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Good afternoon, everyone. I see the numbers of growing. I want to thank you so much for joining and we'll get started in just a second. .

All right. Good afternoon and thank you so much for joining us today for the fireside chat. My name is Ashley Spence. I am with CMS and I am charged with stakeholder engagement for CMS. Today we are here to talk about vaccine safety and we have a number of experts from both the Centers for Medicare and Medicaid Services, from the Centers for Disease Control and Prevention and also from The American Healthcare Association. We're going to kick the call off right now and we are going to start with Dr. Lee Fleischer who is the CMS Chief Medical officer and Director of the Center for Clinical Standards and Quality. Doctor Fleisher.

Thank you, Ashley I'm excited to be bringing this to you and I see over a thousand people joining today on the issue of vaccine safety and it is so important that we reach taught -- sorry about that. That is -- SIR. >>>. It is important it is important that everyone has the information and only with information can we get over the he is Stephen and get better every day for seniors living in care facilities and nursing homes in the country. I, myself continue to be a clinician, twice a month I go and give anesthesia my n95 so I understand what is like to be in PPE and despite got my own vaccine despite having bells Palsy back in March and got my first vaccine and I will get the second vaccination at the 3-week mark. Many of the healthcare providers, Doctor David Gifford and Dr. Amanda Cohn. The idea today Dr. Gifford as spent time talking to focus groups and learning what some of the concerns are and what I would urge you -- we are recording if you have colleagues who want to know from a true expert what are the answers to many of the questions -- what's the truth that they come and use this as that trusted source as I hope CMS has been during the pandemic. So I will turn to you Gif and ask you to start with the first question for Amanda

Thank you, Doctor Cohn. The support has been fantastic. Walgreen's and CVS is stepping and other pharmacies have been great in the last few weeks and great up take by residents out there. And we are having some challenges with the healthcare workforce and we are really pleased the doctors are here to answer some of the questions out there that we're hearing. We've been holding town hall meetings and talking to providers around the country and hearing a lot of the same questions and a number of people put in questions prior to today similar to what we are hearing. We'll try and address -- may not get through all of them but as many as we can today. Probably the first and most common question, Amanda, we've been hearing and I have been hearing over and over again is the vaccine was developed quickly and how do you know it is safe and I should wait to see how it works out. What do you think about that?

Thank you so much for having me and thank you all for being here. I cannot tell you how grateful I am for everything long-term facility staff

has been doing to keep residents safe and supportive and I really am just so thrilled we finally have a vaccine to give back to you to protect all of you. So I really am happy to answer questions and I totally understand why people have questions. This was fast. What I want people to understand is that a couple of things: One is this vaccine was based off of years of research with this type of vaccine and it was being studied to use for other viral diseases before COVID-19 hit at the beginning of last year. So they were really able to jump on developing this vaccine really quickly because it used the same technology already under development. Secondly, the reason why we were able to get to where we are in less than a year is because the U.S. government worked together to enroll people across the country in many, many different sites. I believe there were over 89 clinical sites in the United States that were enrolling people in the clinical trials and enrolled much more rapidly than we normally see. So 30,000 people for each of these products were enrolled in the clinical trials. Over 60,000 people total which is actually as big, if not bigger, as many of the global files we see for vaccines. While I know that it is hard to understand that we got from nothing to be able to using the vaccine when we always say it takes years of testing, it is because, both, the product had already been under development, we drastically expanded the number of sites enrolling patients and put huge effort into enrolling people quickly and the third thing is we made the vaccine at the same time as we were studying it so that when all the results from the clinical trials came back, and you know they kind of blew me away. I was hoping they would work and I am so happy with how much better they work than I thought they would. They are already to be shipped out once we have the data to show they are safe and effective. It is -- I believe these vaccines are safe and I am, you know, waiting my turn but excited to get it myself

You know Amanda, it was funny in that - one of the two people who developed this technology got vaccinated about an hour before me and was very proud of doing it. So he has full faith in his own technology. It was great to see. Gif, what else?

It's actually -- I agree with Amanda. It's amazing to see how effective this is and how safe it is. I was talking to a number of clinicians and we -- you deal with a lot of medications and others out there, but -- people are pointing out that many of the medications that people take for high blood pressure or heart failure, diabetes have -- are less effective and have more side effects than this vaccine. This vaccine is just, you know, off the charts crazy effective and safe when you compare it to everything else out

And I'll just add, you know, it -- when we see new technology I think that word is scary but, in fact, this vaccine is relatively simple and straightforward. Not very many ingredients in it is the messenger RNA almost like an instruction sheet for the cell to mimic the virus in protein and it is surrounded by a couple of lipid particles, fats. It's much, many fewer ingredients no preservatives or aluminum and things like that. We know that vaccines are all very safe. And this vaccine is just, you know, it's remarkable in some ways in its simplicity

We heard a number of questions about, you know, this wasn't rushed and it is really safe, why is there an emergency use and why not a full FDA approval out there? Amanda or --

I can answer that, yes

Sure

That is another really good question. This is in many ways about process. The emergency use authorization is a way to get through the regulatory process quickly and make products widely available. You probably sought these were available for treatments for COVID and some testing, it is not going through the extensive -- it is not going through the extensive regulatory review as it might in terms of the amount of time it took to review it. But, what FDA is they still review all the data they just review it in credibly rapidly. the one thing I will say that is different between a -- and these companies will likely apply for a BLE very soon, the one difference is they have followed -- so most of the participants in the stewed DEES more than half have been followed for more than two months after the last dose, after the second dose, before they submitted and looked at all the safety data and no safety concerns. For the full BLA, they will follow the co-HORT, a smaller group of people for longer for more like 4 to 6 months and that data will be included in the full application but we even know now, it is December 30, and we already know that those clinical trial participants who have been vaccinated over 3 months ago, we still have not seen any serious adverse events that appear to be caused by the vaccine. People do have mild reactions to the vaccines especially after the second dose so people should be prepared to have pain, potentially fatigue and a low-grade fever but that is expected and resolved after one or two days

That's not the disease --

Right

That's not the fever it's not COVID

It's not COVID, it's your body building an immune response to the protein that is mimicking the disease

That's a good sign. A sign we all get whenever we get an infection and our body immune response is making antibodies those are the symptoms we get. It is a good sign

Yeah.

Giff if I have, necessary question

The next common question is I understand it has been tested well and two months follow up, what about the longer term side effects? How do you know what those are?

Yeah, so we do not know that this vaccine, we only have three to four months out, we have hundreds of -- about 100 people were vaccinated even

earlier more like 6 months out now and we're monitoring those for long-term side effects. Here's why I am confident that we -- that these vaccines are safe both in the short-term and long-term. Every -- of all of our vaccines that we've licensed and what we've been using in the United States for dozens of years, 99% of side effects occur within 6 weeks of vaccination. We don't ever see long-term impacts which makes sense from a biological perspective. The potential adverse effects we see 6 weeks out are because of the immune response your body is making in response to the vaccine. So we really don't see long-term side effects from vaccines. Now that does not mean that we will not continue to monitor this closely, we will, absolutely. But we know that the vaccine -- goes into your muscle and into the lymph nodes. Unlike some virus that come back in years, the vaccine is gone and just your immune response that is still there

Anyone who shouldn't get the vaccine? Immuno-compromised or people with cancer, anyone that shouldn't get the vaccine.

People that are truly contraindicated to get the vaccine are people with allergies or severe allergic reactions to the ingredients in the vaccine itself. If you had a major reaction that required epinephrine after getting a medicine indication, you should talk to your doctor about getting the vaccine. For people with the auto immune diseases or have cancer or recently recovered from cancer, that group of people, there were people in the clinical trial that had auto immune diseases and reported history of cancer there and they actually invoked people with HIV. They didn't rule any of the single numbers to say we absolutely did not see any -- we enrolled enough people to say it is 100% fine for people with for example with rheumatoid arthritis but did enroll patients across the board with all different kinds of medical conditions and saw no differences between the people who got vaccinated and the people who got the placebo in terms of flare-ups or adverse events related to the underlying K. I believe that these vaccines are safe with persons with immune-compromising illnesses and these vaccines do not -- they are not live virus which are the ones we worry about and they did not produce a strong immune-response but they are safe and will not cause harm per se. Let me answer the pregnant person question. It is so important because so many of the healthcare workers are of child-bearing age. The clinical trials did not enroll in women known to be pregnant but did enroll women who became pregnant between the doses or soon after. And at this time they do not have reports of adverse events in those women that appeared to be related to the vaccine. They were similar in the placebo and in the vaccinated group. We have -- we have a system that we're using to rapidly assess safety in pregnancy and already enrolled I believe over 1,500 pregnant women have been vaccinated and we're following them closely. But there is no biological that the immune response effects the placenta or fertility in any way and we know that COVID can actually impact a pregnancy. In many ways, the immune response you get from the vaccine is so much less than the illness you get from COVID that the benefit likely outweighs the risk. But it is a personal choice for women who are pregnant and I would look at it from the perspective of how much at risk I am forgetting the disease and -- and my concern about it, it is a personal choice and it is recommended if you are a front line healthcare worker and pregnant, that you consider getting vaccinated.

Amanda you made a point about getting the disease itself and talking to you both Gif and an MA, I am telling my 20-year-old children to get it -- many of their friends got COVID and there are long-term effects of COVID. So I just Dwayne I don't know if you both seen it or certainly I'll let you talk about it. If not, you survived COVID you're necessarily fine and no adverse risk benefits

There is a risk for having long-term consequences and it's definitely a - - lots and lots of people are getting well quickly from COVID but hard to figure GER who is having the longer term circumstances and who is getting really sick and why. Everybody should consider themselves to be at risk for severe impacts from COVID, even though we know it happens relatively infrequently.

I think that's a good point about balancing. There's PROS and consequence and risks and benefits to every decision. There's one if you take it but there is one if you don't. I think you have to weigh those and I think -- Amanda, as you are saying, even young people mostly recovered, this still has 1% mortality rate and other complications of stroke and heart disease and other things we've all read about. We have to balance those two with rare things that we're hearing about in the media, I think

Including long-term fatigue

Yes, exactly

You were going to ask a follow-up question, I apologize.

I want to come back to -- well, why don't we stick with the pregnancy issue for a second but let's come back to the allergies

Sure.

Related to pregnancy we're hearing a lot from people on social media the vaccine will cause infertility is that true?

There is no reason to believe that's true. What my perspective -- there was no hint of that in the clinical trials. The biologic, not a real sound biologic reason you would anticipate to cause infertility. The vaccine really just works in the arm in which you got it. It's not going throughout your body. the reason why I strongly believe that is a is a rumor that is not true if the vaccine called infertility and we would likely see that COVID causes infertility and we are not seeing a side effect from COVID and it would be hard to believe given the immune response is similar to the immune response of having the disease it's hard for me to imagine that if COVID doesn't cause infertility there's any rationale in the vaccine having any impact on infertility. I understand people's concerns. That is a major -- that is always of concern to women of child-bearing age. Once again, from my perspective, the benefit of getting vaccinated especially if I were wanting to have children would far outweigh the potential RIFBSZ of COVID in women of child-bearing age

Both women who got the vaccine and didn't get the vaccine got pregnant at the same rate and there is no decrease infertility from the data

There were about 20 to 30 women in each trial that got pregnant. Not huge numbers but no reason to believe that people that got vaccinated can't get pregnant afterwards

Let's come back to the Allergy issue. Go ahead, Lee, you want to finish on the pregnancy issue before we go on?

You made a quick comment, Amanda and you said one of the years is you said it works in the arm and they get a systemic response for clarifications

The vaccine is injected into the muscle and because the lipids help the vaccine products get from the muscle to the lymph nodes, one side effect is you might have swollen lymph nodes and that's where the immune response happens. It is mimicking a mild, mild, you know it's the same types of -- of proteins and stuff that are being used to generate the immune response can cause the systemic side effects like headache and being tired for a day or fever. It is still -- it is just the cells that have the vaccine that are sort of producing those -- that immune response are in your arm. Or the lymph node sea in the arm

And the rest of the body can respond especially after the next injection

Yes, you have renewed cells then if you get exposed you boost the immune response that protects you from getting sick

Along those lines, what about people -- we heard this if I had COVID why do I need the vaccine and if I do get it, will I have more side effects?

That's a great question, the public trials while they looked -- they were able to do blood testing to see who might have had COVID previously and there were no difference in side effects than people who had blood antibodies pre-existing before vaccine and didn't. So there's no evidence that getting another -- getting a dose after having COVID is -- will cause more adverse events. The reason to get the vaccine if you already had COVID is we don't know how long protection lasts after having COVID so we believe that it lasts -- we have a lot of evidence to show you're protected -- most people are protected for 90 days and many people may be protected for 180 days but this still getting vaccinated will help -- will help provide longer lasting protection and I think, you know, we don't know how long that will be with the vaccine but there's no down side of getting the vaccine in terms of more substantial adverse events and, you know, it's -- it is not in conceivably from the disease itself you will lose protection shortly.

I have been telling people, we get the influenza vaccine every year whether you had it or not and you get the tetanus booster and all the other boosters all the time and certainly consistent with all of that

Very consistent. With pertussis and whooping cough is another one it builds immune notice response with the vaccines.

Are you going to test positive with all the tests when you get the vaccine? You're getting the antigen, aren't the antigen tests out there aren't they going to test positive?

Remember the vaccine is in the arm and not getting into the nasal pharyngeal

There are antibody tests that may show up as positive. And we are looking how to vault different antibody tests in people who got vaccinated. The antigen test should not be positive in a person who got vaccinated especially if the test is done.

We've spoken to BD and others around the country they said there's no cross activity at all.

Let's go back to the Allergy question. I have food allergy and I have seasonal Allergy, pollen Allergy and people with allergic reactions, I shouldn't get the vaccine then?

People are worried about that.

We are definitely looking closely at cases of severe allergic reaction to the vaccine and trying to understand who, you know, which people are getting it. What we do know is that people who do not have a serious risk of anaphylaxis, if you never had that before, you are unlikely to have it after the vaccine. We recommend anyone about seasonal allergies and food allergies who has, you know, mild or moderate allergic reactions to go ahead and vaccine and even people with severe reactions to things components in the vaccine should get vaccines. We are putting precautions in place to make sure that if there is an anaphylactic reaction, we're hearing reports, it is still very rare and not happening frequently. We're backing to needing so many people so quickly and watching it very carefully. We are recommending everyone wait and be watched after vaccinated for 15 minutes and almost all of the anaphylactic reactions watched within 15 minutes and history of severe reaction should be watched for 30 minutes. We are watching people closely. All the facilities have epi Pence and know how to response to the severe reactions. It is something we are watching and the benefit of getting vaccinated is far out weighing the potential risk of anaphylaxis, next week we will have more information about the cases to share.

I know you covered this earlier, what's in the -- what's in the vaccines, you know, because one of the things is allergies, people have egg allergies and worry about the vaccine. Where can people find what's in the vaccine? It's in the FDA package?

Yeah, in a couple of places. The CDC website puts you to the FDA website. the ingredients are a couple of different type of sugars and Polyethylene glycol four lipids, one that is the same and two that are different the problem is that most people, you know, in a severe allergic reactions to the products are rare and only people would know if they have them if they had exposure to inject I believe medications because these are the ingredients in IV pencil Linn and things like that. And this was updated

on the website. Out of an abundance of caution, if you have any allergic reaction to the first dose, we are recommending that you not get that second dose second dose for now until we understand it better. We want to make sure people don't have a worse reaction after the sending dose. That new guidance came out for today but really for people who have hives or clear allergic symptoms even -- not to the extent of anaphylaxis but needing Benadryl and whatnot, we are recommending people defer vaccinations.

Over 2 million people in the United States and millions around the world have got it and these reactions are rare. We're talking single numbers around the world. This is not a common thing that's happening

Yeah, I mean -- the rate -- we are trying to calculate the exact rate it is less than 1 in 100,000. Far less than the rate of what we're seeing for COVID right now, for example.

Pretty funny, after we got our vaccine, a bunch of us sat in chairs for 15 minutes taking selfies with our vaccine and our -- we had little stickers and then we went and scheduled our next immunization --

Then the 15 minutes are up

You really know it -- yeah.

What about the new strain? Coming around; this vaccine going to work there or a new vaccine afterwards, what's going on?

We think the vaccine will work. It doesn't appear that the mutation in the strain is related to where the vaccine creates the immune-response to the protein. We are certainly going to be evaluating that. We are -- I think one of the really important things for me to reassure everyone about is we have so many people who are looking at all of the questions literally day and night right now and so, you know, we're already connected with the new strain and doing studies but from a -- we believe early evidence suggests that there's no impact with this new strain but there will be other new strains. We will have to keep monitoring and keep looking at duration and protection. Obviously we have multiple ways we're looking at vaccine safety. All of you, when you get vaccinated, should get information about enrolling in be safe which is a system where you will get text messages for about two weeks and we'll check in with you to make sure you haven't had reactions that were significant. And so, if you do have something you're concerned about, we'll give you a call and talk to you about that and help you report that adverse event so -- you're showing us your --

You're showing us your Be Safe on your I phone, Lee

I was trying to. My Be Safe daily text I was getting. It doesn't show up.

We already enrolled hundreds of thousands of people in this. One of the many ways we are following everyone as closely as we possibly can. We are check energy with the FAVRM sees administering the vaccine at the

long-term care facilities and regular conversations with all of them with how things are going. We're making sure they have all the tools and everything they need to -- to manage any adverse events that happen during vaccinations. So you know, we don't know everything. We are learning every day and we are watching everything really closely. But everything we do know so far is just incredibly reassuring that the vaccines are safe and effective. It is really remarkable.

Let me answer the one last question and I apologize not to be able to get through all the questions people put in but a lot of them are in the CDC website and I think it is helpful to answer that. The other really common question we hear a lot of from CNAs and staff out there, I understand it is safe and everything I want to wait and watch, should I wait and watch?

What about the thoughts about waiting a couple months more before getting the vaccine?

I wish I could tell people it is okay to wait and watch. We are in -- this virus is so transmissible we are in so much trouble as a country and especially all the people on the front lines that are working, that I would worry about waiting because the risk of you getting COVID and getting sick in the next month or two while waiting is so high. I personally and I have told all of my family members, anyone who asks, that I totally understand that and I would have told you two months ago or six weeks ago that, you know, I don't know. I'm not so sure but all of the data we've looked at is so positive about these vaccines that I don't see any reason to wait. And there's so much risk in not waiting, frankly. It's not just about protecting yourself. It's also, you know, we've got to stop -- we've got to stop the spread and you know, I do -- it is really important to remind everyone that I wish we could say that we could stop wearing our PPE and stop socially distancing. We will learn more about that and pull back on some of those things and find out that hopefully the vaccine also protects against transmission, but for now we know that the vaccines protect and you probably protect your family members and, you know, I just -- that's my personal recommendation as well as CDCs recommendation.

I would recommend the same. That you know, the risk of waiting six more weeks or eight weeks and you may get bumped further back even with the availability of the vaccine out there, getting the virus and the complications from it and then spreading to the residents and staff, I think it is really outweighs it. And the wait and watched. We already waited and watched we've seen millions of doses across the country and tens of thousands of people have gotten it. It's way safer than so many other things out there. I agree with you, ore the summer I was waiting to see what the data is and it has been remarkable stable data out there. And Lee, you went and got it. You had no concerns.

And interestingly my wife said, oh I'm going to wait and I said, no, you're not going to wait. My daughter is there. My wife as soon as she is allowed -- as soon as she gets in line, she will take it. So I really want to --

I was going to say I completely understand where people are coming from. We're really lucky we had the opportunity to look at all data ourselves and I think that's why, you know, it's so important for us to share this with all of you because, you know, it's -- it's hard to understand all the information out there.

Well -- doctor, I will tell you -- let me get back to Lee.

Lee, thank you for pulling us together and thank you for allowing me to bring forth the questions that we're hearing from the CNAs and nurses and housekeeping in the facility to be able to address the concerns. I appreciate that. So, Lee, I hand it back to you.

I want to thank both of you, because what really is important, Doctor and Amanda is the genuine SXNS transparency hopefully people will hear the questions answered. You actually at times said this is what I think and this is what the evidence is but you clearly believe, based upon really good data and we know about that data from -- phone calls from the CDC three to four times a week if not frequently, the CDC is so concerned with ensuring we do this right, that it is a safety issue. That it is tremendous. I want to thank you. We used you to get this to bring it Dr. Gifford. We will try and find someone from housekeeping and CNA and we will try to spend 30 minutes each of the next 4 weeks to 5 weeks and hopefully Dr. Cohen you may come back -- she may be frozen

No I'll come back

For sure, you will come back. And answer the questions so -- as you learn more, I assume you will bring us new data with those millions of people that you're getting data on by the week.

Yes, happily.

So, again, thank you, everyone and get us the information. Ashley, how do they get questions, we have a bunch of information in the chat. How do they get to us and where are we going to post this so that others can see it because I hope you actually share this with co-workers.

Yep, thank you, Lee -- I posted the link in the chat box. So shortly after likely tomorrow, the recording will be available on the CMS backup site so you have the link provided there. And we will provide a transcript along with the recording. So -- we do appreciate your patients but we will get that as soon as we can. Just a reminder this webinar today is part of a special series. So we certainly hope to bring forward more of your questions, answer more of your questions in subsequent sessions throughout the month of January. So please continue to add your questions when registration opens for those calls and also you can send them directly to the CMS box and I'll drop that in the chat box as well. But it is COVID-19@cMS.hhs.gov please feel free to send questions there. Lastly I sent a resource with you, as the doctor said, the CDC has a ton of resources available. One of is the long-term care tool kit you can find now. I shared that link in the chat box as well. That's it for me.

Okay. Thank you.

Thank you, everyone. .

The recording has stopped. [Event concluded]