Covid-19 Webinar for Critical Access Hospitals and Outpatient Facilities

Presented in collaboration with Nebraska ICAP, Nebraska DHHS HAI Team, Nebraska Medicine, and The University of Nebraska Medical Center

Moderated by Mounica Soma

Guidance and responses were provided based on information known on 9/8/2020 and may become out of date. Guidance is being updated rapidly, so users should look to CDC and jurisdictional guidance for updates.

Questions and Answer Session

Use the QA box in the webinar platform to type a question. Questions will be read aloud by the moderator

If your question is not answered during the webinar, please either e-mail it to NE ICAP or call during our office hours to speak with one of our IPs

A transcript of the discussion will be made available on the ICAP website

https://icap.nebraskamed.com/coronavirus/
https://icap.nebraskamed.com/covid-19-webinars/

Panelists today are:

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COVID-19 Vaccine Development

Presented by Dr. David Brett Major
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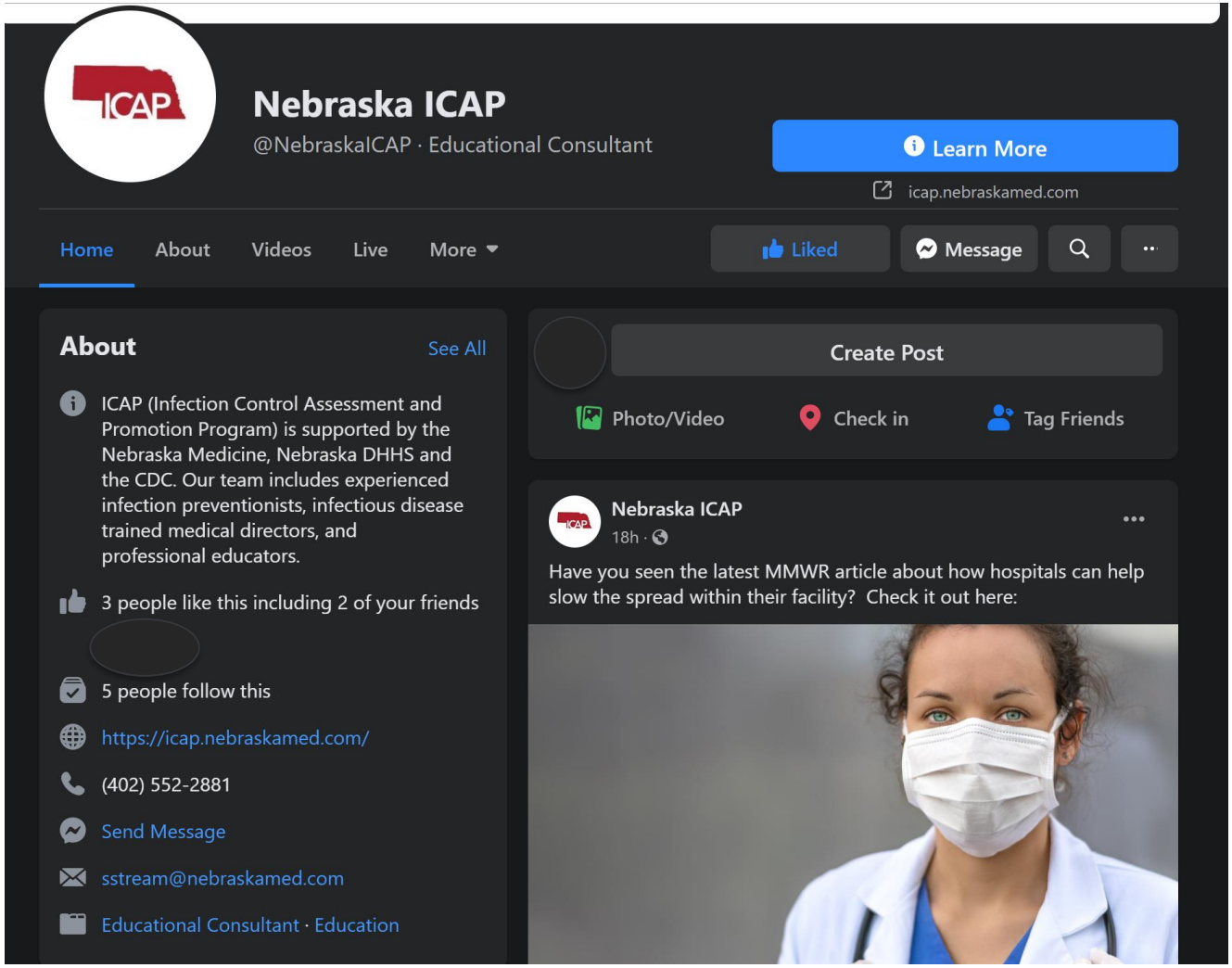
ICAP
Infection Control Assessment and Promotion Program

We are on Facebook!

Like and follow us for daily snippets and updates on critical information.



Upcoming IPC Training

- ICAP is collaborating with the CDC to launch a new healthcare provider infection control training series
- Training will be available to all healthcare providers that express an interest or need in basic and advanced infection control training
- Facebook will be used to get information out about training activities and events
- Share the Facebook page with your staff so they are able to stay up to date on upcoming infection control training
- Completion of this training will include a certificate of completion to show participation in the CDC infection control training curriculum

Infection Prevention and Control Office Hours

Monday – Friday
8 AM – 10 AM Central Time
2:00 PM -4:00 PM Central Time
Call 402-552-2881

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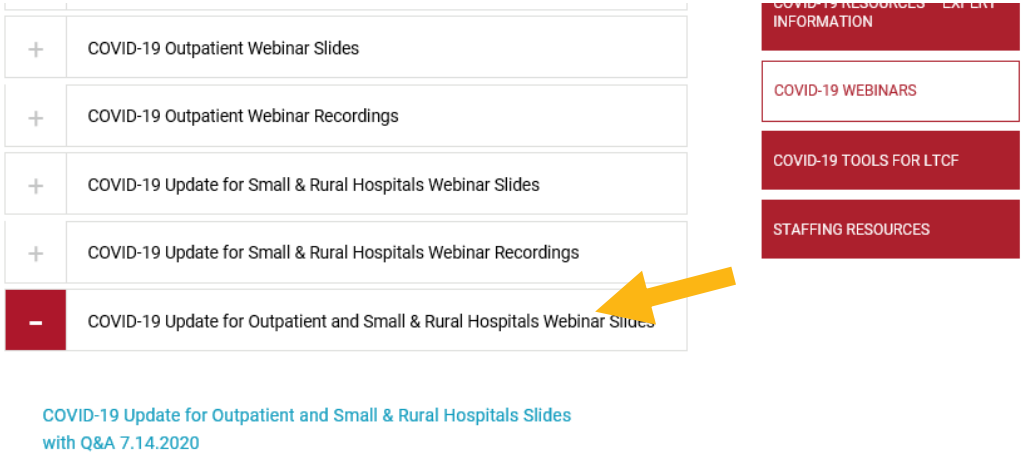
Sarah Stream, MPH, CDA

Moderated by Mounica Soma, MHA

Supported by Sue Beach, Marissa Chaney, and Margaret Deacy



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NETEC – NICS/Nebraska DHHS HAI-AR/Nebraska ICAP
Small and Critical Access Hospitals-Outpatient Region VII Webinar on COVID-19 9/8/2020

1. **Is there a tracker in the vaccine that allows a person to be tracked somehow? There has been some discussion about that.**

   Dr. Brett-Major asked for clarification, but said that if the question being asked is if there is something in what is being injected, that then allows someone to be tracked, he has not heard of anything like that. It sounds a little bit like science fiction right now, he said. The answer to his knowledge is no, but if there is more to that question, please send that in. *(No more information on this question was submitted during this call).*

2. **Dr. Ashraf thanked Dr. Brett-Major for his presentation and detailed information on COVID-19 vaccines. Dr. Ashraf noted that many of the attendees joining today's webinar are infection preventionists and others working in the healthcare setting, Those attendees are also thinking about logistics of the vaccine when it is ready. He asked if Dr. Brett-Major has any idea of how many of the vaccines that are closing the Phase 3 testing right now are going to be requiring multiple doses. For the healthcare setting, what would that mean when they are planning to get everyone vaccinated? Would that complicate logistics of tracking who has gotten the first dose and/or the second dose? Would all of these vaccines be in at least two doses or are there going to be vaccines that are single doses and being studied that way?**

   Dr. Brett-Major thanked Dr. Ashraf for the question and said that the answer right now is that we are not sure. Many of the Phase 3 vaccines trials include arms that receive a single dose and other arms that receive boosts. Dr. Brett-Major suspects that some vaccines trials that currently have single arms will subsequently add boosts, perhaps at a 3, 6 or 12 month. It is not clear yet what ultimately will be needed. It is more common to require the boost in the replication deficient or live attenuated products. We have not gotten a lot of information from the larger Phase 2 trials yet, so have much to learn still on what the immune response profile looks like.

   So while it is clearly being considered by the regulatory agency and the sponsors putting the vaccines forward, it is too early to say. He thinks Dr. Ashraf is correct that some of them will require multiple doses and some will not. It is actually is quite interesting how little we know about the consequences of annual influenza vaccination, he said. He has some colleagues who have been working on assessing prospectively what happens to the immune profile over time in high vaccination groups like the military. It is an open question whether we are going to end up talking about annual vaccination for coronaviruses for some time. All of that is really an unknown and really needs better data, coming from these larger trials to be able to tease that out.

3. **In Nebraska, has it been decided what groups will receive vaccine first? Will it be seniors healthcare workers, essential workers?**

   Dr. Brett-Major said this is a great question for Nebraska Public Health. Dr. Brett-Major thinks those decisions are still in process in every jurisdiction. It will be a matter of discovery for all of us as we actually see the Phase 3 performance data out of these vaccine trials. If we have clear signals of efficacy across age groups and across risk groups, then absolutely Dr. Brett-Major would think that most public health entities would prioritize vaccine the same way the National Academies have articulated in their recent recommendations, where the people with the highest likelihood of either acquiring it or suffering its consequences would be those who receive the first doses. But it could be that we have a situation where we have a vaccine that performs very well for people with lower risks but not really well for higher-risk groups. We are going to have to be guided by the data.

   Dr. Ashraf asked if it is correct clarification of Dr. Brett-Major's answer that when the vaccine comes out, either one or all of them that are in Phase 3 right now, we will have to see which age groups they have approval for and how they are performing in those age groups. If they have indications for elderly people for use and they have shown effectiveness in them, then it would make sense to prioritize those populations.

   Dr. Brett-Major agreed with that with the caveat that studies tend not to go after the highest risk folks because of the constraints he talked about earlier in the presentation. We could easily be in a situation where we have regulatory clearance to use certain vaccines in higher risk groups, but we do not really have a sense whether they will be as efficacious as we would like, nor to understand. He said there will be a role for operational public health research when the vaccines are fielded. The big hurdle for broad application of the vaccine will be safety. They are likely to be very safe, but we will need to see that data. We may have a couple of the vaccine trials that are more aggressive in their build that would have those high-risk groups represented where that data may be present. Dr. Brett-Major said that Dr. Ashraf had a good point in his clarification question.

   Kate Tyner added to the response that the ICAP team, as they are part of the state effort, have seen some forecasts and planning advice that the CDC has sent out to public health departments and all of the likely suspects are included in the prioritized population in the anticipated vaccine groups. She said this is fraught with lots of assumptions; we don't how they will play out. The CDC has advised public health departments to start planning for healthcare professionals, including long-term care facility staff, essential workers (but who are essential workers have not been defined) and national security population and the long-term care facility residents and staff. She does not think those are surprising groups, and that would not be controversial, but certainly the CDC is planning well in advance of these vaccines coming on the market. It takes a lot of planning to carry out these huge vaccination initiatives, so the CDC has released some forecasts and advice to work with for state health departments.

4. **Knowing that the vaccine will probably come under an EU approval initially; do you think this will push the willingness to receive the vaccine even lower?**

Dr. Brett-Major commented that the European Medicines Agency is a fine regulatory agency and they have a long tradition of coordinating with the Food and Drug Administration as well as the WHO and the other major actors involved in regulatory conversations. He thinks that before it is used in the United States, it will have to be gated by the Food and Drug Administration to be here, so he does not think so. In terms of international uptake, the larger international community is well-acquainted with products that have come through EMA rather than FDA review, and so he thinks that would be fine, too.

Kate Tyner added that she read the question a little differently. She was presuming that the audience member was assuming it would be approved under an emergency use operating issue. Based on what Dr. Brett-Major said early about a New York Times website, there are no short-cuts here, that it is a very straight-forward process and nobody is getting a short-cut because of COVID, correct?

Dr. Brett-Major said this a good question about the EUA. This was a danger of acronyms, because we may actually see European Union and European Medicine Agencies approval first, because some of these products are not U.S. based products. It is a double-pronged question. For emergency use authorization, Dr. Brett-Major said he was unsure how to answer this. For an emergency use is a recognition by the regulatory agency that the risks of not having the vaccine are high and the benefits of having the vaccine are high. With the information available, it is reasonable to proceed. It is not unrestricted licensure and every once in a while, in Phase 4, sometimes, for fully licensed medical products when assessed; when already on the market, we occasionally pull them. We occasionally recognize that there is an issue. With that said, the scrutiny on the vaccines is going to be very high. Some very good vaccine products in other emergencies like the rVSV-EBOV product, which ultimately had tens of thousands of participants' data behind it, before receiving approval, has proved very safe and very effective and was mostly utilized under EUA situations. Dr. Brett-Major thinks that regardless we will have to look closely at the data and the safety profiling. Dr. Brett-Major agrees that there is definitely a risk communication bit and a social mobilization bit to be said about the fact that it is under an emergency use authorization. It behooves all of us just to focus on the risks and benefits present, the data known, and; acknowledge it, but not worry too much about the name EUA.

5. **Are there any phase 3 trials for children? How will we determine if it is effective in this age group?**

Dr. Brett-Major said he is not aware of a Phase 3 vaccine study in the U. S. yet for children. Children certainly can be impacted directly by this virus and COVID-19 and also indirectly by the consequences of transmission in households to vulnerable individuals with whom they have close associations; so, it certainly matters to children. But the big signal of disease is in adults, and folks are always reticent to bring things forward (test vaccines) in children, if they are not the primary recipients of the vaccine because of study participant vulnerability issues that I think are quite valid. So I understand why we do not have it now. But he agrees that they are needed. Dr. Brett-Major thinks most people understand that. He thinks that what we will see is as soon as we get past checkpoints in the Phase 3 trials where safety data is apparent, some of the

sponsors will then proceed with pediatric Phase 2 and Phase 3 trials. He is actually not aware of a lot of Phase 1 work, frankly, in children either. The focus right now has really been with adults.

So how do we know when the data is starting to come together in a Phase 3 trial? Interventional trials have something called a data safety and monitoring board, and there are pre-designed looks when this group of people in it (they are meant to be people who are not really vested in the trial; they're not part of the primary study team) come in and they look at the data from the trial in a systematic way. They are asked particular questions about safety and about feasibility.

We experienced some mixed messaging about DSMB results actually with the Remdesivir trial. People thought that when the look at about 15% enrollment of the study said that Remdesivir was doing well, it was doing well. But it was doing well under a very particular question that was asked, which is, "Should the study continue, because there still might be something to be seen by continuing to enroll people?" The question was not, "Is this a fabulous drug?" So we will have to be a little careful about that when the DSMB results start coming out from these Phase 3 trials. If they are reported, these are designed looks that happened at certain phases of enrollment in the trial. The looks give us a sense about whether the trial is going to answer the question that we asked, and whether or not there any alarm signals about safety that we ought to be concerned about early. He thinks once we get past those points we will start to see the pediatric trials discussed a little bit more on earnestly.

6. **From what I have seen, the vaccine will require "very cold" storage. Most small rural hospitals, clinics, and pharmacies do not have this type of storage. Is there going to be any kind of help purchasing the very cold storage?**

   Dr. Brett-Major said this is a systems question that he would have to refer to others on the call or elsewhere that participate in the logistics and provision processes in Nebraska Public Health and other agencies. One thing to say about that, though, is that he has seen cold chain work in very rudimentary settings in resources limited and conflict. There is a lot of technology out there now to be able to move things and keep them cold. There are coolers that plug in the cars that keep things in minus 80^{o}C. He suspects, rather that more rural settings are probably not going to be stockpiling these vaccines, anyway. They will arrive and be delivered. He is not sure how much expansion of the cold chain capacity would actually be required under that model, but he will defer to others on the panel.

   Dr. Ashraf added that he is pretty sure those are all the discussions happening in the health departments all across the country right now about the distribution off the vaccines, which ever vaccine comes out. Dr. Ashraf doesn't think we have all the answers today about that, but he knows that the preparations and discussions are already starting. Dr. Ashraf said when ICAP learns more, he will bring that information back on a future webinar.

7. **CDC reports a potential vaccine that will be out in the next 60 days. Do we know if that vaccine will be on that passed out of the Phase 3 trials?**
   Dr. Brett-Major said he thinks the questioner is responding to something that came up earlier on the call. He thinks they are referring to CDC having reached out to its network of jurisdiction partners, saying, "Look, you all really need to be planning now for how your will actually

disseminate a vaccine." To Dr. Brett-Major's knowledge, that is really all CDC has said, and they are right. We are behind thinking about what to do when the vaccine is in our hands and how best to distribute it and use it. It is always more complicated than we think it is going to be. It needs run-throughs that are very simple to do but have to be done, so you can see all of the things that happen with the logistics. As we talked about with influenza vaccine experience, this is a larger roll out than what we do every year, and what we do every year is quite a lift. Dr. Brett-Major said he really thinks that is all CDC was saying, to start planning now because these things are not really all that complicated, but they do take effort.

Whether or not we are going to have a vaccine soon *(Dr. Brett-Major saw another question in the chat about whether or not something will be done by the end of the year)*. No, when he was asked in the beginning of the pandemic, what the earliest time he expected to see a vaccine available to folks, he said next summer, the summer of 2021. He still thinks that is the case. He could be surprised; we may have a limited-availability vaccine product available well before that. He would be shocked if it happens before the end of the year. It will have to be driven by the data. Personally, he said he will still be surprised if we are substantially rolling out a vaccine before next spring or summer.

Dr. Ashraf asked to clarify Dr. Brett-Major's position that he just want to clarify if he is considering that is, not only the vaccine has to pass through the Phase 3 trial, and then it has to get the approval. And after the approval, they have to make large scale doses that are going to be out and those are going to go to the communities and on all of that process, it can add on to the time frame too, correct? Dr. Brett-Major said that absolutely it can take a good six months to take a facility, once you know that you want to produce a particular kind of product, it before a facility is actually able to give it to you.

Links used in the program:

https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

https://clinicaltrials.gov/ct2/show/NCT04456595?term=vaccine&cond=covid-19&draw=2

https://www.cdc.gov/flu/fluvaxview/coverage-1819estimates.htm