COVID-19 VACCINE TASK FORCE

Prepared for Alaska Senate Health and Social Services Committee 12.07.2020 Presentation

Agenda

- Opening Remarks (Dr. Anne Zink)
- Overview of Vaccine Candidates (Dr. Anne Zink)
- Alaska COVID-19 Vaccine Task Force (Tessa Walker Linderman)
- ANTHC Partnership, Tribal Health Partner Work (Dr. Bob Onders)
- Phases & Allocations (Tessa Walker Linderman)
- Ordering, Receiving, and Distribution (Matt Bobo)
- Community Planning (Tessa Walker Linderman)
- Vaccine Confidence (Dr. Anne Zink)
- Questions from the Committee

VACCINE TASK FORCE

Vaccine Candidates

Vaccine Candidates - Pfizer

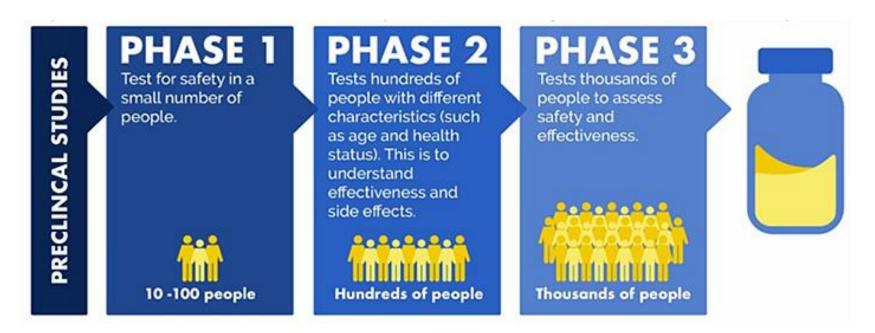
- Submitted for Emergency Use Authorization
- Final analysis 170 confirmed cases of COVID-19 were evaluated, with 162 observed in the placebo group versus 8 in the vaccine group; 95% effective against COVID-19 7 days post dose 2
- Efficacy was consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%
- 43,000 participants; no serious safety concerns
- -70 degrees Celsius storage
- *Information from manufacturer press release

Vaccine Candidates - Moderna

- Submitted for Emergency Use Authorization
- Interim analysis 95 cases included 90 cases in placebo group and 5 cases in vaccine group; vaccine efficacy against COVID-19 was 94.1% 2 weeks post dose 2; vaccine efficacy against severe COVID-19 was 100%
- 30,000 participants; no serious safety concerns
- On December 2, Moderna announced that it would soon begin testing its coronavirus vaccine in children ages 12 through 17
- -20 Celsius storage
- *Information from manufacturer press release

Vaccine Candidates

No steps are skipped during the clinical trial process for COVID-19 vaccine. Manufacturing and trials can happen at the same time, which speeds up the timeline for a vaccine to reach Alaska should it be authorized by the FDA.



Vaccine Candidates

For more info on clinical trials, including other vaccines see presentation by Dr. Jay Butler, Deputy Director for CDC Infectious Disease, provided to Alaska's health care community:

https://www.youtube.com/watch?v=tWpC7Y5WSws

Vaccine Candidates

According to current federal government estimates, Alaska's initial allocations of vaccines could include:

Pfizer: 35,100 doses

Moderna: 17,900 doses

These vaccine doses will be distributed statewide among public, private and Tribal health systems.

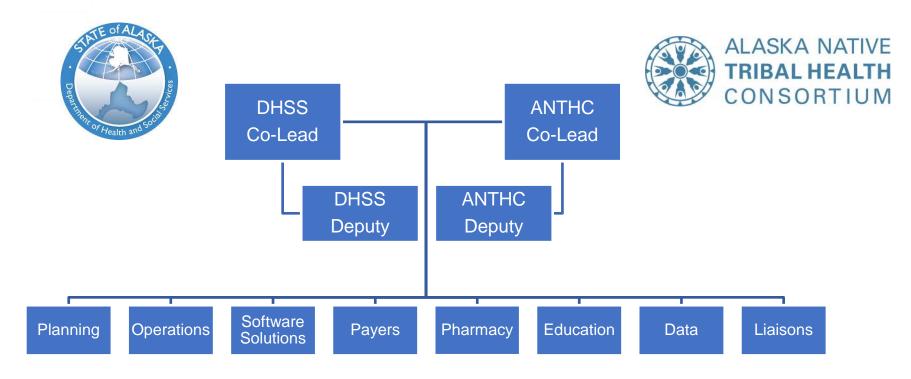
Vaccines made available via an Emergency Use Authorization cannot be required or mandated by governments and businesses.

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Task Force

Alaska COVID-19 Vaccine Task Force

A partnership between the Alaska Department of Health and Human Services and the Alaska Native Tribal Health Consortium



VACCINE TASK FORCE

Dr. Bob Onders, Medical Director of Community and Health Systems Improvement, Alaska Native Tribal Health Consortium

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Phases and Allocation

Timeline

Expect dates to change as we find out more

December 1: CDC Advisory Council on Immunization Practices (ACIP) met and voted on a recommendation for who gets the vaccine first

December 3: Alaska Allocation Committee met to recommend prioritization and distribution model for Alaska

December 4-7: Vaccine shipment details (including estimated doses) reported to hospital leadership or hospital vaccine planners

December 10: FDA meeting on Pfizer vaccine. Additional CDC guidance is expected. If EUA approved, vaccine shipment may begin.

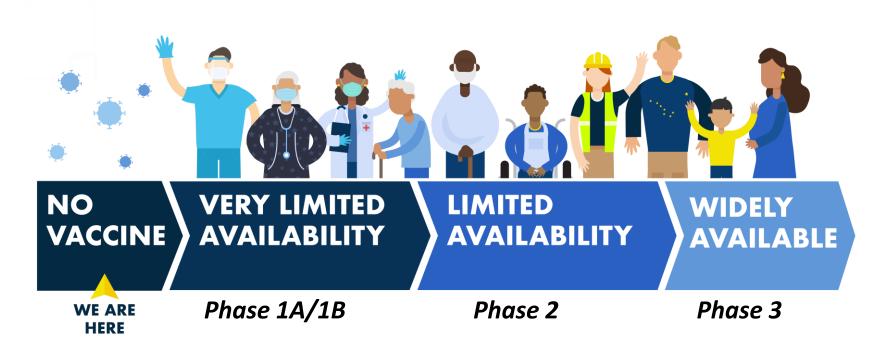
Mid December: Pfizer vaccine shipments arrive in Alaska

Mid-End December: Moderna vaccine shipments arrive in Alaska

Expect regular shipments to continue throughout 2021.

Vaccine Availability Phases

Vaccine supply will be limited at first and will be increasingly available into 2021.



(Image for illustrative purposes, details subject to change upon future guidance)

Vaccine Allocation - Federal

CDC Advisory Council on Immunization Practices (ACIP)
approved the following recommendation by majority
(13-1) vote at its December 1, 2020 emergency meeting

When a COVID-19 vaccine is authorized by FDA and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1A) should be offered to both 1) health care personnel and 2) residents of long-term care facilities

 More information: https://www.cdc.gov/vaccines/acip/index.html

Vaccine Allocation - Federal

Further CDC Advisory Council on Immunization Practices (ACIP) Recommendations:

- Healthcare personnel (HCP) with direct patient contact
 - -Unable to telework
 - -Including those who work in inpatient, outpatient, or community settings
 - -Provide services to patients or patients' family members
 - -Handle infectious materials
- HCP working in residential care or long-term care facilities
- HCP infected with COVID-19 within the preceding 90 days may choose to delay vaccination for other HCP more susceptible to infection
- No current data to inform recommendations for pregnant or breastfeeding women

Vaccine Allocation - Federal

Further CDC Advisory Council on Immunization Practices (ACIP) Recommendations:

- Long-term care facility resident sub-groups
 - -Skilled Nursing Facilities
 - -After Skilled Nursing Facilities:
 - Assisted living facilities
 - Intermediate care facilities for individuals with developmental disabilities
 - Residential care facilities
 - State Veterans Homes

Vaccine Allocation - Analogy

Decisions on who gets initial COVID-19 vaccine are like nesting dolls. Each layer builds on the previous layer, and no layer stands on its own.



The Alaska COVID-19 Vaccine Task Force is working with federal, state, Tribal, military, and community partners to plan for Alaska's needs.

Vaccine Allocation - Alaska

On December 3, Alaska COVID-19 Vaccine Allocation Committee met and unanimously determined a portion of the groups that will be included in Phase 1a. These groups include:

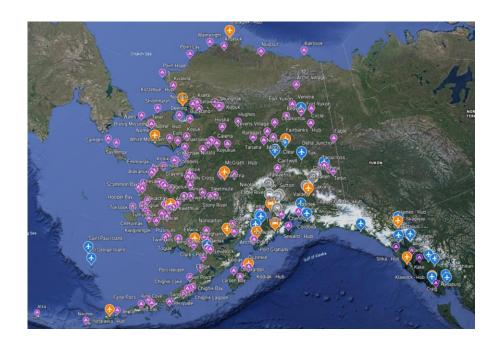
- Hospital based front-line health care workers at highest risk for COVID-19 infection
- Long-term care facility residents and staff
- EMS/fire personnel
- Community Health Aides
- Individuals who are required to perform vaccinations

The committee will reconvene to discuss additional groups to include in Phase 1a Thursday, December 10.

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Ordering, Receiving, Distributing Vaccine

Alaska has an existing system to get vaccines from the manufacturer all the way to the most rural parts of our state.



COVID-19 vaccination providers may enroll in the CDC COVID-19 Vaccination Program administered by the Alaska Immunization Program, a program within the Alaska Department of Health and Social Services:

http://dhss.alaska.gov/dph/Epi/id/Pages/COVID-19/VaccineProviders.aspx

As of December 4, 265 health care providers are fully enrolled.

Integrated IT systems —both public and private, as well as new and existing—are needed to ensure successful vaccine allocation, distribution, administration, monitoring, and reporting.

Jurisdictions are not advised to purchase ultra-cold storage equipment at this time:

- Ultra-cold vaccine will be direct shipped from the manufacturer in coolers that are packed with dry ice
- Direct shipments to the vaccination provider site will be in 975-dose increments on a real-time, day to day basis

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Community Planning

Community Planning

- DHSS focused on lifting burden of planning for Phase 1a, so communities can focus on subsequent phases
- Regional Technical Assistance Advisors
- Preparedness Public Health Nurses

Community Planning - TAA

Technical Assistance Advisor (TAA) Responsibilities:

Assess planning progress

Provide individualized outreach and support

Provide updated information

Assist with problem solving, provide resources

Engage in regular communication

Support THE COMMUNITY's planning efforts

Community Planning - TAA

Technical Assistance Advisors (TAA's) Serve as Task Force Point-of-Contact for the Following Entities:

Public Health Center	Pharmacies
Regional Emergency Preparedness	Home Health/In Home Care Agencies
Emergency Management	Law Enforcement
Local Government Leadership	Agencies Serving Individuals with Disabilities
Tribal Leadership	EMS
Hospitals	Agencies Serving People Experiencing Homelessness
Community Health Clinic (FQHCs, etc.,.)	Long Term Care Facilities
Tribal Health Organizations	Agencies Serving People 65+
Critical Industry Partners	

Community Planning – TAA

- Southcentral
- Interior
- Southeast
- Northern
- Municipality of Anchorage

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Vaccine Confidence

Information/Outreach

 New Public Service Announcement: How COVID-19 vaccine clinical trials, manufacturing and distribution https://vimeo.com/486684321



http://Covidvax.Alaska.gov

- Regular updates: Learn about vaccine availability
- Communications tools: Weekly updated written <u>messages</u>
 you can use to discuss COVID-19 vaccine in your community
- Learning opportunities: Weekly Thursday 2 PM publiclyavailable virtual learning opportunity to stay informed about planning, distribution and vaccine science
- Planning resources: Healthcare stakeholder and community partner resources

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Questions?

Preston Simmons, Providence St. Joseph Health, Chief Executive, Alaska	Mike Levy, EMS Medical Director, (multiple orgs), EMS Physician
Ryan Smith, South Peninsula Hospital, Chief Executive Officer	Nick Papacostas, American College of Emergency Physicians, Emergency Room Physician
Kay Turner, SEARHC Sitka Long Term Care + SEARHC Wrangell Long Term Care, Administrator	Eli Powell, Alaska State Medical Board (ASMA), Orthopedic Surgeon Physician
Ruth Johnson, Wildflower Court, Administrator	Teresa Holt, AARP, Executive Director
Karen Mailer, Providence Transitional Care , Medical Director	Jon Zasada, Alaska Primary Care Association, Director, Policy Integration
Holly Alfrey-Van, Alaska Native Medical Center, Chief Medical Officer	Jocelyn Pemberton, The Alaska Hospitalists Group, Chief Executive Officer
Angelique Ramirez, Fairbanks Memorial Hospital, Chief Medical Officer	Michael Cooper, Southcentral Foundation, Family Medicine
John Bramante, Central Peninsula Hospital, Internal Medicine	Daniel Hartman, Southcentral Foundation, Medical Director
Tim Bateman, The Alaska Hospitalists Group, Hospitalist	Bob Onders, Alaska Native Tribal Health Consortium, Medical Director / Interim Administrator
Mark Carr, Providence St. Joseph Health, Medical Ethicist	Ellen Hodges, Yukon Kuskokwim Health Corporation, Chief of Staff
Denise Evey, Fred Meyer (Kroger), Pharmacy, Pharmacist	Mark G. Peterson, Norton Sound Health Corporation, Medical Director
Mark Bohrer, Fred Meyer, District 9 Pharmacy Practice Coordinator, Pharmacist	Paul Mueller (invited), Eastern Aleutian Tribes, Chief Executive Officer

Existing Safety Monitoring

VAERS (Vaccine Adverse Event Reporting System) serves as the nation's early warning system to detect possible safety issues with U.S. vaccines

VAERS traditionally has provided initial data on the safety profile of new vaccines when they are introduced for use in the population

COVID-19 vaccine report processing times

- Death reports: 1 day
- Reports classified as serious: 3 days
- Reports classified as non-serious: 5 days

CDC and FDA receive updated datasets daily

Existing Safety Monitoring

- FDA scientists review all VAERS reports classified as serious
- Attempts are made to follow-up on all serious* reports to get medical records and other medical documentation
- CDC scientists will review VAERS reports for adverse events of special interest (AESI)
- CDC and FDA coordinate on analysis of VAERS data and both agencies conduct data mining





Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

http://vaers.hhs.gov

^{*}Based on the Code of Federal Regulations if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect (FDA routinely reviews all serious reports)

NEW Safety Monitoring: V-SAFE

V-SAFE is a smartphone-based text, text-to-web survey, and email-to-web survey active surveillance program for early vaccine recipients

Conducts health checks on vaccine recipients via text messages and email

- Daily for first week post-vaccination
- Weekly thereafter for 6 weeks post-vaccination

Active telephone follow-up will be conducted with a person reporting a clinically important adverse event during any V-SAFE health check

A VAERS report will be taken during telephone follow-up, if appropriate