COVID-19 Region 7 Webinar for Critical Access Hospitals and Outpatient Facilities

Presented by Nebraska Medicine and the University of Nebraska Medical Center in collaboration with the Centers for Disease Control (CDC) through NICS (National Infection Control Strengthening for Small and Rural Hospitals)

University of Nebraska Medical Center

Nebraska Medicine

Today's topic:

Guidance and responses were provided based on information known on 12/1/2020 and may become out of date. Guidance is being updated rapidly, so users should look to CDC and jurisdictional guidance for updates.

Margaret Deacy, Moderator

Panelists:

Dr. Nada Fadul, MD	nada.fadul@unmc.edu
Kate Tyner, RN, BSN, CIC	ltyner@nebraskamed.com
Jody Scebold, EdD, MSN, RN	jodscebold@nebraskamed.com
Karen Amsberry, MSN, RN	kamsberry@nebraskamed.com
Dr. Diana Florescu, MD	dflorescu@unmc.edu
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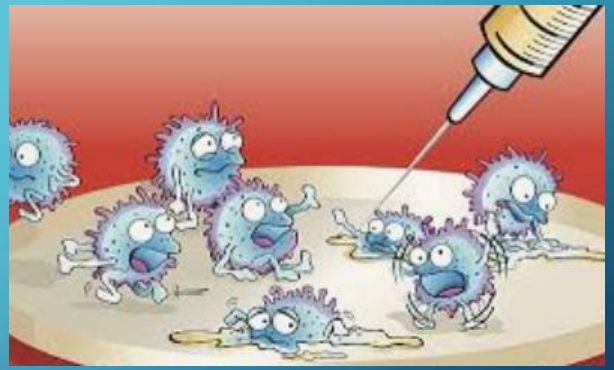
Colleen Malashock, PharmD, BCPS	cmalashock@nebraskamed.com

Acknowledgement:

Today's presentation is produced in cooperation with Nebraska ICAP (Infection Control Assessment and Promotion Program)

COVID VACCINES DEVELOPMENT



DIANA FLORESCU, MD

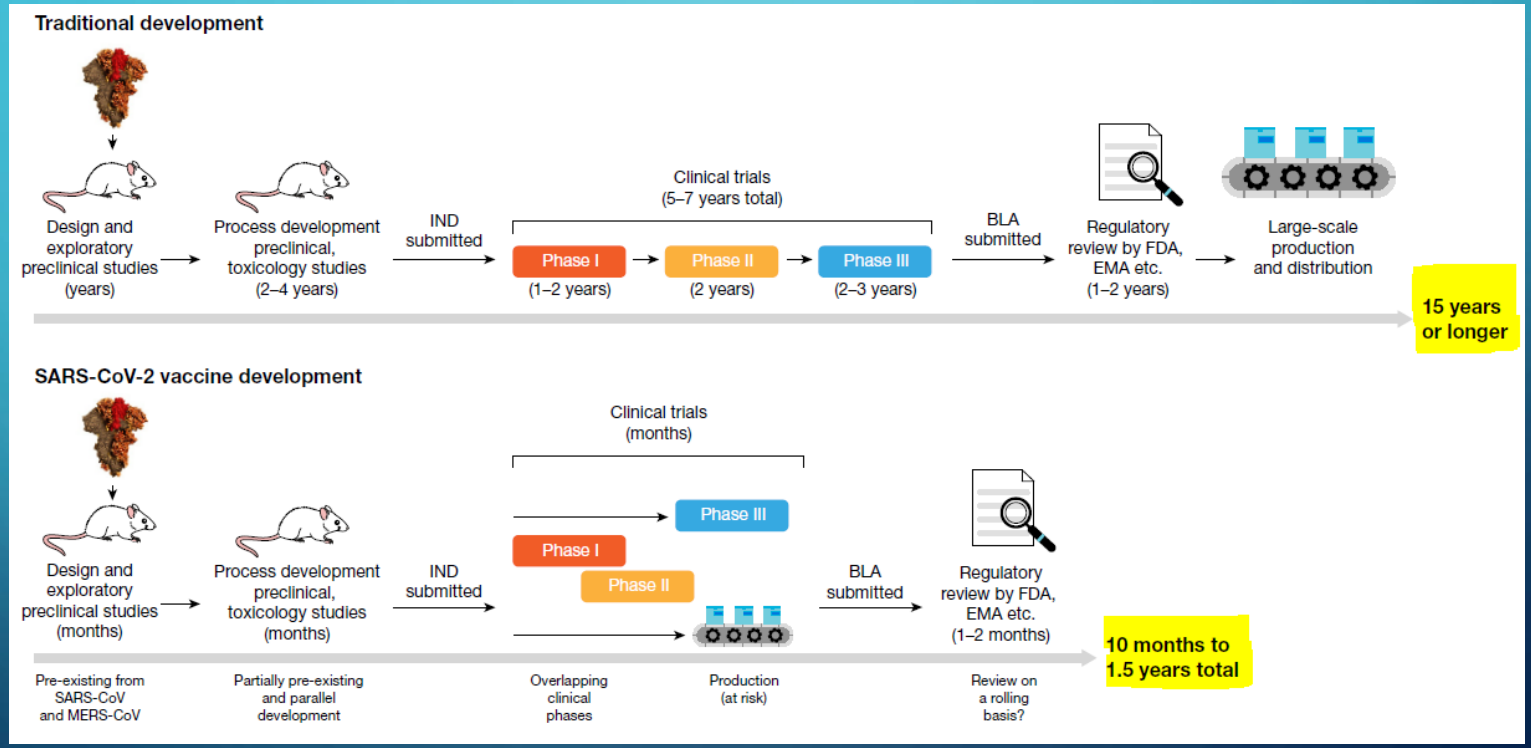
PROFESSOR

INFECTIOUS DISEASES DIVISION

VACCINE LANDSCAPE

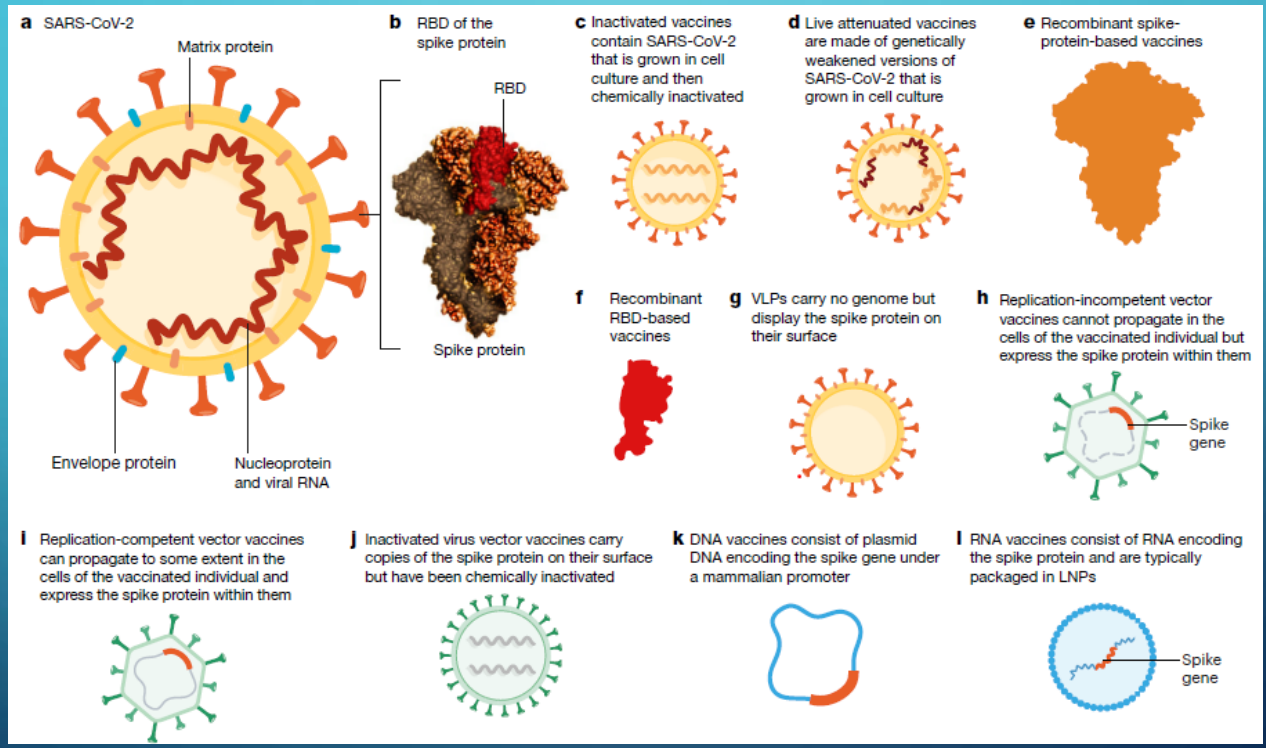
- December 31, 2019 - Outbreak of COVID-19
- January 10, 2020- Genetic sequencing of the virus
- January 21, 2020 – first US case
- March 1, 2020 – first phase 1 trial of a vaccine – at Kaiser Permanente in Seattle, funded by NIH
- March 2020 – WHO declares pandemic

VACCINE DEVELOPMENT



SARS-CoV-2 vaccines in development, F. Krammer. Nature, Oct220, 2020

PLATFORMS FOR VACCINE DEVELOPMENT



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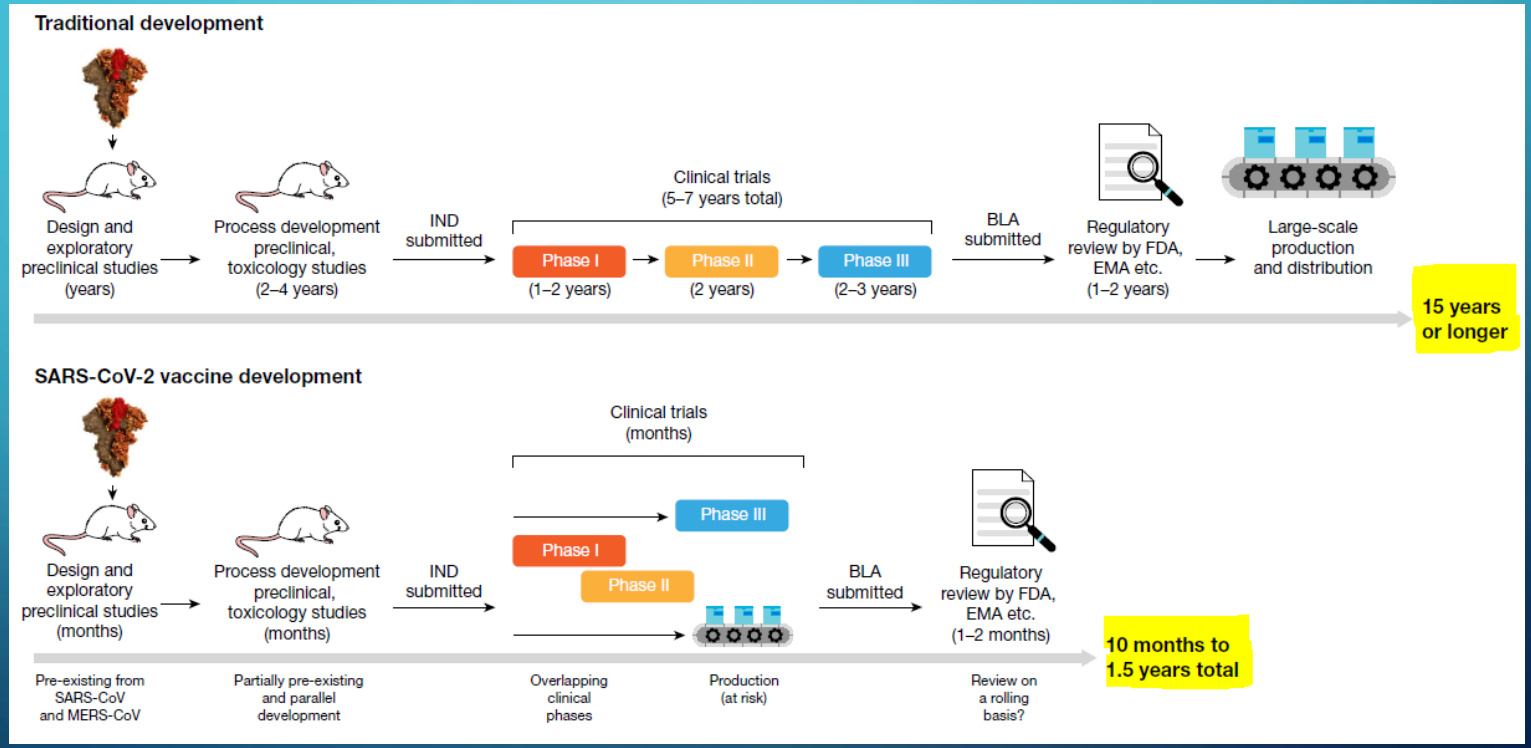
VACCINE DEVELOPMENT



SARS-CoV-2 vaccines in development, F. Krammer. Nature, Oct220, 2020

SARS-CoV-2 infection

Symptomatic infection (disease)

Asymptomatic infection

Severe disease

Non-severe disease

moderna

Moderna's COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study

November 16, 2020

-20C

First interim analysis included 95 participants with confirmed cases of COVID-19

Phase 3 study met statistical criteria with a vaccine efficacy of 94.5% (p <0.0001)

Moderna intends to submit for an Emergency Use Authorization (EUA) with U.S. FDA in the coming weeks and expects the EUA to be based on the final analysis of 151 cases and a median follow-up of more than 2 months

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 16, 2020-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced that the independent, NIH-appointed Data Safety Monitoring Board (DSMB) for the Phase 3 study of mRNA-1273, its vaccine candidate against COVID-19, has informed Moderna that the trial has met the statistical criteria pre-specified in the study protocol for efficacy, with a vaccine efficacy of 94.5%. This study, known as the COVE study, enrolled more than 30,000 participants in the U.S. and is being conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.

The primary endpoint of the Phase 3 COVE study is based on the analysis of COVID-19 cases confirmed and adjudicated starting two weeks following the second dose of vaccine. This first interim analysis was based on 95 cases, of which 90 cases of COVID-19 were observed in the placebo group versus 5 cases observed in the mRNA-1273 group, resulting in a point estimate of vaccine efficacy of 94.5% (p <0.0001).

A secondary endpoint analyzed severe cases of COVID-19 and included 11 severe cases (as defined in the study protocol) in this first interim analysis. All 11 cases occurred in the placebo group and none in the mRNA-1273 vaccinated group.

The 95 COVID-19 cases included 15 older adults (ages 65+) and 20 participants identifying as being from diverse communities (including 12 Hispanic or LatinX, 4 Black or African Americans, 3 Asian Americans and 1 multiracial).

The interim analysis included a concurrent review of the available Phase 3 COVE study safety data by the DSMB, which did not report any significant safety concerns. A review of solicited adverse events indicated that the vaccine was generally well tolerated. The majority of adverse events were mild or moderate in severity. Grade 3 (severe) events greater than or equal to 2% in frequency after the first dose included injection site pain (2.7%), and after the second dose included fatigue (9.7%), myalgia (8.9%), arthralgia (5.2%), headache (4.5%), pain (4.1%) and erythema/redness at the injection site (2.0%). These solicited adverse events were generally short-lived. These data are subject to change based on ongoing analysis of further Phase 3 COVE study data and final analysis.

PFIZER AND BIONTECH CONCLUDE PHASE 3 STUDY OF COVID-19 VACCINE CANDIDATE, MEETING ALL PRIMARY EFFICACY ENDPOINTS

Wednesday, November 18, 2020 - 06:59am

- *Primary efficacy analysis demonstrates BNT162b2 to be 95% effective against COVID-19 beginning 28 days after the first dose;170 confirmed cases of COVID-19 were evaluated, with 162 observed in the placebo group versus 8 in the vaccine group*
- *Efficacy was consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%*
- *Safety data milestone required by U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) has been achieved*
- *Data demonstrate vaccine was well tolerated across all populations with over 43,000 participants enrolled; no serious safety concerns observed; the only Grade 3 adverse event greater than 2% in frequency was fatigue at 3.8% and headache at 2.0%*

-70C

News Release

Regulatory News Service

AstraZeneca

This announcement contains inside information

23 November 2020 07:00 GMT

AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19

Two different dosing regimens demonstrated efficacy with one showing a better profile

No hospitalisations or severe cases of COVID-19 in participants treated with AZD1222

Positive high-level results from an interim analysis of clinical trials of AZD1222 in the UK and Brazil showed the vaccine was highly effective in preventing COVID-19, the primary endpoint, and no hospitalisations or severe cases of the disease were reported in participants receiving the vaccine. There were a total of 131 COVID-19 cases in the interim analysis.

One dosing regimen (n=2,741) showed vaccine efficacy of 90% when AZD1222 was given as a half dose, followed by a full dose at least one month apart, and another dosing regimen (n=8,895) showed 62% efficacy when given as two full doses at least one month apart. The combined analysis from both dosing regimens (n=11,636) resulted in an average efficacy of 70%. All results were statistically significant ($p<=0.0001$). More data will continue to accumulate and additional analysis will be conducted, refining the efficacy reading and establishing the duration of protection.

NOVAVAX

Creating Tomorrow's Vaccines Today

Novavax Announces COVID-19 Vaccine Clinical Development Progress

November 30, 2020

- *Pivotal Phase 3 trial in United Kingdom completes enrollment*
- *Phase 2b efficacy trial in South Africa completes enrollment*
- *U.S./Mexico Phase 3 trial expected to begin in the coming weeks*

GAITHERSBURG, Md., Nov. 30, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today provided an update on its COVID-19 vaccine program. NVX-CoV2373 is a stable, prefusion protein antigen derived from the genetic sequence of the SARS-CoV-2 coronavirus spike (S) protein and adjuvanted with Novavax' proprietary Matrix-M ™ .

"Novavax is in a leading position to significantly contribute to the need for safe and efficacious vaccines that will ultimately end the worldwide COVID-19 pandemic," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We continue to make meaningful progress as we work to test, manufacture and ultimately deliver NVX-CoV2373 with unprecedented speed, as well as put partnerships in place that would ensure widespread and equitable access worldwide."

Two of the three planned late-stage efficacy trials for NVX-CoV2373 sponsored by Novavax are fully enrolled, and more than 20,000 participants have been dosed to-date. The primary efficacy endpoints for these trials have been harmonized and reviewed by global regulatory agencies in order to facilitate regulatory approval and ensure that the results are generalizable across global populations. In alignment with Novavax' commitment to transparency, Phase 3 clinical trial protocols are posted to the company's website at Novavax.com/resources upon finalization.

GROUPS FOR INITIAL VACCINE ALLOCATION

- health care personnel- **21 mil**
- other essential workers – **87 mil**
- adults with high-risk medical conditions - **>100 mil**
- adults aged ≥65 years (including residents of long-term care facilities) – **53 mil**

MMWR weekly report 2020 Nov, 69(47) – The ACIP ethical principles for allocating initial supplies of COVID -19vaccine, US 2020

CHALLENGES

- Vaccine hesitancy
- 5-10 billion vaccine doses to be manufactured, distributed, stored and administered
- 1-2 vaccines to be administered
- Duration of immunity
- Storage at refrigerator conditions (2-8 °C) vs. frozen storage (≤ -20 °C).
- A number of countries pre-ordered ~4 billion vaccine doses and have options for another 5 billion
- COVAX, a global alliance seeking to ensure that low- and middle-income countries get adequate vaccine provision, secured vaccines for only around 250 million people

THANK YOU!


WE are CLOSING in on A COVID-19 VACCINE.
NOW, if WE COULD JUST FIND A VACCINE for POLITICS.

COVID-19 Vaccine Planning & Preparation

December 1, 2020

Presented by:
Colleen Malashock, PharmD, BCPS
Nicole Skinner, RN, MHA

Nebraska Medicine

Planning for COVID Vaccines

Planning for COVID Vaccines

Who?

What?

When?

Where?

How?

Planning for COVID Vaccines

- Key Resources
  - Internal
    - Human Resources, Infectious Disease & Prevention, Legal, Information Technology, Pharmacy, Employee Health, Supply Chain, Process Improvement, Ethics, Operations
  - External
    - CDC Playbook
    - State
    - Others:
      - SHEA
      - John Hopkins
      - NAS

Overall Goal

- Protect our most at risk of developing COVID and/or having a severe case of COVID if transmission occurs

  - Ensure
    - equitable allocation
    - minimal to no waste of product
    - timely allocation

Planning for COVID Vaccines

- Presumptions:
  - 1 or more vaccines are coming
  - We will have limited quantity
  - We will have tracking and reporting requirements
- Lessons Learned:
  - H1N1
  - Flu Vaccines
- Unknowns:
  - Timeline 1month-12months
  - Which vaccine & quantity
  - Duration of protection
  - Correlation of immunity
  - Long-term safety
  - Effectiveness and safety in population subgroups (children, pregnant women, immunocompromised persons)

Planning for COVID Vaccines

SIX potential COVID Vaccinations being evaluated by US with four vaccines in Phase3 trials or evaluation phase:

- Pfizer & BoNTech BNT162
  - *FDA to review EUA request 12/10/2020*
- Johnson & Johnson - JNJ-78436735
- Moderna/NIAID mRNA 1273
  - *FDA to review EUA request 12/18/2020*
- The university of Oxford/AstraZeneca AZD 1222

Vaccine Logistics/Storage

One or more vaccine will require ultra-cold storage/supply chain

- Estimated each freezer can hold 30,000 vials
- Thawing takes 3 hours in refrigerator or 30 minutes room temp
- Vials are multidose
- Vaccine must be administered within 6 hours of dilution
- Vials: Removed from the freezer can be kept in refrigerator up to 5 days ONLY
- Requires reliable temperature monitoring system

Vaccine Logistics/Storage

Administration & Documentation

- On-site & Off-site options
- Recruitment of Volunteers
- Support from Pharmacy
- Support from Supply Chain/Logistics
- Leveraging Existing Documentation Systems

- Initial vaccines will require two doses
  - Different vaccines have different 2nd dose schedules (21 or 28 days)
  - Same vaccine must be given for both doses

Prioritization in the US

CDC Proposed “Phase 1” Priority Groups

Healthcare Personnel (~21M people)	**Essential Workers (non-healthcare)** (~87M people)	**Adults with High-Risk Medical Conditions** (>100M people)	**Adults age ≥ 65 years** (~53M people)
Hospitals, Long-Term Care Facilities, Clinics, Home Healthcare, Pharmacies, EMS, Public Health	Food & Agriculture, Food Service, Transportation, Education, Energy, Police, Firefighters, Manufacturing, IT & Communication, Water & Waste water	Obesity, Diabetes, COPD, Heart conditions, Chronic kidney, Cancer, Smoking, Solid Organ Transplant, Sickle Cell disease	Community Dwelling, Skilled Nursing Facilities, Assisted Living Facilities, Residential Care Communities, HUD Senior Housing

ACIP November 2020 Presentation Slides Immunization Practices

Allocation Plan

Phase 1:

- Colleagues and students at **increased exposure risk**
  - Phase 1A: Those without consistent airborne PPE
  - Phase 1B: Those directly caring for COVID + patients

Phase 2:

- Colleagues and students at **potential exposure risk**
  - Providing care for Non-COVID patients
  - Other HCP such as EVS, Transportation, Access Staff

Phase 3:

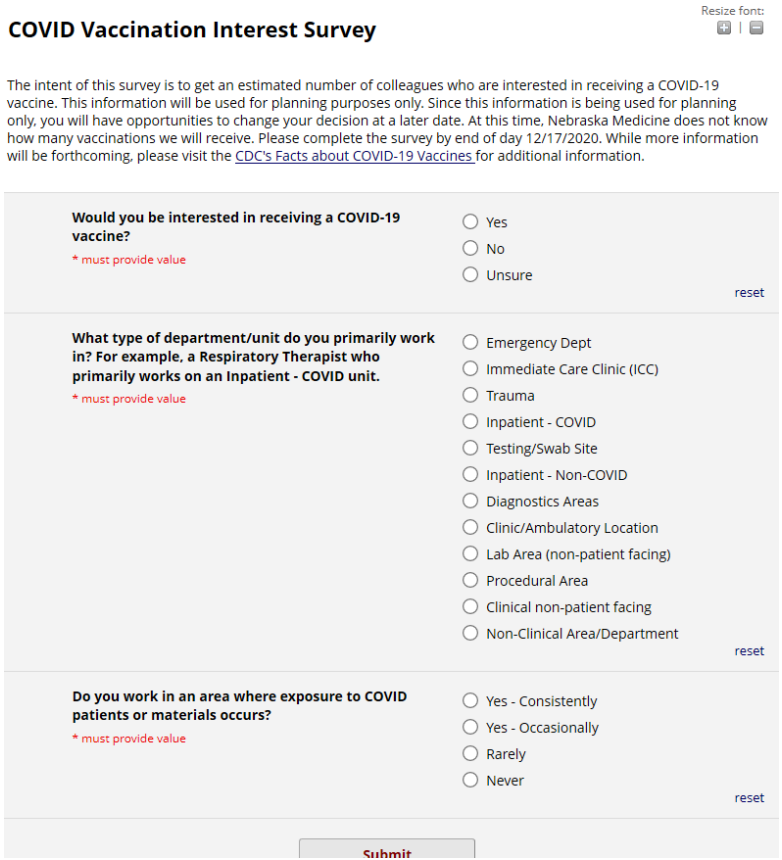
- Medically vulnerable

Planning for COVID Vaccines

Summary:

- Break deliverables into segments
- Leverage your experts
- Learn from past experiences
- Draft a logistics plan
- Draft an allocation plan
- Be Flexible

COVID Vaccination Interest Survey



COVID Vaccination Interest Survey

Resize font:

The intent of this survey is to get an estimated number of colleagues who are interested in receiving a COVID-19 vaccine. This information will be used for planning purposes only. Since this information is being used for planning only, you will have opportunities to change your decision at a later date. At this time, Nebraska Medicine does not know how many vaccinations we will receive. Please complete the survey by end of day 12/17/2020. While more information will be forthcoming, please visit the CDC's Facts about COVID-19 Vaccines for additional information.

Would you be interested in receiving a COVID-19 vaccine?

* must provide value

- ○ Yes
- ○ No
- ○ Unsure

reset

What type of department/unit do you primarily work in? For example, a Respiratory Therapist who primarily works on an Inpatient - COVID unit.

* must provide value

- ○ Emergency Dept
- ○ Immediate Care Clinic (ICC)
- ○ Trauma
- ○ Inpatient - COVID
- ○ Testing/Swab Site
- ○ Inpatient - Non-COVID
- ○ Diagnostics Areas
- ○ Clinic/Ambulatory Location
- ○ Lab Area (non-patient facing)
- ○ Procedural Area
- ○ Clinical non-patient facing
- ○ Non-Clinical Area/Department

reset

Do you work in an area where exposure to COVID patients or materials occurs?

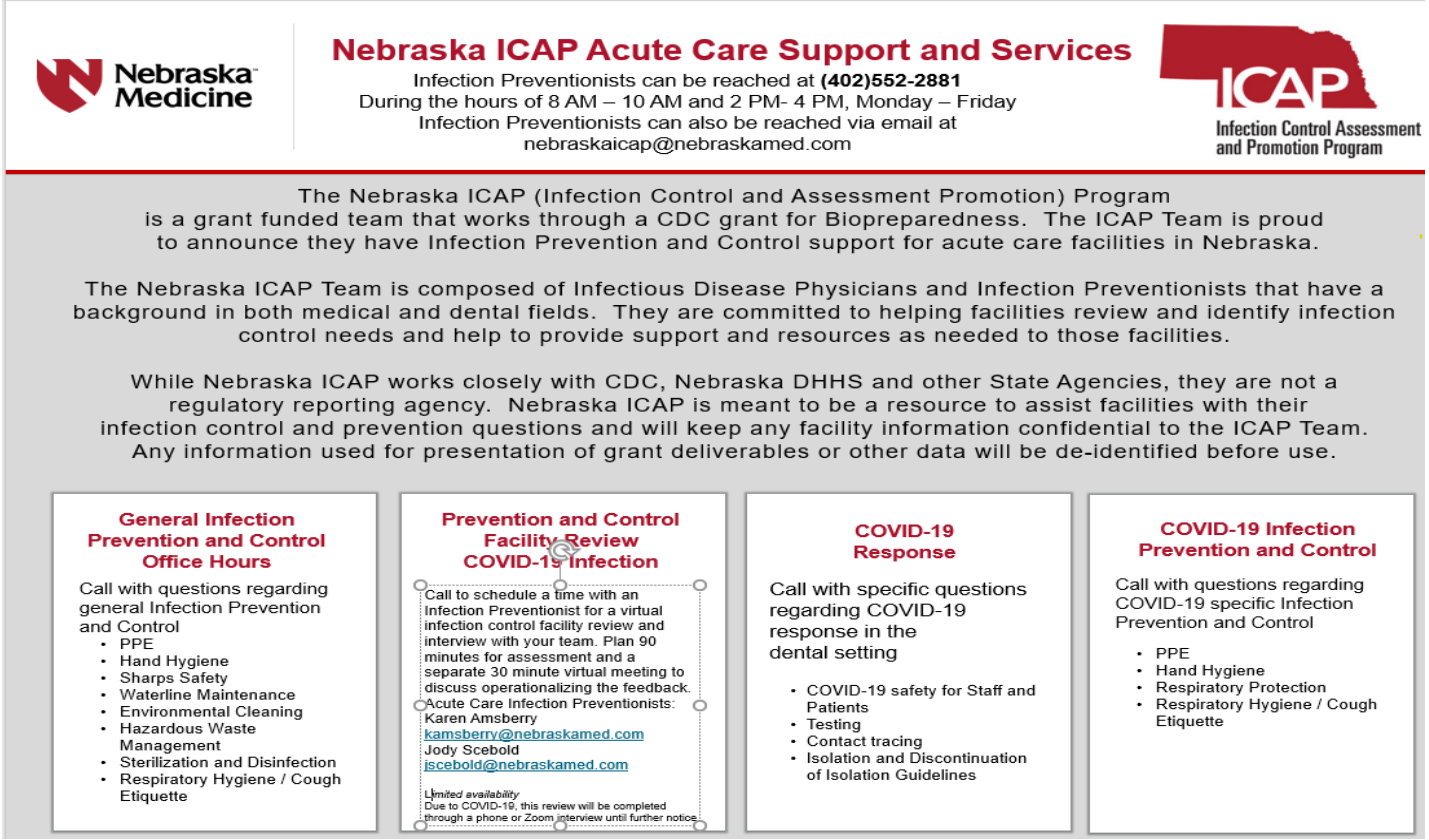
* must provide value

- ○ Yes - Consistently
- ○ Yes - Occasionally
- ○ Rarely
- ○ Never

reset

Submit

Nebraska ICAP Acute Care Services and Support



Nebraska ICAP Outpatient Care Services and Support

Nebraska Medicine

Nebraska ICAP Outpatient Support and Services

Infection Preventionists can be reached at **(402)552-2881**
During the hours of 8 AM – 10 AM and 2 PM- 4 PM, Monday – Friday
Infection Preventionists can also be reached via email at
nebraskaicap@nebraskamed.com

ICAP
Infection Control Assessment and Promotion Program

The Nebraska ICAP (Infection Control and Assessment Promotion) Program is a grant funded team that works through a CDC grant for Biopreparedness. The ICAP Team is proud to announce they have Infection Prevention and Control support for outpatient clinics and facilities in Nebraska.

The Nebraska ICAP Team is composed of Infectious Disease Physicians and Infection Preventionists that have a background in the outpatient setting. They are committed to helping facilities review and identify infection control needs and help to provide support and resources as needed to those facilities.

While Nebraska ICAP works closely with CDC, Nebraska DHHS and other State Agencies, they are not a regulatory reporting agency. Nebraska ICAP is meant to be a resource to assist facilities with their infection control and prevention questions and will keep any facility information confidential to the ICAP Team. Any information used for presentation of grant deliverables or other data will be de-identified before use.

General Infection Prevention and Control Office Hours

Call with questions regarding general Infection Prevention and Control

- PPE
- Hand Hygiene
- Sharps Safety
- Waterline Maintenance
- Environmental Cleaning
- Hazardous Waste Management
- Sterilization and Disinfection
- Respiratory Hygiene / Cough Etiquette

Prevention and Control Facility Review COVID-19 Infection

Call to schedule a time with an Infection Preventionist for a virtual infection control facility review and interview with your team. Plan 90 minutes for assessment and a separate 30 minute virtual meeting to discuss operationalizing the feedback.
Outpatient Infection Preventionists:
Lacey Pavlovsky
lpavlovsky@nebraskamed.com
Sarah Stream
stream@nebraskamed.com

Limited availability
Due to COVID-19, this review will be completed through a phone or Zoom interview until further notice.

COVID-19 Response

Call with specific questions regarding COVID-19 response in the dental setting

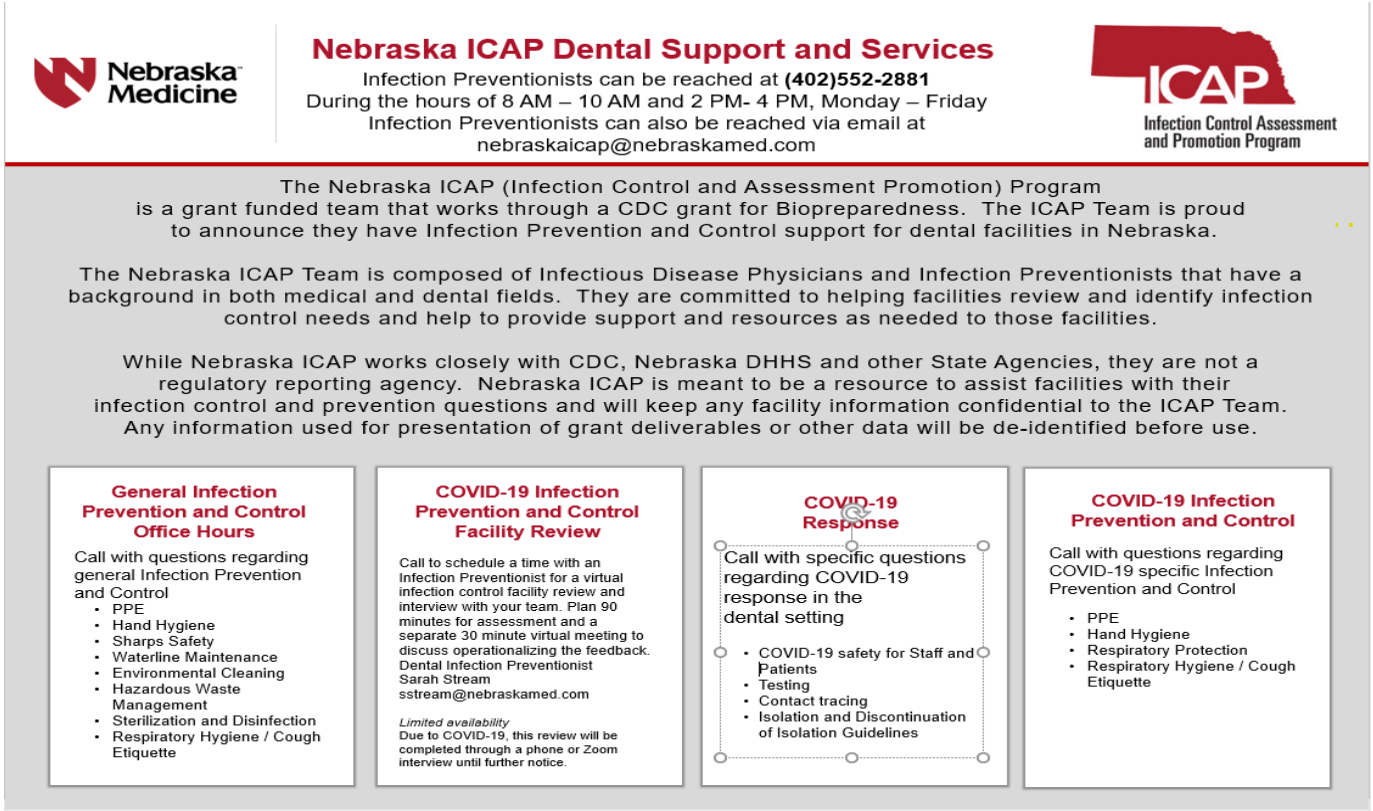
- COVID-19 safety for Staff and Patients
- Testing
- Contact tracing
- Isolation and Discontinuation of Isolation Guidelines

COVID-19 Infection Prevention and Control

Call with questions regarding COVID-19 specific Infection Prevention and Control

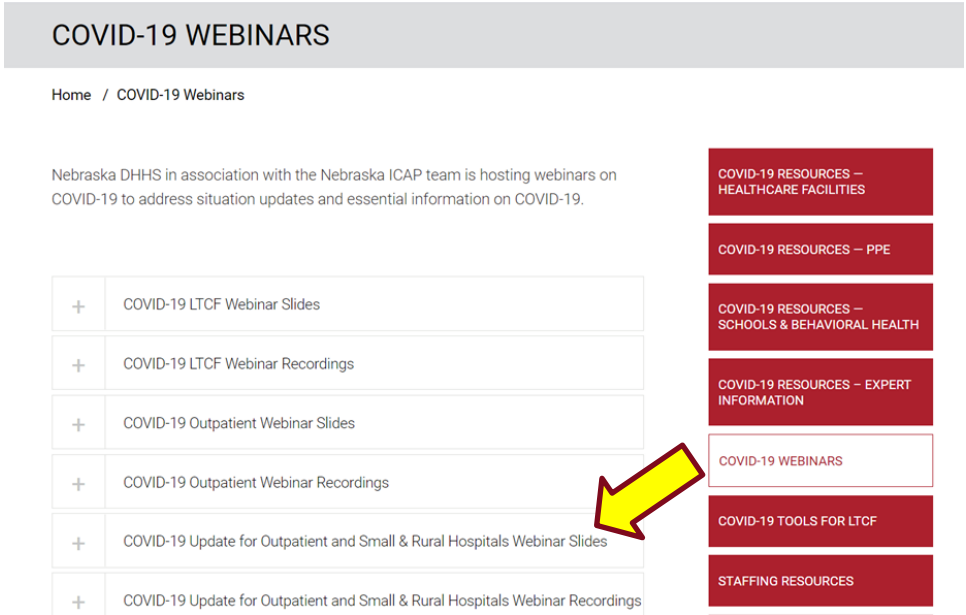
- PPE
- Hand Hygiene
- Respiratory Protection
- Respiratory Hygiene / Cough Etiquette

Nebraska ICAP Dental Support and Services



Question and Answer session

Use the QA box in the webinar platform to type a question. Questions will be read aloud by the moderator; in the order they are received. A transcript of the discussion will be made available on the ICAP website



Infection Prevention and Control Office Hours

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

University of Nebraska Medical Center

Nebraska Medicine

Note: A screenshot of the COVID Vaccination Interest Survey is at the bottom of this document

Responses were provided based on information known on 12/1/2020 and may become out of date. Guidance is being updated rapidly, so users should look to CDC and NE DHHS guidance for updates.

NETEC – NICS/Nebraska DHHS HAI-AR/Nebraska ICAP
Small and Critical Access Hospitals-Outpatient Region VII Webinar on COVID-19 12/1/2020

1. **How long after administration of the vaccine will a person be monitored for adverse reactions?**
   Dr. Florescu said that if the question is related to if it just monitoring right after administration, the person would just be given the vaccine and then go back to work. However, the time for reactions could occur are 24-48 hours. It has been reported that in reaction to vaccines, patients can get fevers, headaches, myalgia, and some rather mild COVID symptoms. This is where it is very important to educate the patient. Otherwise, they can get fevers off of the vaccine, they might end up in the emergency room or go see their physicians for this and increase the workloads.

2. **What are the expected side effects of the vaccine?**
   Headaches, fever, muscle pain, these are in the first 24 hours. Kate Tyner added lately that the side effects people are getting can be compared to the side effects people can get after the shingles vaccine. She asked if we can leverage existing educational tools comparing it to the effects of the shingles vaccine to help get education out on this? Dr. Florescu said that in talking to other P Is on this, it is not quite the same as what is experienced after getting the shingles vaccine. In the first 24 hours you can see side effects of high fever, headache and malaise. Her colleagues have told her that it is not like shingles.

3. **Will a person test positive with the PCR antigen test after receiving the vaccine?**
   Kate said she has heard this question, but that really, she would expect that after someone receives the vaccine they would not be part of antigen testing anymore. Dr. Florescu answered that if a patient develops symptoms, she thinks they need to be tested so that we don't have either mild infection or a patient who is going to develop more severe infection. It depends what type of the vaccine is being used. If it is live virus in the vaccine and the patient is tested, then probably the person is going to test positive. If it is just a protein-based vaccine, she does not think the PCR test would be positive. However, if anyone is going to be tested for antibodies, those will remain positive, so it won't necessarily help if the person has been administered a vaccine prior to an infection. Dr. Fadul agreed with Dr. Florescu, that the antibody test is not going to be helpful in that scenario. If somebody is symptomatic, they should be tested and you can follow the same algorithm you would follow otherwise. If the patient is truly symptomatic, then an antigen test would probably indicate infection but she would probably have a low threshold for following with a PCR in those type of patients. Kate added that for today's listeners, which include a number of people from long-term care population, and that once vaccination begins, we will see updated guidance from CMS about facility-wide testing. That would be on when to do that and when not to do that. That will be

fair to see updated guidance once we see vaccine, so Kate asked listeners to "stay tuned" for more federal guidance on that.

4. **Where do long-term care settings fall into the guidance on the HCP phases?**
   Dr. Florescu said that falls in to the "older 65 group". Kate added that for healthcare providers who are working in long-term care facilities, based on the timeline that Colleen and Nicole had shared, she would presume that healthcare providers are in that first group, regardless of setting. Nicole Skinner agreed, saying that the guidance definitely called out the employees of long-term care facilities in Phase 1. Kate added that she heard on the state-wide call today that it sounds like for the long-term care employees, the group that is meeting today from ASIP that is looking at things nationally who are looking at how that would be deployed, they are looking at whether that will be deployed with the dosage for residents, or would it be done separately, through a different apparatus. Some of those things are just not decided yet. But the right questions are being asked and she thinks good teams are looking at those things nationally.

5. **Where can people get a copy of the survey?**
   This will be posted with the slides today on the ICAP website. Nicole Skinner said that the survey is being kept very short and sweet. If she is going to be surveying 14,000 colleagues, she wants to be very specific about what she is going to do with that information. Is it meaningful? She advises that people will want to think about what they want the survey to answer. For UNMC-Nebraska Medicine, we will be looking at allocation and how many people from the trauma team, or the ED and clinics are going to be actually interested. Nicole said that Dr. Malashock brought up a great point, that we were going to put it in our health tracking system from the "get-go", but since we don't have the EUAs for this, she can't really have someone tell her yet "yes, they are interested" without providing that information. So that is why they decided to go the survey route. UNMC-Nebraska Medicine is also going to allow people to "opt in" or "opt out". So if someone opts out right now because they don't feel comfortable with the vaccine, in a month, if that person changes his/her mind, we will allow them to opt back in and get back on the list. Dr. Fadul asked for some clarification, asking Nicole if the healthcare provider phases that she outlined are specific to Nebraska Medicine. Dr. Fadul said she is under the impression that these Phases are specific and that each facility can make their own phases based on their own populations and procedures and what is done locally. Nicole said Dr. Fadul is correct, that the phases shown today are specific to UNMC-Nebraska Medicine**.**

6. **How will visitation be handled if residents of long-term care are or are not vaccinated?**
   Kate said this is good question, and that we will have to look to CMS. They are the federal rule-makers on this. We won't be expected to come up with this on our own. Kate is sure we will be following the guidance that is given to us at the time. She advises patiently waiting and saying that we will know more when that is available and that ICAP will be glad to bring that guidance to people as it becomes available, and to talk it through. She is sure Connie Vogt and Becky Wissell of Nebraska DHHS will be very available to talk about those things when they come out.

   Dr. Florescu added a comment about immuno-compromised patients, those on some type of immune suppression, including HIV patients, solid organ transplant patients, bone marrow transplant patients, those on TPN, were excluded from clinical trials. We don't know how this

special population will be approached because we don't know if they need a higher dose or more doses of the vaccine. Also, this is a population that will not be able to receive live virus vaccine. This is something to keep in mind.

6. **Currently, any staff that presents with the symptoms that are listed as side effects of the vaccine, we are doing a PCR test on for COVID-19 before allowing them to return to work. Are there guidelines for testing the staff who have had the vaccine to determine if they can return to work?**

   Kate responded that there are no guidelines yet. Remember that we are just beginning to see those emergency use authorizations and she would expect that as the vaccines become available, we would have to tailor those screening protocols to match what the manufacturers are telling us. Right now, Kate's "gut instinct" tells her that we would vaccinate people who are expected to be off work for a little while, so that: a) we are not relying on people who we expect to have a fever or expect to feel terrible to come in and work the next day. She thinks that would be a dangerous strategy. She thinks the timing would be important. As Nicole said, you don't want your front line staff to all have those symptoms at the same time. You will probably try to work in phases. We would expect that between the manufacturers, CMS and CDC, we would expect to have more guidance on this topic (for long-term care, especially).

   Dr. Fadul asked Dr. Florescu, since she is leading the vaccine trial here at Nebraska Medicine, with recruiting to start hopefully later this month, were there any recommendations in the trial if somebody develops side effects related to the vaccine, to go ahead and test them for COVID-19? Dr. Florescu responded that if somebody develops symptoms after receiving the vaccine that is within the first 24-48 hours we ask them to return to be re-evaluated and tested for COVID, we will be able to provide results of those tests within 24 hours of the test. Those with symptoms less severe are asked to remain home with fevers, to be swabbed at home to see how long they remain positive. There is a plan to see who tests positive for COVID after vaccination. She stressed that we still need more trials. We have two vaccines that would be approved, but that isn't enough to vaccinate everybody. Please encourage people to participate in trials, which are out there in all the states, because it is important to bring new vaccines to market. There is always a plan on what to do if a vaccine is approved, for people who are already in a trial. These are trials that will have to go on. Kate asked Dr. Florescu if she could recommend a resource for people to learn more about those ongoing trials, because ICAP would be glad to help share that information. It would be posted on the ICAP website. Dr. Florescu said that as soon as the trial here in Nebraska is going to open, information will be posted on the UNMC and Nebraska Medicine websites. She noted that several other institutions and companies are trying to bring different vaccines out. People will need to know more about which types of vaccines are being produced and if they are comfortable with that. Some patients, she said, would not be comfortable with a live vaccine, but they would be okay with a protein-based vaccine.

Q & A typed replies during the webinar

1. Will these slide be sent out to attendees?

Slides and a recording of this presentation will be available on the ICAP website following the presentation: https://icap.nebraskamed.com/covid-19-webinars/

2. What are the vaccine recommendations for those who have had confirmed covid?

There is no clear guidance at this time. We hope to have more information once we have granular data from the clinical trials. In clinical trial baseline serologies were collected.

3. If an employee has been positive for covid-19; should they take the vaccine?

We will know more once clinical trial data will be available. We don't know yet how long the immunity lasts. My guess is that yes, we will vaccinate those who previously had COVID-19.

4. We are a SNF and I have employee threatening to quit working if they are going to be mandated to take this vaccine. Do you know if it is going to be mandated for long term care employees?

I don't know if it will be mandate. Different institutions have different policies. For example some institutions mandate flu vaccines, other do not.

5. What is the expected immune response at this time (i.e. duration of effectiveness) for the vaccine candidates likely to be available?

At this time we have 28 day data. Mid-December we will have 2 month data for effectiveness. Patients who are enrolled in the trial will be followed for 2 years to understand when we need to revaccinate, if we have to revaccinate.

6. Why cannot the January production be utilized for the 2nd dosage vs holding onto half the Dec production for the second shot; or are they different and come as a set? This would double the amount of people that could receive the vaccine.

The January production will be used for 2nd vaccination. If we have 35 mil vaccine administered in December, the second dose will be in January. So from 50 mil doses in January, 35 mil will be revaccination and 15 million will be new people.

7. Any information regarding what if second dose missed? Or are their guidelines as to what days within the 21/28 day dose are acceptable still?

The data is not available yet to know if only one dose is enough for protective immunity. Each company designed their own regiment and we need to follow the schedule for each vaccine as specified by the company. We don't know what happens if doses from different vaccines are mixed.

8. Being a Pfizer vaccine study participant who also subsequently became PCR positive, (albeit asymptomatic), I've been told by the study PI that I shouldn't receive the vaccine for at least 3 months at this point until more is known. Comments?

There is no clear recommendation at this time. FDA is trying to decide how the study participants would be vaccinated and when. Usually immunity from infection lasts 3 month, probably this is why you were recommended to wait 3 months.

9. Did I hear that you need to be tested for COVID-19 before getting vaccinated?

No, we will not be completing serology testing prior to vaccination.

10. Can you please share the survey document you will be sending out asking about interest in the vaccine?

I will send a screen shot to the ICAP team. We kept it very simple. We are trying to understand interest and then risk for exposure as we have many team members that historically are in administrative locations and now working in clinical areas.

11. Did she say that you can or cannot return to work right after the vaccine has been administered?

CAN return to work

12. What may be some of the contraindications for receiving the COVID vaccine?

It will depend on the type of vaccine. Live vaccines cannot be administered to immunocompromised patients. Allergy to certain component is another contraindication. We don't know how well the vaccine works in immunocompromised patients, these patients were excluded from studies.

13. Is HR involved in the planning, just in case employees are not able to work for a couple of days after receiving the vaccine due to side effects?

Yes HR, Legal and Employee Health. We are working on what our plan would be if someone should develop a post-vaccine fever. More to come.

14. Can you type the side effects that you verbally shared?

Headache, fever, myalgia.

15. Can you type how long people need to be monitored for side effects that you shared verbally?

Symptoms are self-limited - usually resolve 24-48h.

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COVID Vaccination Interest Survey

The intent of this survey is to get an estimated number of colleagues who are interested in receiving a COVID-19 vaccine. This information will be used for planning purposes only. Since this information is being used for planning only, you will have opportunities to change your decision at a later date. At this time, Nebraska Medicine does not know how many vaccinations we will receive. Please complete the survey by end of day 12/17/2020. While more information will be forthcoming, please visit the CDC's Facts about COVID-19 Vaccines for additional information.

Would you be interested in receiving a COVID-19 vaccine?

* must provide value

- ◯ Yes
- ◯ No
- ◯ Unsure

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What type of department/unit do you primarily work in? For example, a Respiratory Therapist who primarily works on an Inpatient - COVID unit.

* must provide value

- ◯ Emergency Dept
- ◯ Immediate Care Clinic (ICC)
- ◯ Trauma
- ◯ Inpatient - COVID
- ◯ Testing/Swab Site
- ◯ Inpatient - Non-COVID
- ◯ Diagnostics Areas
- ◯ Clinic/Ambulatory Location
- ◯ Lab Area (non-patient facing)
- ◯ Procedural Area
- ◯ Clinical non-patient facing
- ◯ Non-Clinical Area/Department

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Do you work in an area where exposure to COVID patients or materials occurs?

* must provide value

- ◯ Yes - Consistently
- ◯ Yes - Occasionally
- ◯ Rarely
- ◯ Never

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