Vaccine Advisory Committee (VAC) Meeting

December 15th, 2020

Chair/Facilitator:

Dr. Kathy Lofy	Washington State Department of Health

Members Attending:	**Representing:**
Dr. Amy Person	Washington State Association of Local Public Health Officers
Amy Poel	Urban Indian Health Institute
Anita Alkire	Childcare
Annie Hetzel	Office of Superintendent of Public Instruction
Dr. Beth Harvey	Consultant
Dr. Christopher Chen	Washington State Healthcare Authority
Dr. Daniel Moorman	Washington Chapter of the American Academy of Pediatrics
Dr. Ed Marcuse	Consultant
Dr. Jeff Duchin	Public Health – Seattle/King County
Dr. Jenny Arnold	Washington State Pharmacy Association
Dr. John Dunn	Managed Care
Dr. Linda Eckert	Consultant
Dr. Mary Alison Koehnke	Naturopathic Medicine
Dr. Mary Anderson	Internal Medicine Organization
Dr. Rachel Wood	Washington State Association of Local Public Health Officers
Sarah Murray	Washington State Association of Local Public Health Officers
Dr. Stephen Pearson	Washington Chapter of the American Academy of Pediatrics
Dr. Susan Westerlund	Washington Academy of Family Physicians
Tam Lutz	Northwest Tribal Epidemiology Center
Tara Tumulty	National Association of Pediatric Nurse Practitioners
Tristen Lamb	Washington State Association of Local Public Health Officers
Dr. Usha Rao	Washington Academy of Family Physicians
Wendy Stevens	American Indian Health Commission

Washington State Department of Health Staff:

SheAnne Allen	Mary Huynh	Dr. Kathy Bay
Dr. Scott Lindquist	Michele Roberts	
Hannah Febach		

Topic	Presented Information
Welcome and Introductions **Dr. Kathy Lofy**	Dr. Lofy gave a warm welcome to the newest Vaccine Advisory Committee (VAC), Dr. Chen, for participating. Public and returning members were welcomed. An overview of meeting expectations and processes were introduced. As Dr. Lofy transitions out the state officer role, Dr. Scott Lindquist will assist Michelle Roberts to run meetings until a new officer is appointed.
Approval of Previous Meeting Minutes **Dr. Kathy Lofy**	Meeting minutes from the November 2020 VAC meeting were approved.

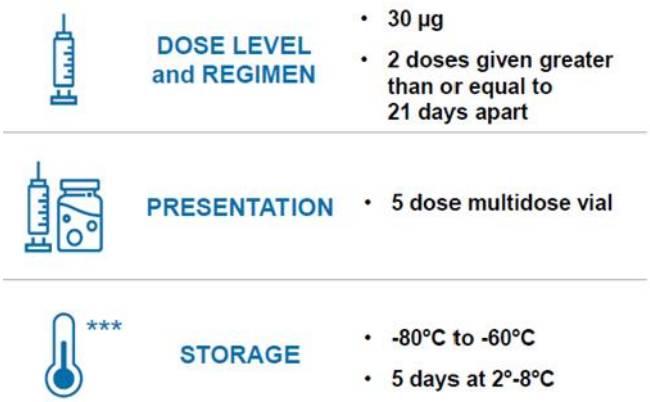
COVID-19 Vaccine Response Update
 	
SheAnne Allen
	• The Moderna vaccine is still waiting to receive an emergency use authorization (EUA). However, if the vaccine is proven safe and effective, it will receive an EUA within the week.
	• The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet on December 17th regarding the Moderna vaccine. After VRBPAC comes to a verdict, it will go to the FDA for approval and, once approved, the CDC's Advisory Committee on Immunization Practices (ACIP) will meet in the following days to make vaccination scheduling, dosage, and appropriate use recommendations.
	• As of this meeting, the Department's allocation projections are approximately 62,400 doses for the Pfizer vaccine allocated in week 1. As January approaches, the vaccine response team will continue tracking and receiving weekly allocations.
	• Previous vaccine allocation decisions in place:
	  ○ ACIP shared allocation guidance for Phase 1A, which includes high risk workers in healthcare settings and first responders.
	  ○ ACIP also approved the inclusion of long-term care facilities (LTCF) in phase 1A.
	  ○ The timeline continues as ACIP is scheduled to meet on Dec. 20th about Phase 1b-c equitable allocation of COVID vaccines.
	• The guiding principles of Washington's Phase 1A guidance suggest to comprehensively look at what groups are being targeted, such as workers in health care settings. Workers would include workers in a site where direct patient care is being delivered and other workers with an elevated risk.
	
	Question: Many people have questions about provider enrollment, can you put that on the website?
	
	Answer: The enrollment link can be found here, along with a FAQ to help with the enrollment process. You can find information about COVID enrollment and more information on Phase 1A prioritization.

Pfizer-BioNTech COVID 19 Vaccine Safety and Efficacy **Kathy Bay**	<u>Introduction to mRNA Vaccines</u> Kathy Bay introduced how the Pfizer COVID vaccine functions within the body and its pathology. The spike glycoprotein (S) are what facilitates the virus to attach to cells and eventually replicate. Pfizer vaccine is a messenger RNA (mRNA) vaccination. To expand this, an mRNA vaccine works by taking advantage of the process our cells use to make proteins to trigger an appropriate immune response. After triggering an immune response, the vaccine prompts your body to form antibodies that can block the spike protein from binding to cells. By blocking this cell adhesion interaction, therefore, it prevents a SARS-COV2 infection. To emphasize some common misconceptions about mRNA vaccines, the following facts were stated:

1. COVID-mRNA vaccines were rigorously tested for safety before being authorized for use in the United States.
2. mRNA technology is new but not unknown. It has been studied for over a decade.
3. The mRNA vaccines do not contain live virus.
4. mRNA from vaccines never enter the nucleus of the cell and does not affect or interact with a person's DNA.

Vaccination Dosage, Regimen, Presentation, and Storage

The Pfizer vaccine dosage and regiment, presentation, and storage are as follows:



ACIP Review of Evidence

ACIP reviewed the clinical trial data for the Pfizer COVID vaccine. The trials demonstrated very high efficacy of the 2-dose series against symptomatic, laboratory confirmed COVID-19 cases. For hospitalization due to COVID-19, vaccine effectiveness against hospitalization was 100% within a confidence interval of 9.9%. Within both the vaccine and the control group, the number of adverse reactions were approximately the same (0.5% vaccination vs. 0.6% placebo). Any severe reactions were more common in the vaccinated groups than the control (8.8% vaccination vs. 2.1% placebo).

Pfizer COVID-19 mRNA Vaccine Side Effects

The Pfizer vaccine's most common side effects of the vaccine are similar to those of some routine vaccines, such as a sore arm, fatigue, headache, and muscle pain. HOWEVER, among all vaccine recipients asked to complete diaries of their symptoms during the 7 days after vaccination, 77.4% reported at least one systemic reaction.

- The frequency of systemic adverse events was higher in the younger than the older age group (82.8% vs 70.6%). Within each age group, the frequency and severity of systemic adverse events was higher after dose 2 than dose 1.
- Vomiting and diarrhea were exceptions, and similar between vaccine and placebo groups and regardless of dose. For both age groups, fatigue, headache and new or worsened muscle pain were most common.
- The majority of systemic events were mild or moderate in severity, after both doses and in both age groups. Fever was more common after the second dose and in the younger group (15.8%) compared to the older group (10.9%).
- Overall, the median onset of systemic adverse events in the vaccine group in general was 1 to 2 days after either dose and lasted a median duration of 1 day. Four grade 4 fevers (>40.0°C) were

reported, two in the vaccine group and two in the placebo group.

- No other systemic grade 4 reactions were reported. Data on systemic reactions were not solicited from persons aged 16-17 years. However, their reactions to vaccination are expected to be similar to those of young adults who were included.
- Frequency of these effects in people younger than 55 include:

1. Approximately 80 percent of people reported pain at injection site
2. Approximately 50 percent of the people reported fatigue and headache
3. Less than 30 percent muscle pain.

Most side effects occur within two days of getting the vaccine and last about a day.
Side effects are more common among people 55 years or older than among those younger than 55.
Side effects are more common after the second dose than the first dose.

<u>Pfizer COVID-19 mRNA Vaccine Administration</u>
The Pfizer vaccine is administered intramuscularly in a 2-dose series three weeks apart. The administration of the 2nd dose within 17- 21 days of the first dose is considered valid. If it exceeds 21 days since the 1st dose, the 2nd dose should be administered at the earliest opportunity, but no doses should need to be repeated. However, the maximum efficacy would be to complete the 2nd vaccine in the series within the 17-21 day period. Both doses are necessary for protection due to the efficacy of a single dose has not been clinically evaluated.

<u>Pfizer COVID-19 mRNA Vaccine Reactogencity</u>
It is expected, before vaccinating a patient, for providers to counsel vaccine recipients about expected local and systemic symptoms (local meaning soreness of injection site and systemic meaning symptoms such as headache and nausea). Unless a person develops a contraindication to the vaccine, the patient should be encouraged to complete the series. If a patient develops post-vaccination symptoms, oftentimes the series should be continued to optimize protection against COVID-19. Most post-vaccination symptoms can be treated by antipyretic or analgesic medications.

<u>Public Health Recommendations for Vaccinated Individuals</u>
The public health recommendations for vaccinated persons are as follows:

- Protection from the vaccine is not immediate; vaccine is a 2-dose series and will take 1 to 2 weeks following the second dose to be considered fully vaccinated.
- No vaccine is 100% effective.
- Given the currently limited information on how well the vaccine works in the general population, how much it may reduce disease, transmission or severity: and how long protection lasts, vaccinated persons should continue to follow all current safety and social distancing guidelines.

<u>Contraindications and Precautions for the Pfizer COVID-19 Vaccine</u>
The package insert of the Pfizer-BioNTech vaccine classifies a severe allergic reaction as a contraindication to the vaccine. The appropriate medical treatment used to manage an allergic reaction must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine. Due to the reports of anaphylactic reactions outside of clinical trials, persons who have had a severe reaction to any vaccine or injectable therapy should not receive the Pfizer vaccine at this time. Vaccine providers should observe patients after vaccination for the occurrence of immediate adverse reactions:

	• Persons with a history of anaphylaxis: 30 minutes • All other persons: 15 minutes • Tools are available to monitor safety of patients – active, passive, individual case consults. Monitoring systems and populations systems such VAERS, V-safe, and others can be effective in managing large patient loads. <u>Provider Resources</u> Provider resources are still being developed by the Department and the CDC. Kathy shared links to what is currently available and will continue to update the Department of Health website with new information. <u>Discussion</u> Question: Once vaccinated, could you still be asymptomatic/ is there any evidence for that? Answer: The clinical trials did not look at this. They looked at vaccine effectiveness against symptomatic SARS-COV2 infection. After getting vaccinated, individuals should continue social distancing and other safety measures. Question: Regarding the vaccine trials, what product/ingredient was used for the placebo? Answer: Saline injection
Vaccine Science Advisory Workgroup **Kathy Bay**	Kathy gave a quick update on the work being done by the Vaccine Science Advisory Workgroup. She will continue to report on their work to VAC. Her update included: • Timely input on provider education and tools needed • Development of science document for reference related to vaccine platforms • Review/discussion of post vaccination reported events • Continued development of vaccine tools

Public Comments:

Public comments were received during the meeting. The comments expressed concerns around the fast-paced development of the vaccine, informed consent, and vaccinations among vulnerable populations. As a reminder, the Committee does not respond directly to comments. Members receive comments and take them into consideration during discussions.