IDAHO DEPARTMENT OF HEALTH & WELFARE
DIVISION OF PUBLIC HEALTH

IDAHO COVID-19 VACCINE ADVISORY COMMITTEE (CVAC)

TALKING POINTS FOR CVAC MEMBERS TO EFFECTIVELY COMMUNICATE ABOUT COVID-19 VACCINES

December 9, 2020

Idaho Governor Brad Little convened the Idaho COVID-19 Vaccine Advisory Committee (CVAC) to:

- advise him on and assist state and local entities with the prioritization of vaccines when they are in limited supply;
- guide planning efforts; and
- broadly communicate messaging to ensure equitable access to COVID-19 vaccines across the state.

Committee members represent stakeholders across Idaho, including Idaho's Tribal nations, at risk populations, healthcare systems and providers, and immunization organizations. They lend their broad expertise to best enhance Idaho's vaccine distribution plan in adherence with federal guidance and requirements, ensuring Idahoans have equitable access to COVID-19 vaccination by considering population across Idaho's vast geography, burden of disease on particular groups of people, and the need to return our economy to normalcy as soon as possible, to name only a few considerations. Advancing health and wellbeing for all Idahoans through the COVID-19 pandemic requires broad, multi-sector engagement to support policy, environmental, programmatic and infrastructure changes that lead to COVID-19 vaccines that are **accessible, affordable and equitable.**

Meetings of the CVAC are open to the public, and meeting details are available at https://healthandwelfare.idaho.gov/about-dhw/public-meetings. Specific documents regarding the committee are:

- Statement of Purpose
- Executive Summary
- Interim Vaccine Plan
- Idaho COVID-19 Vaccine Advisory Committee Members

Communicating effectively about vaccines to the public has never been more crucial. CVAC members may find this document useful when communicating with their constituents, community members, or others who have questions about immunization efforts in Idaho.

Information on the arrival and distribution of the vaccine is constantly changing. This document will be updated regularly as the Idaho Department of Health and Welfare (DHW) receives new information.[1]

COMMON QUESTIONS AND TALKING POINTS

#1 WILL THE VACCINE BE SAFE?

The Centers for Disease Control and Prevention (CDC) is working with partners across the country to make sure people have the information they need to be confident in deciding to get vaccinated. Key priorities for CDC are:

- Regularly sharing clear and accurate information with people to make sure they understand the risks and benefits of getting vaccinated and can make informed decisions.
- Helping healthcare personnel feel confident in their decision to get a COVID-19 vaccine and helping healthcare providers answer their patients' questions about the vaccine.
- Engaging communities and individuals in an equitable and inclusive way to ensure that people have opportunities to ask questions and get clear, accurate information about the COVID-19 vaccine.

COVID-19 vaccines must pass multiple safety tests. The Food and Drug Administration (FDA) and panels of experts independently and thoroughly review vaccine clinical trial safety and efficacy data before making a decision about the use of vaccines for the public. Although the COVID-19 vaccines are on track to become the fastest-developed vaccine in history, rigorous safety standards and strict regulations are in place.

- Potential COVID-19 vaccines go through multiple rigorous stages of testing in people to ensure they are both safe and effective.
- Phase I tests for initial human safety and dosage in a small number of people.
- Phase II tests hundreds of people with different characteristics (such as age and health status) to obtain more safety information and evaluate the immune response.
- Phase III tests thousands of people to further determine safety and show whether the vaccine is effective. Once all clinical study phases are completed, the FDA reviews

[1] This guide was modeled after the Association of State and Territorial Health Official's (ASTHO) Risk Communication Field Guide Questions and Key Messages and Alaska Department of Health and Social Services' COVID-19 Vaccine Message Maps. Both of those documents can be found here: https://www.astho.org/COVID-19/Q-and-A/ and http://dhss.alaska.gov/dph/Epi/id/SiteAssets/Pages/HumanCoV/COVID-19VaccineMessageMaps.pdf.

the trial results and conducts other necessary safety inspections before allowing use of the vaccines.

The FDA's Vaccines and Related Biological Products Advisory Committee and CDC's Advisory Committee on Immunization Practices, both independent committees of experts, will review the data and make recommendations prior to vaccine use in the U.S.
Once a vaccine is in use, government agencies (e.g., FDA and CDC), manufacturers, health care institutions, non-governmental organizations, and other public and private sector organizations continue to monitor and evaluate vaccine safety.
The CDC uses multiple systems to monitor vaccine safety, which includes:

- The Vaccine Adverse Event Reporting System (VAERS): an early warning system, comanaged by CDC and FDA, to monitor for potential vaccine safety problems where anyone can report possible vaccine side effects to VAERS.
- The Vaccine Safety Datalink (VSD): a collaboration between CDC and nine health care organizations that conducts vaccine safety monitoring and research.
- The Clinical Immunization Safety Assessment (CISA) Project: a partnership between CDC and several medical research centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.

An additional safety monitoring system available for COVID-19 vaccines is called v-safe. This is a voluntary, smart phone, texting based system. Vaccine providers are asked to inform vaccine recipients about this system and how to sign up. Volunteers who sign up will help with real-time monitoring of potential adverse reactions by responding to text messages about symptoms or side effects they may experience after vaccination.

- More information about v-safe and other vaccine safety monitoring is available at https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-09/COVID-03-Shimabukuro.pdf.

An Emergency Use Authorization is the authority of the U.S Food and Drug (FDA) Commissioner to permit an emergency use of certain medical products under Project BioShield Act 2004. The FDA can authorize an EUA for unapproved (i.e. unlicensed) medical products for an unapproved use of a previously approved product (e.g., a new indication).

The following statutory criteria must be met for an EUA of a vaccine or other medical product:

- Serious or life-threatening disease/conditions caused by a chemical, biological, radiological, or nuclear (CBRN) agent or emerging infectious disease referred to in the Health and Human Services Secretary's EUA declaration
- Reasonable belief the product may be effective
- Known/potential benefits outweigh known/potential risks
- No adequate, approved, available alternative
- Allows for rapid and widespread deployment for millions of individuals during a public health emergency
- Case-by-case waivers may be permitted

The FDA evaluates safety data from clinical trials in making a decision about an EUA. For the COVID-19 vaccines, from 30,000 to >40,000 people have been included in clinical trials for each vaccine. While these studies are large, rare adverse events may not be identified in trials. Thus, after a vaccine is authorized or approved for use, additional vaccine safety monitoring continues. Many vaccine safety monitoring systems are utilized to watch for adverse events (possible side effects) of all vaccines (not just COVID-19 vaccines) on a continual basis after licensure. This continued monitoring can detect rare adverse events that were not observed during clinical trials. If an unexpected adverse event is identified, experts quickly study it further to assess whether it is a true safety concern. Experts then decide whether changes are needed in U.S. vaccine recommendations. This monitoring is critical to help ensure that the benefits continue to outweigh the risks for people who receive vaccines.

FDA's June 2020 guidance document included important recommendations for ongoing safety evaluation after any COVID-19 vaccine is made available in the United States. CDC is scaling up existing safety monitoring systems and has added new ones as well.

The following systems and information sources add additional layers of safety monitoring, giving CDC and FDA even more ability to evaluate COVID-19 vaccines' safety in real time and make sure COVID-19 vaccines are as safe as possible[2]:

- **CDC: V-SAFE** pdf icon[644 KB, 21 pages] — A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. The system also will provide telephone follow up to anyone who reports medically significant (important) adverse events.
- **CDC: National Healthcare Safety Network (NHSN)** — An acute care and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS
- **FDA: Other large insurer/payer databases** — A system of administrative and claims-based data for surveillance and research

#2 AM I REQUIRED TO GET THE VACCINE?

There is no mandate in Idaho for people to get the COVID-19 vaccine. Further, EUA patient fact sheets specifically state that persons have a choice in receiving the vaccine or not. The Governor and health officials will continue to share information about the safety and efficacy of the vaccine as more information becomes available. While there is no vaccine mandate, vaccination with COVID-19 vaccines approved by FDA for EUA and recommended by CDC will also be recommended in Idaho. Education regarding COVID-19 vaccines' safety and effectiveness, as information becomes available, will be critical to help Idahoans make informed decisions regarding

[2] Additional information about these systems can be found at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-09/COVID-03-Shimabukuro.pdf.

vaccination. Widespread adoption of safe and effective vaccines will be critical to the health and economic and societal recovery of Idaho and allow children to return to in-person learning, and businesses to return to normal operations.

#3 INFORMATION ABOUT THE FIRST TWO COVID-19 VACCINES LIKELY AVAILABLE IN THE UNITED STATES: PFIZER/BIONTECH AND MODERNA[3]

	Moderna	Pfizer/BioNTech
Vaccine type	mRNA	mRNA
Dosing	Two doses Days 0 + 28	Two doses Days 0 + 21
Ages studied	18+ yrs.	12-85 yrs. (n=100 12-15 yo)
Number of persons in clinical trials	30,000	44,000
Prelim. Vaccine Efficacy Estimates	94% against lab confirmed COVID-19 after 2 doses	94-95% against lab-confirmed COVID-19 after 2 doses among persons with and without prior COVID-19 infection
Safety	Most side effects were reported as mild to moderate. Grade 3 (reactions that prevented normal activity): fatigue 9.7%, muscle ache 8.9%, joint pain 5.2%, headache 4.5%, pain 4.1%	Most AE mild to moderate and lasted 1-2 days. Grade 3 reactions that were 2% or greater: fatigue 3.8%; headache 2.0%. More reports of grade 3 reactions after dose 2 than dose 1.
Shipping and storage temperature	-20C	-60/-80 C (dry ice)
Days at 2-8C	30 days MAXIMUM	5 days (120 hours) MAXIMUM
Time at room temp	<12 hours MAXIMUM	< 2 hours MAXIMUM
Preservative	None	None
Doses per shipment	100 minimum	975 minimum
Doses per vial	10	5 doses of 0.3mL per dose after reconstitution
Reconstitute	NO	1.8 mL of sterile normal saline (0.9% NaCl) - one 2 mL vial of sterile saline shipped per vaccine vial
Use time	6 hours after vial punctured	6 hours after reconstitution
Route of administration	Intramuscular	Intramuscular

[3] EUA's, once available, should be consulted for updates. Pfizer/BioNTech data review by FDA available at https://www.fda.gov/media/144245/download.

#4 WHEN WILL VACCINES ABOVE ARRIVE IN IDAHO?

We anticipate that limited supplies of both vaccines may be available in Idaho before the end of 2020. This is contingent on review and approval timelines of both the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Once vaccines are approved by FDA and CDC, vaccine doses will be allocated to each state about every week based on each state's population.

The federal government will oversee a centralized system to order, distribute, and track COVID-19 vaccines. All vaccines will be ordered through CDC. Vaccine providers will receive vaccines from CDC's centralized distributor or directly from a vaccine manufacturer.

Many COVID-19 vaccine candidates are in development, and clinical trials are being conducted at the same time with large-scale manufacturing. With first doses expected before the end of 2020, planning and preparing for a COVID-19 vaccination program is very important.

Vaccine development and availability information will continue to change, and planning will progress as information about authorized or approved vaccines becomes available. A safe and effective COVID-19 vaccine is a critical component of the U.S. strategy to reduce COVID-19-related illnesses, hospitalizations, and deaths and to the health, economic and societal recovery of Idaho. The goal of the U.S. government is to have enough COVID-19 vaccine doses for all people in the United States who choose to be vaccinated, but that will take time.

#5 WHO WILL GET THE VACCINE FIRST AND HOW WILL IT BE DISTRIBUTED IN IDAHO?

When the FDA first authorizes or approves the use of one or more COVID-19 vaccines in the United States, there will be a limited supply. This means that not everyone will be able to be vaccinated right away. It is understandable how concerning this would be for people, especially for those who are at increased risk for serious illness from this virus and for their loved ones.

That is why, early in the response, the federal government began investing in select vaccine manufacturers to help them increase their ability to quickly make and distribute COVID-19 vaccines. This will allow the United States to start with as much vaccine as possible and continually increase the supply in the weeks and months to follow. The goal is for everyone to be able to get a COVID-19 vaccine as soon as possible. Several thousand vaccination providers will receive vaccine for their patients, including doctors' offices, retail pharmacies, hospitals, and federally qualified health centers. Easy access to COVID-19 vaccines is equally critical. CDC is working with public health, healthcare providers, and other partners to make sure people can easily get a COVID-19 vaccine and that cost is not a barrier.

CDC is working with state, tribal, territorial, and local jurisdictions on the development of COVID-19 vaccination plans for their respective areas. CDC has also worked with private

partners, such as pharmacy chains and networks of independent pharmacies, and other federal agencies (e.g., the Indian Health Service) on plans to more widely distribute COVID-19 vaccines. For example, CDC is working with pharmacies to offer on-site COVID-19 vaccination services for residents in long-term care settings, including skilled nursing facilities, nursing homes, and assisted living facilities where most individuals are over 65 years of age.

In Idaho, CVAC makes recommendations to the Governor. At every CVAC meeting, members are presented with current information about vaccines under consideration for by the FDA, or preliminary data from vaccines still in clinical trials, priority population groups identified by the CDC's Advisory Group on Immunization Practices, and other topics. At each meeting, members are asked to consider and decide on critical vaccine planning information. One of the items on which CVAC provides input is on the sub-prioritization of populations to be vaccinated. This assists the state to provide limited vaccines in a manner that allows for those most critically at risk of exposure to get the vaccine.
https://coronavirus.idaho.gov/idaho-covid-19-vaccine-advisory-committee/

#6 WHEN WILL THERE BE ENOUGH VACCINE FOR EVERYONE?

A small amount of COVID-19 vaccine should be available in Idaho by mid-December, pending FDA authorization and CDC approval. The first doses of vaccine will be distributed in a way to ensure groups of people prioritized for vaccination will receive it.
Since the first vaccine approved will be a limited supply, it means that not everyone will be able to be vaccinated right away. But supplies will increase over time, and all adults should be able to get vaccinated later in 2021. However, a COVID-19 vaccine is not expected to be available for young children until more studies are completed.

#7 WHAT CAN I DO NOW TO HELP PROTECT MYSELF FROM GETTING COVID-19?

Idahoans can slow the spread of SARS-CoV-2, the virus that causes COVID-19, by choosing the following behaviors:

- Wear face coverings
- Keep at least six feet between you and others
- Stay home if you are sick
- Wash your hands often
- Cover coughs and sneezes
- Disinfect surfaces and objects regularly
- Limit contact with persons outside of your household when not wearing a mask

Even after the first Idahoans get vaccinated against SARS-CoV2, we will still need to engage in these behaviors until a large percentage of the population is vaccinated.