a harder sell for the hepatitis B and especially at birth. I don't know whether we really -- I don't know where to go with this.

We can try to show it more prominently, at least, and maybe try to without getting into too much detail explain why it is important.

[Pause]

Actually, I misspoke. Number one acute and number two chronic or two different things. This applies to vaccines in general and the disease in general. We can try to make that a more -- and I know that's a problem particularly since people think of hepatitis B as a sexually transmitted disease, premier l eague. They wonder why they need to get it at all.

-- -- disease, primarily.

They wonder why they need to get it at all.

Anything of the number one? Should we make the fact that it prevents cancer more prominent? That seems like the major -- it's been a major selling point of the vaccine that up until HPV was license it was the only cancer preventing vaccine. This is Ed. I'm going back to what Sylvia was saying. Really do think that, that just struck me. One of the most -- this is so important in one of the main concerns is people are suspicious of the vaccine schedule and the push to vaccinate hepatitis B at birth. There's only so much that can be done about perceptions. I think it could really help if it said why get vaccinated? If you broke it out, babies should get vaccinated because there is a risk that the mother is infected and then have a separate part or section that says you can also become infected by hepatitis B with whatever. I want to point that out. I think it's a really good point.

We will do our best to emphasize that.

I may be wrong about this -- I'm sorry, this is a Vito, acquiring hepatitis B neonatal he or the tyranny of time period is more likely to lead to chronic hepatitis B as opposed to getting it later. Because the chronic hepatitis be leads to the cancer. That is not communicated here.

I was thinking of that. This is Charlene Douglas. The problem is these are such limited points and the basic chronic rate for most diseases is two to five% but if the child is infected before the age of 490% so that baby and if that month the carrier and that months infected and you don't protect them you have it.

That's a tale, it's a long e-mail.

The communicators will find a way of saying it.

It's a good point if you want to emphasize that. There's two things to emphasize. One there is the risk that the baby will acquire hepatitis B from a mother who may not know she's infected but then if they do then the risk is very high that they're going to develop chronic disease and possibly cancer. The possibility of being affected and then the consequences if the baby is.

This is and, you do need that hard selling point even though we are not using selling point in general that that's the issue that Sylvia was addressing also.

That's a way of emphasizing the benefits of the vaccine by emphasizing the risk of the disease.

Anything else in section one?

Section two? Hepatitis B fixing?

This is [Indiscernible]. First bullet second paragraph, older children [Indiscernible]. When and most of them received that by now or are you just trying to catch up?

I think that's for catch up.

There shouldn't be catch up for 91 anywhere.

Skip, this is Vito. I'm still stuck on number one when we say 2,938,000 people, do we have the data pre-vaccines? Would that be helpful to say before the vaccine was available 138,000 people were infected per year?

I think that would be good. Down at the very bottom of that page we talked about the 95% and 75% reductions but that might be one of the situations that we talked about at the beginning of the session where would be better to have the beginning -- the actual numbers.

Exactly.

Okay.

Anything else in section two?

This is Anne. On the bullet points were talked about adult and again to emphasize what Sylvia had already mentioned, people who travel to countries where hepatitis B is, and and somewhere you need to reference the travel section on the CBC -- CDC website.

Let's see if we dude at the end.

They reference CDC vaccines.

We can add another -- that the travel website there in addition to that.

Right.

Okay.

Section three?

Steve -- it has a typo.

Yes. We will fix that. Thanks.

Skip, this is Vito, there's also the issue as with hepatitis A, anyone else that wants to be attacked it can get the big thing in the we list the people that shouldn't get it.

Where do we say that there?

It is the third bullet above number three.

Above number three. I got you. Yes.

Thank you. Skip, this is Sylvia. I don't know why I am having such a problem with this but in section two, my brain focuses on pregnant women, babies, older kids, adolescents, and adults. Again, have to be able to talk to families in a certain group. See where you have towards the end of two pregnant women may be vaccinated?

Yes.

We may want to look at the pregnant women, the babies and the moms because again our focus is clear really looking at a lot of adult injuries now I'm trying to be able to talk to families about younger kids. This is a real major problem. It's hepatitis B is not seen in certain populations as a kid problem. I'm trying to do more education and trying to be able to have it flow a little bit better work and my brain this is really a food salad. It's not making sense to me. This is heart put out to folks.

This is Melissa. As welcome I know that kidney dialysis patients are only listed as adults and there our children who are dialyzed in their art adolescents that me engage in some of these behaviors who may be at greater risk so these risk factors are not just for adults.

I guess the reason they are included under adults and it's routine for kids and they should already be vaccinated in don't have to think about other risk factors.

[Pause]

Anything else on either two or three?

This is Anne again. I am assuming you're going to make similar changes hundred number three such as your Doctor, your healthcare professional.

Those will applied to all VIS's.

It seems like maybe they should get it at a later date? It just seems like one of these statements.

Which statement?

If the person is not feeling well --

We did not used to say that but someone, I can't remember who suggested adding during some recent discussions.

The concept is good.

We can get it at a later date.

Come back and get the vaccines.

Okay, I never actually like that wording much either.

[Pause] .

Here it says you should come back and here it says they should come back.

[indiscernible - Multiple Speakers]

Sorry, go ahead.

Skip, in the prior one you have it where you should come back and on this one it says they should come back. It's kind of different tenants that we are working with because of you have if you are not feeling well on the prior one and if you are pregnant and on this one is if the person is getting their vaccine is not feeling well.

This is something we have to deal with on a case-by-case basis on whether it's likely to be a child or an adult getting the vaccine. It would be nice in this came up on the meeting this afternoon too to find some language that would work for everyone. You say the person getting vaccinated it's kind of awkward. If you say you and it's a child then I think people understand what we mean, maybe --

Instead of the words they you could use the word one so one should come back.

[Laughter]

Will use that as the British version.

[Laughter]

Charlene?

[Laughter]

That is something you're trying to find a solution to.

Anything under risks if we are finished with number three?

We still have some of the same issues we talked about and it's going to apply to all vaccines, the discussion about death and whether we have to move the last section of to the top that will applied to it every VIS. Is there anything specific with this one?

This is Anne again. Temperature 99.9 or higher, is that within a certain timeframe or are we just went to leave it out there?

I'm not sure. This was probably copied from that ET IP and I don't think they specified a time fair -- a time frame. I can check on that. Okay? If there's nothing else there, is there anything in sections five, six, or seven that we haven't already discussed?

This is Vito to compare with hepatitis a and we say after [Indiscernible] if these problems occur that usually ask -- last one or two days and I think adding something similar to hepatitis B would be useful.

Okay. The first sentence in number four? If you look --

If you look at hepatitis A under mild Rob loans it says if these problems occur that usually last one or two days. As far as I can tell there's no comparable time frame within number four for hepatitis B. Okay?

With all the business of having a timeframe is helpful. Frequently for example a headache is an adverse event and it's expected to last one or two days and we frequently get claims within the program with folks with chronic headache saying that it's a side effect of the vaccine when it may not really be.

Yes. And questions we get here, we hear the same thing. People will break back a year later and talk about a sore arm.

When we can, when we can we will try to provide a timeframe for the adverse events.

Cool.

Anything else?

I guess we ran a little long.

This is Dave King here. We ran -- we ran a time we needed to run.

Thank you.

As always, thank you for your comments. It's one of the most useful forms for discussing VIS, I think.

Okay. Skip, thank you very much. Think all of you.

While it is not on the agenda we are having a break.

[Laughter]

All right? So we will go to five minutes after 11:00 a.m. and that will give us a 13 minute rate. A rate?

-- -- all [Event on break. Will return atright?

[Event on break. Will return at 11:05 A.M. EST]

Jeremy? Jeremy, can you hear me?

I can.

We're going to restart the court -- session.

Is there anything I need to do?

One moment.

At this time the conference will now reconvene. This call speak -- this call is being recorded.

Dave King here, prior to moving through and getting the reports to the CDC with Tom Shimabukuro, we have a question and I want to make sure that you are aware of something, we are thinking in the interest of time and because while we may not have to hard stop immediately at the stroke of noon there are some individuals with travel arrangements that require them to begin to move shortly thereafter. We are in a conversation here and we are thinking that possibly -- we were thinking that Tom S himabukuro -- pneumococcal safety review from a lame Miller we were thinking maybe we might be able to postpone that to another meeting and the question that I have is does any commissioners here have an objection to that or is that something that they must have in this meeting?

This is Charlene Douglas and we as the commission concur with the chair.

Thank you, Charlene.

[Laughter]

You link, if you can hear my voice, we appreciate the fact that you are willing to do this and we know you spent a significant -- a significant portion of your day here to speak and it will only be that much more exciting at our next meeting when we have you do that. Thank you very much.

Thank you. By.

Having said that we will then move on to the update on the immunizations safety office center for disease thing -- disease control and prevention. Tom Shimabukuro.

Morning. I am on slide two now. I will be giving and update of the February 2014 advisory committee on immunization practices meaning safety presentations. Actually, because the a CIP just just met and I have to create this presentation and it has to go through multiple settings I don't actually have up to review but I can give a brief preview of what happened and at the next meeting I will give a more in-depth review. I will talk about the Princeton University and fixing programs that are ongoing and go through some selected publications.

On flight three. February 2014 ACIP -- during that influenza session there was an interim influenza vaccine safety update looking at live attenuating vaccines and inactivated vaccines for persons less than 18 years of age. A comparative safety review of L AIV versus II-B and it's part of the [Indiscernible] process and grade is some kind of acronym but it means they grade the quality of the evidence as they consider making recommendations. Just to briefly discuss what was going on in influenza session is we are making a presentation of using the vaccine and younger children and they requested that the CDC given interim safety update on LAIV and also they wanted this grade presentation because we are currently at the point int where some type of recommendation is going to be made it needs to be made fairly quickly for the upcoming season. You may be aware we may not be aware but live influenza vaccine went from [Indiscernible] to Quadra valent a complete switch from last year to this season. Indices and all live flu vaccines is [Indiscernible] were previously it was [Indiscernible]. We did a year between seasons comparison of live versus live from this season versus last season. And then for inactivated influenza vaccine there's a period of transition going on where there is sub -- some [Indiscernible] being used but it's mostly [Indiscernible] fixing and when you look at [Indiscernible] we did and in season comparison. Comparing live and inactivated vaccines with [Indiscernible] safety but one was between seasons and one was within seasons. The interim results were that the safety profiles on the [Indiscernible] live vaccine and that [Indiscernible] inactivated vaccine are comparable to the [Indiscernible] formulation. And then in the LAIV versus Jenny Levin, they look at [Indiscernible] Jenny Levin and in one season there was a transient increase of fever after live attenuated vaccine versus inactivated influenza vaccines. The bottom line is as far as making a recommendation for live versus inactivated and number two -- younger children, that there does not appear to be a safety concern. The safety prologue -- safety program is the [Indiscernible] live of that [Indiscernible] vaccines are comparable to the [Indiscernible] fixings. Next there was a presentation at the Tdap in pregnancy and we're giving regular presentations to ACIP following the recommendation for repeat vaccination of Tdap and each pregnancy and we had a VAERS review and the bottom line for these two reviews is right now there is not a whole lot of data on repeat dose of Tdap in pregnant -- pregnant women in each pregnancy but the data we have on Tdap and the small amount of data is reassuring at this point. I will provide additional updates of the ACIP sessions at the next meeting.

You may have heard about couple of vaccination programs going on to address prolonged outbreaks of serogroup B meningococcal disease occurring at Princeton University and University of California in Santa Barbara. It is a serious and potentially fatal disease. Outbreaks are rare but they do happen in the United States. They usually are contained and self limited however it prints didn't -- at Princeton there was ongoing transmission and same at Santa Barbara. The CDC is currently working with these institutions, the public health agencies and the states to help coordinate vaccination with groups for the serogroup B meningococcal vaccine programs. They just finished their p rograms -- program it prints it and Santa Barbara is in progress. The vaccine is not licensed in the US and it is been given under an expanded access to investigational new drug protocol approved by FDA in if you'd like more information on meningococcal B disease you can visit that website.

I'm on slide five now. Some selected publications. I will start off with the stock while paper risk of fever after pediatric trivalent inactivated influenza vaccine and 13 valent pneumococcal conjugate vacate -- -- vaccine. In 2010/2011 CDC and FDA detected a signal for febrile seizures f iling -- following trivalent influenza and young children. Further assessment of the signal indicated that the risk actually was highest when TIB and PCB 13 Word ministered together. And six to 23 months old picking at about age 16 months. However we actually didn't have any evidence at that time of increased fever -- fever. Febrile Caesar, you have the fever in the seizure of febrile seizures are generally benign. Children recover. Febrile seizures are not associated with future seizure disorders in neurologic problems. In this study actually looked prospectively the children who received TIB MPC the 13 and track fever and what they found was that simultaneous TIB MPC feet 13 was associated with higher transient increased risk of fever in the administration of either vaccine without the other products when they are administered together there's more fever then if you administered them separately and children got them on separate visits. Just to remind people, the study took place in 2011 and 2012 and that was the same TIV formulation. It was a good year to do the comparison. Did you have a question?

The next paper reports to the vaccine adverse event reporting system after hepatitis A and hepatitis A B, this was a VAERS review that looked at reports. Efforts -- most of the vaccines were given in the first trimester in these vaccines are routinely recommended for pregnant women and we're given to women when the provider did not realize they were pregnant but the bottom line is the review of that VAERS report to not identify any concerning pattern in pregnant women following maternal hepatitis A during pregnancy.

The Guillain-Barré syndrome influenza and influenza v accination. This was a -- let me forward it. This paper is actually more a review of existing evidence. Not a review paper but more a review of the existing evidence. I'm not going to spend too much time on this. I believe you're all getting PDF files of this see you can review this if you want the next page -- the next paper which is notes from the field on rotavirus, this was a review of VAERS reports and in this report CDC identified 39 reports of rotavirus vaccine administration by injection in VAERS in 27 reports of I-letter/us. Rotavirus that vaccine is an oral vaccine. You squirt it into the mouth of the child

and what CDC did was look through VAERS and look for errors in administration and found there were some reports of providers actually drawing this vaccine up or attempting to administered by injection. The root of the problem there appears to be lack of training or knowledge or not reading the package insert.

This is powerful and I never knew before because we do so much discussion about GBS, the risk following influenza is a greater risk than following vaccination. Does everybody else now that?

It's such a topic of conversation.

There are no risk factors for GBS like V-uppercase-letter infection and upper respiratory infections to include influenza. This look at the evidence and clearly there's an increased risk of GBS after influenza disease which needs to be balanced when you look at the risks after v accination.

GBS was identified before we had vaccinations. It is the disease on its own. It does develop. We have spoken of it so extensively as a consequence of influenza vaccine that I have never heard of it as a consequence of the influenza disease.

Exactly the next paper is an actual study. This is a paper by [Indiscernible]. The cumulative risk of Dion very syndrome among back the dated and unvaccinated populations. This looked at surveillance data from the emerging infections program which is about 45 million people under surveillance and what they found was that the cumulative, this was looking after the fact. So they went back retrospectively after the pandemic and looked at cumulative GBS risk and it was last in vaccinated then and him vaccinating populations. They did not really get into specific desk specifically speculating for reasons for that but certainly it's ones of the vaccines that can protect you from influenza and influenza disease is a risk for GBS and so you can see how vaccination may be protective against GBS. I will say there is a known risk of GBS after respiratory illness with the flu. We have evidence of increased risk of GBS after influenza vaccination in some years with some formulations and some of our surveillance systems. I think the take-home message from this and the other paper is it's just important to consider the risks and the benefits when talking about influence of that nation.

That's it. And I would be happy to answer any questions.

This is Sylvia. I have the advantage of being in clinic right now. I pulled the rotavirus outcome of the oral in the box is very well labeled for oral use only but I can understand that error because they are and syringes. When I'm staring at and I can send you guys a cell see if you want of it. I could imagine were some people would put a needle on that. I won't mention the manufacturers name. It's an interesting problem just looking at it I think busy clinics just got to the instep needle on this thing.

There are two presentations, if you will on the rotavirus vaccine. One is and it looks like a plastic tube with a twist the cap.

That's a good one.

And the other one is, at least in the US, you have a [Indiscernible] and I believe it's a dry formulation and you have to mix these using a mixing syringe and a file. Those are the to presentation. I'm not going to comment on the manufacturers. We just look at the VAERS data and looked at basic counts of this occurring. If you want to actually read. It takes about three minutes to read the paper in it has photos if you'd like to look at that post. I believe the file you get has about 10 pages of other papers in the last page of the entire [Indiscernible] is that article.

Dave can -- Dave King. Anne, this is what was forward to us?

This is Anne. Did data come back from the manufacturer to suggest that maybe the packaging is not the best?

We haven't. Issues around packaging is more really the purview of FDA. We are just reviewing -- all we did is review the VAERS data and I just want to add that with roughly 57 million doses being distributed, even though this may seem a particularly egregious met -- it ministration error they appear to be extremely rare.

We're the mistakes primarily with one manufacturers product?

It was more with one manufacturer than the other.

This is Sylvia. I can literally have the box in my hand in looking at it. Tom, I think it's important what Anne is seen is that for quality in for variability again it's only 39 kids but it is our administration error. The manufacturer can look at this and granted it could be somebody that can breed but at least we can look at -- read but at least we can look at 39 self inflicted injuries because of packaging and I think it's minimal I think it's worth getting back to the company.

Sylvia, I don't know if we can say that it's all because of packaging. We can say that there are these errors and their are more from one manufacture than the other and there is different packaging.

That's all we can say, Tom, but the issue is for us and for me anyway as a Commissioner, I went to look at very simply, is there an error with us looking at syringe are looking at the way administering so the families have faith in us. That thought. This is a minimum. I think it's an easy fix and I appreciate [Indiscernible] looking at this. Who would've looked at this? It is a minor error and something that me as a patient centered medical home I have to say wait, guys I have to train you, this is really important. Don't put a needle on this syringe. That's my point.

The good news is it doesn't appear to be harmful to inject this vaccine but there are costs such as having to, loss of confidence, parent time having to bring the kid back kids back and if it was

detected after the fact in that type of thing. Errors or even if they may not cause adverse health event there's certainly no cost to a dministration.

Time, I don't think you can say that. With only 30 or so cases you can't say it's not unsafe or there are no adverse events.

What evidence do we have right now it doesn't. We don't have evidence to suggest.

We really don't know.

That's a good point. We did not detect -- we did not detect in adverse health event pattern.

This is Anne. A couple of things. One is the number of people who might report that to VAERS is probably a lot smaller than that -- them that has occurred and in this error of trying to reduce medication errors among all professionals involved in the process of administering medications I think it is an important issue to certainly have packaging. We brought that up once before and I don't remember what the situation was, one of the other files in the vaccine of the boxes or whatever, I think one of our first meeting. It was discussed I believe it went back to the manufacturer. I don't know if it was from your department. I don't know how the communication flows from one organization central agency to the next.

The manufacturers are aware enough that they posted it on the box. They are aware of it.

Dave King here. I know we're talking about primarily the injection but the ice places were there many -- any major adverse issues?

There was a minor eye irritations. I think one person also had reported some gastrointestinal symptoms but the ice places, that's really kids during the administration. I'm just speculating. While they are ministering it the kids, vomiting or so hitting or coughing it back up into the face of the provider who is probably in pretty close proximity and their art instructions in the package insert on the best way to administer vaccines to minimize that.

Dave King again. So the statement that the ministration errors are largely vegetable with proper education and training. So who's responsible for doing the education and training?

I think at the basic level it would be the organization's that is administering. If it was the clinic it would be -- certainly CDC put that information on proper administration but I think at the level that these are happening I believe the organization would be responsible for training its own individuals.

Dave King here. So since we know that it is largely preventable and there's somebody responsible for the training, but they know -- do they know their responsible what is the process for saying the Steve to be looked at closely? From this data I don't know if it was located in one and maybe you would now -- was in one geographic area? It's the data that

begins to point us to the story and where we need to focus but we don't know and I don't know and does anybody know and who that -- who is responsible and accountable for that and this stuff should get been in this -- in you should be doing this.

I can't answer the question of who it the facility -- I can't answer that question. I will say though avoid don't recall, I was actually involved in this paper but it's a matter of disclosure I'm actually the author on this paper. I don't actually recall any geographical regional issue but I do recall a cluster of six injection errors by a single individual. You might expect that that person is not -- is not properly trained.

Thank you.

Any other questions? Comments? Tom, thank you so much. Let us move on. The next item on the agenda is for the update on the national Institute of allergy and infectious and -- infectious diseases.

Clerk, come on down.

Claire, tell us your full name again. Claire [Indiscernible] representing allergy and infectious diseases.

Thank you.

Sorry about that.

No problem.

I have a few updates on recent papers and some resources. Within the past couple of months there have been a few papers looking at differences in mean m ute -- immune responses and vaccination. The first slide this paper from a Mayo Clinic look at race sex in immune -- immune response to rubella vaccine. They looked at two large racially diverse cohorts of healthy children older and Celeste -- adolescents and docile adults and they did find a difference based on race. Specifically they found individuals of African distant -- percent -- decent had significantly higher antibody response compared to individuals of European descent a nd/work has been neck ethnicity.

And another study investigators at Stanford University which is the next slide looked at sex differences in relationship to immune response to seasonal influenza vaccine the study included 53 moment -- women and 34 men. I found a significant difference based on sex with women produced antibodies that we're effectively neutralize the influence of virus in laboratory tests and investigators wanted to see if they could find out what was responsible for the difference. They searched for patterns in gene expression and they found that testosterone seems to suppress the immune responses related to vaccine response I altering expression of specific

genes? A while this can explain some difference in the [Indiscernible] to vaccination, more research is needed.

Another recent publication that extra came out this week in the journal vaccine focuses specifically on vaccine development for sexually transmitted i nfections. In this special issue of vaccine is a call from the world health organization and [Indiscernible] to try to accelerate X -- vaccine development including priority areas such as herpes simplex virus, chlamydia, gonorrhea, trichomoniasis, and syphilis. The link to this journal is at the bottom of the slide.

And now I will move into resources we have available on the website and the slide shows the NIAID research advances in it highlights this -- highlights the scientists that are supported by NIAID throughout the US and across the world. It describes some examples related to vaccines. The shot -- slide shows the malaria vaccine but we also have slides related to dengue, malaria, and the universal flu vaccine. In addition we talk about research advances with some of the new and emerging threats such as 879 influenza in the Middle East respiratory sinus syndrome also known as Merz. Also recently added to our website we have a new report on the antibacterial resistance program current status and future direction in this report includes an overview of the research going on in this area from basic research to clinical and also some new innovative erection that we are pursuing pick among these are vaccines for healthcare acquired infections.

Excuse me. Vaccines for healthcare acquired infection.

Right. Along those lines. Yes.

A vaccine to prevent Mercer would be one of the many goals outlined in that hat report.

The next slide presents collaboration between NAH, industry and nonprofit organizations and in the accelerating medicines partnership really hopes to help increase the number of diagnostics and therapies being pursued in reduce the time and cost of developing them. Specifically if looking at discovering new drug targets and biomarkers used for the development of new therapeutics and d iagnostics. In this first part of the effort it's focusing mainly in three disease areas. The Alzheimer's disease, type II diabetes, and autoimmune disorders such as arthritis and lupus.

For more information you can go to the NIH NIH website.

Finally I just wanted to mention a few back seating -- vaccine related meetings and meeting reports. This week in Maryland, WHO and the NIAID in the Bill and Melinda Gates foundation convened a form and at this meeting there were 200 scientists, vaccine developers and public health officials and other stakeholders for more than 40 companies participation they were look at setting priorities and vesting progress for vaccines of global importance to improve public health worldwide. And also we have found -- several NIAID reports recently published. One is on malaria research and the other on herpes simplex virus vaccine. Thank you.

Okay. Any questions, comments? Claire, thank you so very much.

Thank you.

The next item on the agenda will be the update on the center for Biologics evaluation research food and drugs and is Teresa. You're going to give that report for us.

In lieu of Valerie.

I have a very short update from the office of vaccines and the centers for Biologics evaluation and research. One particular event was last week of February the 28th the vaccines and related biologic products advisory committee met in open sessions to discuss immigrant -- recommendations on the selection of strains for the influence of virus vaccine for the 2014, 15 season. The bottom line is that all the strains of the same as those recommended for the 201314 season. -- the 2013 -- 2014 season. I won't go through the names but the bottom line is they are the same as last year. That's all I have.

Okay. Any questions? Comments? Teresa, thank you very much. Appreciate it.

And that we have the update from the national vaccine program o ffice.

This is Cheryl Douglas. I would like to ask how often is it the exact formulation used from year to year?

It's very rare.

I think it may have only happened a couple of times.

Steve, proceed.

I'm going to give you an update on the meeting that was held back in the middle of February. First of all in your books you have a copy of it annual report of the national vaccine and I think you also have a copy of [Indiscernible]. The annual report describes the contributions and accomplishments made by several partners to progress the cycles that initial vaccines and and also describes where greater effort is needed. The online version of this has some added fun. Video commentaries by several leaders in the immune is ace and enterprise. And also highlights and it also has a commentary by Doctor Paul [Indiscernible] who is the chair discussing the accomplishments over the last 25 years and also most importantly about this is the 2010 plan is approaching its midcourse review. So and EPO is going to be engaging with other federal agencies and other enterprise partners to prepare for this mid-course reprieve you and looking at mid priority objectives and identify ongoing gaps in areas of opportunity and potential methods of checking progress. Some of the conversations we had yesterday especially about where they might be better synergies especially in linkages we had back in this commission is

probably something [Indiscernible] Vito or whoever succeeds him and we will chat about moving forward. The CDC provided a comprehensive update on recent changes to state immunization programs including a detailed breakdown of funding for all of CDCs administration activities and how these have been affected and uncertainties in the federal budget in the rollout of the Affordable Care Act. The CDC divided information on recent changes needs -- and these programs milestones and continuing areas of need such as to preserve core public health immunization infrastructure at local, state and federal levels, make strategic investments to modernize immunization structure and improve efficiency and to maintain be adequate vaccine purchase as a safety net targeted towards him and toward adult outbreaks and other urgent needs.

Of particular interest was a session on vaccine research development and innovation. Typically the [Indiscernible] hasn't felt this early in the vaccine enterprise continuum. One presentation was given by the Institute of medicine where they presented on this smart vaccine and smart is an acronym and one of the goals of the plan was to develop new and improved vaccines and one of the objectives is to develop a prioritized list of vaccines for development. [Indiscernible] has been funded by and EPO for number of years and recently they released a a report and a software tool that allows you to add attributes of with vaccines and certain Pollock -- publications that help beta and gamma relative ranking for any scores are vaccines you might want to prepare. This is basically an idea to help nucleate discussions between enterprise stakeholders about what vaccines for example should be first on our list it for prioritization was going to influence approvals or other things like that.

As part of that they discussed the current phase of that is along with IOM we're recruiting potential users, government, state governments and international partners to use the software with IOM and IOM will release the report in September about the utility of the software and who they designed it for. Again, Sparta that it did a library with all the data sets I mentioned will be part of this where it will eventually be housed and what it will look like. Any [Indiscernible] presented on the form you just heard from Claire which is a venue to help track progress of the research [Indiscernible] vaccine in track progress on the R&D [Indiscernible] and identify actions for the community and the vaccine research opportunities include operational, implementation and transitional -- transitional research. It was held March 4th through 6th in convened jointly as you heard the Bill and Melinda Gates foundation. As part of the session we heard from our dock because the part of the session was to hear about ways where there might be places in the research continuum from discovery through [Indiscernible] recommendation where there might be more blocks to innovation or just general how can we make a more enabling environment for vaccination R&D. . BARDA is the development arm and what they do for those of you not familiar, they prioritize what they're going to target for medical countermeasures and vaccines based on threat assessment about which books for that chemical [Indiscernible] as well but from the vaccine perspective what bugs might be the biggest threats and that's based on other information from other parts of the government but they basically go about this by supporting research and parts of the continuum where the so-called Valley of death were NIH might not support as much because it's in a phase where usually venture capitalists come in and for difficult vaccines like this where there are no --

there's not really a market except for emergency preparedness purchasers like averments, it's difficult to get the investment enthused about this. BARDA has a model that supports this in a way that makes some sense so we have them to present to see if there are things we can learn from the nonemergency vaccine enterprise. And to follow that up we had Doctor Stan [Indiscernible] who is kind of a rock star in the vaccine development community. It's responsible for the development for number vaccines and work for number of companies and he discussed the importance of the federal government in Leno priorities for vaccine candidates. He had things to say about smart in a very rousing and critical way and also talked about coming up with financial incentives a lot BARDA to incentivize in de-risk the vaccine development for the industry and also what FDA and CDC [Indiscernible] can do to harmonize what approval and licensure requirements there are with what ACIP might approve forgiving vaccine including things like developing programs such as BARDA describing what a vaccine would need to look at for approval. Very controversial stuff and very insightful and exciting stuff. The offices considering what to do with our federal partners in response to this session. Next, the CDC provided a historical overview of vaccine supply management and for the children in pediatrics stockpile. It was established in 1983 funded with congressional appropriations from 1983 to 1991. Following creations, the CDC was charged to purchase vaccines for the stockpile for outbreaks. Following vaccine shortages occurring in 2002 in 2003 recommendations were made to expand the program. The current status and management of the pediatrics stock pile relies primarily on vendor managed inventory is on storage a rotation orbit the CDC is still the centralized distributor for some doses. Purchases for the stock out are dependent on monitoring vaccine purchases rose -- relative market share and [Indiscernible]. This is different than stockpiles for season fluke which are purchased annually. The pediatric vaccine stockpile has been successful in managing vaccine shortages including recent shortages and resulting in loans from the stock about the manufactures. The CDC what vaccine shortage -- shortfalls updated regularly. The ongoing theme is you've heard me talk about in previous meetings with an emphasis on adult immunization. The NVAC received a comprehensive overview of coverage data and efforts to improve double coverage. Conclusions from the adopted it included and indicated just some highlights a modest increase in 2012 versus 2011 fully for v accines. Tdap, [Indiscernible] of 4.4 increase at HPV a five% increase in women 19 to 26 years old. There is no overall improvement in coverage another vaccines in racial and ethnic vaccines.

That NVAC was adopted and laid out a comprehensive list of professionals, healthcare organizations and public health department to ensure that everyone is assessed for immunizations at each healthcare encounter. [Indiscernible] as well as changes in the immunization environment including the role of farm scenes and community vaccinators in reaching adult populations. The NVAC then discuss CDC plans to implement standards and how other organizations professional societies and stakeholders could support standards among providers. [Indiscernible] travel plans to include identifying priorities, identifying targets for performance indicators to be included in the plan and conducting policy analysis and including the development of the effects of ACA on access and barriers for people under-financial circumstances and finally drafting the national adult immunization plan based on stakeholder input and feedback. A draft of the plant is expected this August. MVP also announced it's collaborating with other offices within the office of the assistant Secretary for health to

administer the grant entitled mobilization for health, national prevention and partnership awards. The program seeks to establish integrated collaborative local state, regional, and tribal partnerships to increase community awareness and action on preventative health services including immunizations. The application process closed March 3rd.

We heard from two working g roups. The vaccine [Indiscernible] working group which I mentioned some time ago when we were discussing that vaccine affirmation sheets. There continuing their work to measure vaccine attitudes in place among parents and also discussing out an medication should be used as a surveillance tool and how to intervene on vaccination issues. We will be drafting recommendations for discussing at the June NVAC meeting. The working group has completed the first draft of report and recommendations of will be available for public comment on the next week or so and all are invited to provide comment. Following comment it will be sent back for deliberation. There was a presentation from the President's Cancer panel on HPV vaccination. A representative from that president's Cancer panel presented their new release report and recommendations for accelerating HPV vaccine entitled urgency for action to prevent cancer. Increasing HPV vaccinations was the most profound opportunities for cancer prevention. The report was released on F ebruary 10 and is available o nline. Almost done. The president's Cancer panel is an advisory committee to advise the president on the execution of activities on the national Cancer program the recommendations of the report were developed from four stakeholder workshops and recommendations center around three goals for increasing HPV vaccine uptake and adolescents. Reduced missed clinical opportunities registered recommended vaccines increased acceptance of HPV that can -- vaccines and maximize access to HPV vaccination services. Implementation of the recommendation was also discussed at the present panel felt a credible organization for example Jenny Levin given the responsibility for monitoring the implementation of the recommendations and their impact on update and coverages. The NVAC working group also provided updates in their working to determine the best way to support the president's Cancer power recommendations in alignment with their charge from the assistant Secretary for health. Which is up and then presented the NVAC letter entitles what m atters -- what you say matters and how you say it more. It's endorsed and encourages providers to give strong clear instructions for HPV adolescents. And finally there was a session that was supposed to be very short and brief but turned into a fun one. I'm vaccine storage and handling. Some time ago the inspector general office received a report about losses because of poor storage and handling practices in the vaccine and children's program. We heard about that in the previous NVAC meeting and we were telling the NVAC we're probably going to host a workshop on this and believed or not this has to do with canceling and shipments and how they are handled input into the proper refrigerators and stored on fight -- site at vaccinators facilities. Things as silly as using dorm refrigerators and things that aren't up to snuff to store by i t -- biologicals. CDC had a very extensive review of the OIG report and the whole problem and has created guidelines and is in the process of releasing them and implementing them. What would happen moving forward is a workshop that might raise awareness with professional organization so it filters down to the appropriate vaccinators such as the CDC recommendations are followed and in excuse won't be that they won't -- they weren't evangelized properly. Also they are technology such as vending machine models if you will wear separate devices that are wireless and mean

team temperature and report Rick the central facility and all that. Those kinds of things are starting to become available from technology companies for managing this type of thing and this effort we have ongoing partnership with CDC is to just evangelized the need for this. Again it's not a huge problem in the vaccine enterprise but it's enough of one that NVAC decided to pay some attention. So that's it.

Okay. Anybody have any questions? Comments?

I'm not sure -- Ed Crouse.

In the state of the national vaccines plans there's the bit about the FDA scheduled program so I guess that's maybe FDA domain but can we perhaps can update that at the next meeting because that sounds really interesting.

I would move that to the FDA. FTA administers prism and it's a system that you can think of it similarly to [Indiscernible] and time you can correct me if that's too broad a stroke. It's a similar kind of surveillance system using similar kinds of records and things. Duet say anything about that?

Electronic health record based.

It out -- how's that the FDA in that would be up to them to provide an update.

This is Ed. It just seems interesting is part of our charge to think about fixing safety because it's inactive. It doesn't require anybody supervising -- supervising unlike VAERS, this is just looking through data and pulling of things that might raise concerns about the safety of vaccines.

I think it's more focused and that -- than that. Our office doesn't run the program.

This is Teresa speaking.

Our office doesn't run that program. I think it's a system where you have an event that you want to specifically look at you can do that but I don't believe they used [Indiscernible - low audio]

--

This is Vito. Which is opposed to VAERS which is hot but that's generating -- hypothesis generating, it's not just a general look at safety looking for signals. That would be something like VAERS.

Can I say something --

This is Tom. Jen five does signal strength thing we do do these and it's almost like [Indiscernible] data however unlike VAERS where people reporting those events are coded using these terms and you can do data mining. In the system like the athlete you have to prespecified up front what you are looking at you don't dredge through.

Just echo -- Steve. The prism and the FDA is managed through the office of biostatistics not through the office of vaccines and so we would have to -- it would be up to Teresa to include them in these discussions and who's ever going to do that kind of a presentation.

This is Anne. I've a question about the emergency preparedness vaccine. There is some effort in that to have program similar to [Indiscernible] [Audio cutting in and out]

To have that available so the manufacture and the person [Indiscernible].

That program already exist. It is also housed within our programs we currently cover small box -- smallpox vaccine, pandemic influenza vaccine, [Indiscernible] vaccine and in addition to the vaccines for anthrax, smallpox, botulism and radiation we cover anything to diagnose or treat. It's not just vaccines. We've already received claims for flu. There is no commission for that program. It's administered differently. It's not for that [Indiscernible] system. It's all administrative within HR essay.

Thank you.

(Operator Instructions).[Captioner has to disconnect to

[Captioner has to disconnect to get to a previously scheduled event] [Event concluded]