This webinar will begin shortly.

Thank you for joining us.

HAWAI'I DEPARTMENT OF HEALTH

COVID-19 Vaccine Information Meeting For Medical Professionals & First Responders

Thursday, December 10

Welcome

Dr. Steven Hankins

Presenters

- Dr. Josh Green, Lieutenant Governor
- Dr. Sarah Kemble, DOH State Epidemiologist
- Ron Balajadia, DOH Immunization Branch Chief
- Jon Shear, ReadyZoneHQ
- Dr. Sandra Chang, DOH Medical Advisory Working Group Co-Chair
- Dr. Steven Hankins, DOH Medical Advisory Working Group Co-Chair, Facilitator
- Hilton Raethel, President & CEO, Healthcare Association of Hawaii

Q&A Sessions

- Submit questions through the Q&A bar on the bottom of your screen
- Questions may be emailed to vaccinequestionshi@gmail.com
- Due to volume of

Beware of Fraud

- You receive a telephone call, text message, email or computer pop-up that you did not solicit.
- The solicitor requests unusual payment terms (for example, prepaid debit or gift cards or electronic wiring of funds)
- The solicitor requests your bank account information, social security number or other personal information or credit card number.
- The solicitor instills a sense of urgency.

Beware of Fraud

- HPD COVID hotline- 723-3900
- FBI Honolulu- 808-566-4300
- Dept. of Homeland Security (DHS)
  Mrs. Jimmie L Collins
  jimmie.l.collins@hawaii.gov
  Office: 808-369-3750
- 9-1-1

Dr. Josh Green, Lt. Gov.

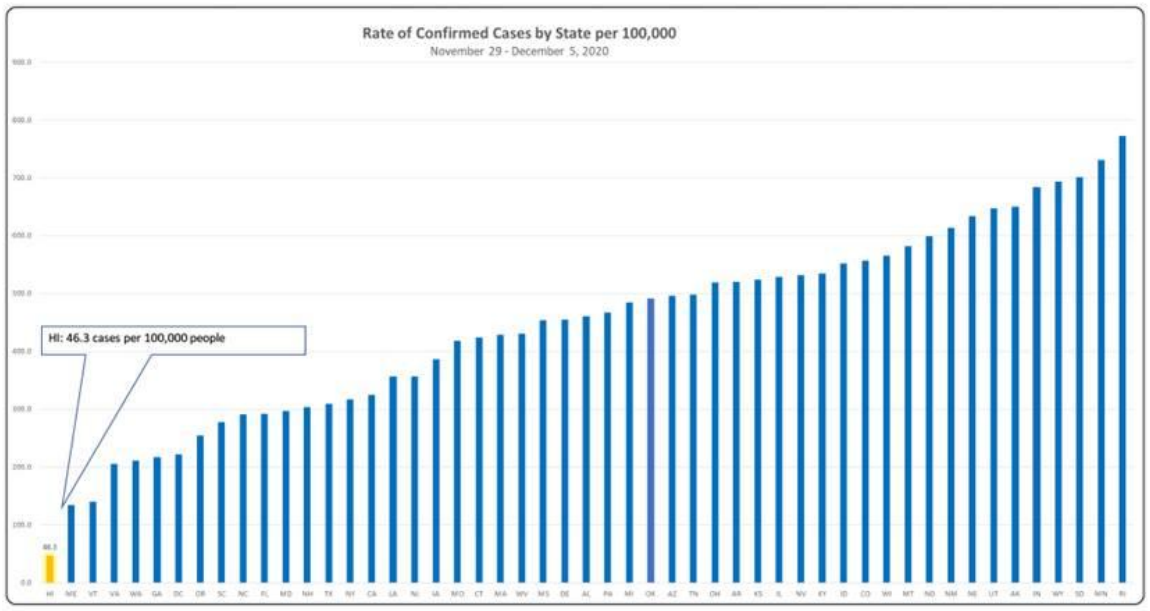
Dr. Sarah Kemble
DOH State Epidemiologist

COVID-19 - State Overview

- Where we are in containment
- Testing
- Contract-tracing

COVID-19 in Hawai‘i

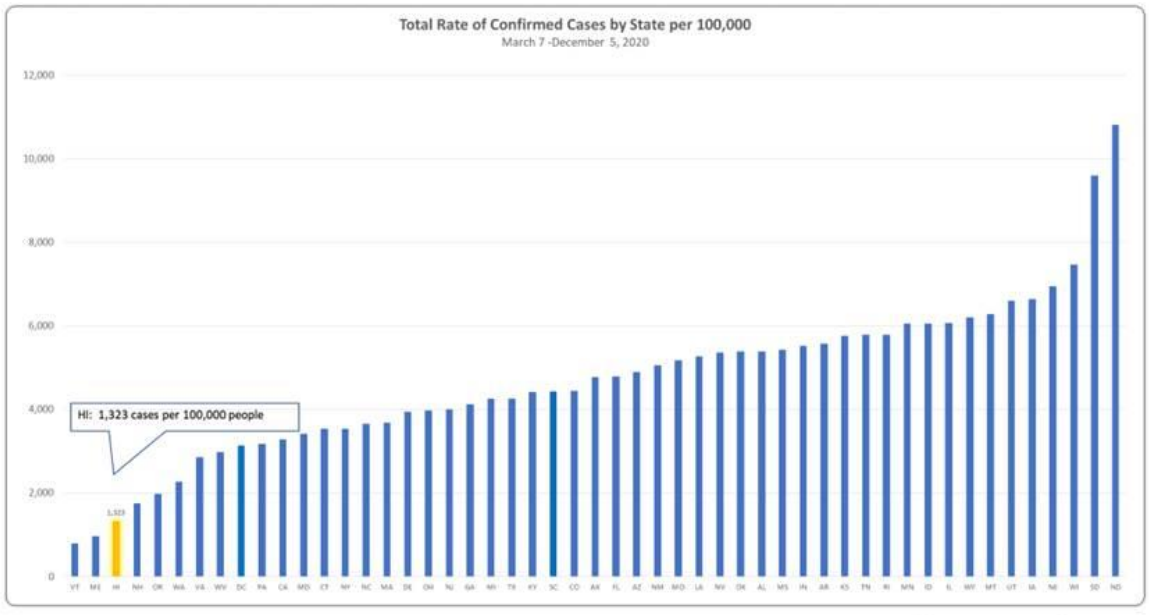
For the week of Nov. 29 – Dec. 5, Hawai‘i had the lowest infection rate in the U.S. Hawai‘i’s rate was less than half of the next lowest state for that week.



Data source: https://covidtracking.com/data

COVID-19 in Hawai‘i

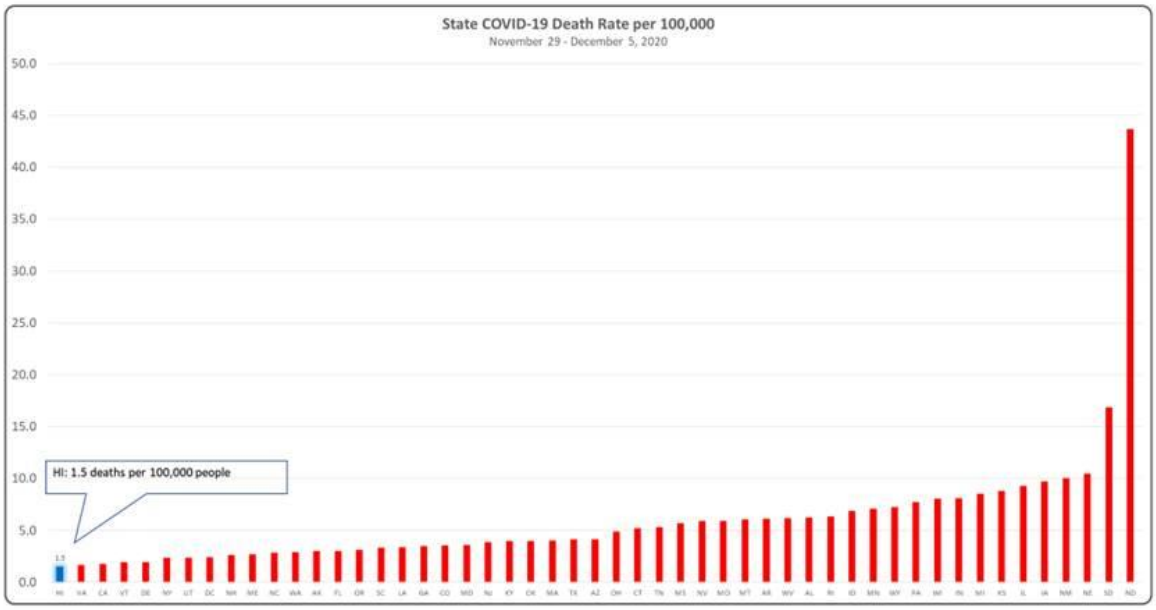
For the entire measurement period, March 7 – Dec. 5, Hawai‘i has the third lowest infection rate in the U.S.



Data source: https://covidtracking.com/data

COVID-19 in Hawai‘i

For the week of Nov. 29 – Dec. 5, Hawai‘i had the lowest death rate in the U.S.



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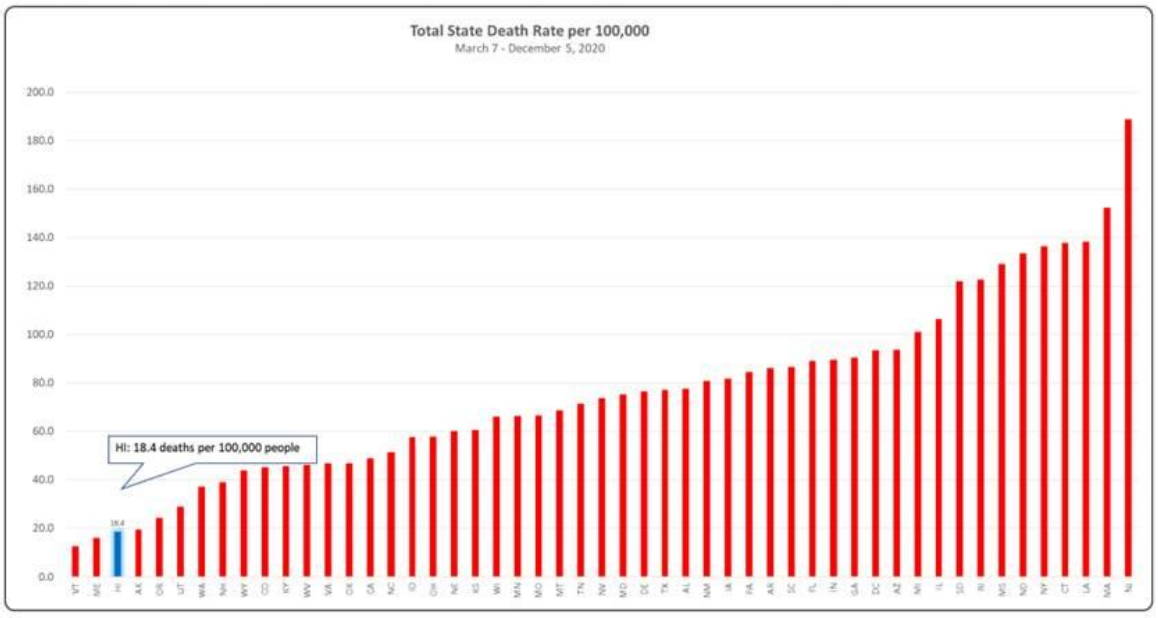


Data source: https://covidtracking.com/data

COVID-19 Statewide Overview

- Prevention
  - DOH Mask Use Survey – updated Dec. 3 (last update Nov. 25)
    - Statewide: 88% (+3%)
    - Hawai‘i County: 89% (-1%)
    - C&C Honolulu: 92% (+9%)
    - Kaua‘i County: 79% (-2%)
    - Maui County: 93% (+3%)
- Test, Trace, Isolate
- Healthcare System
- Safe Travels Hawai‘i
- Vaccination Strategy

COVID-19 in Hawai‘i – Case Trends / Hospitalizations

- **October 14:**
  - Hospitalized: 105
  - Statewide average daily new cases: 92
  - Statewide test positivity rate: 2.8%
    - Hawai‘i County: 20 / 2.8%
    - C&C Honolulu: 70 / 3.6%
    - Kaua‘i County: 0 / 0%
    - Maui County: 2 / 0.1%
- **December 10:**
  - Hospitalized: 51
  - Statewide Average Daily New Cases: 90.4
  - Statewide test positivity rate: 1.67%
    - Hawai‘i County: 10.9 / 1.47%
    - C&C Honolulu: 66.4 / 1.97%
    - Kaua‘i County: 1 / 0.69%
    - Maui County: 12.1 / 1.5%

Dr. Sarah Kemble

DOH State Epidemiologist

Healthcare Providers as Contact Tracing "Extenders"

- Partnership with Hawaii Department of Health to prevent spread of COVID-19
- Best situated to provide initial guidance to cases and their contacts, at time of testing or when medical advice or care is first sought
- Understand and disseminate isolation and quarantine guidance
- Return to School/Work letters
- Pilot projects for more extensive collection of information on household contacts of cases by providers
- Know when to call Hawaii Department of Health (upcoming reporting requirement revisions)

Provider Resources

Clinician Guidance Documents —

Healthcare Facility Transfer Guidance for COVID-19 Patients

Advising Patients Who Are Tested for COVID-19

Advising Patients Who Test Positive for COVID-19

Medical Advisories – Updated August 19, 2020

Patient Guidance Documents —

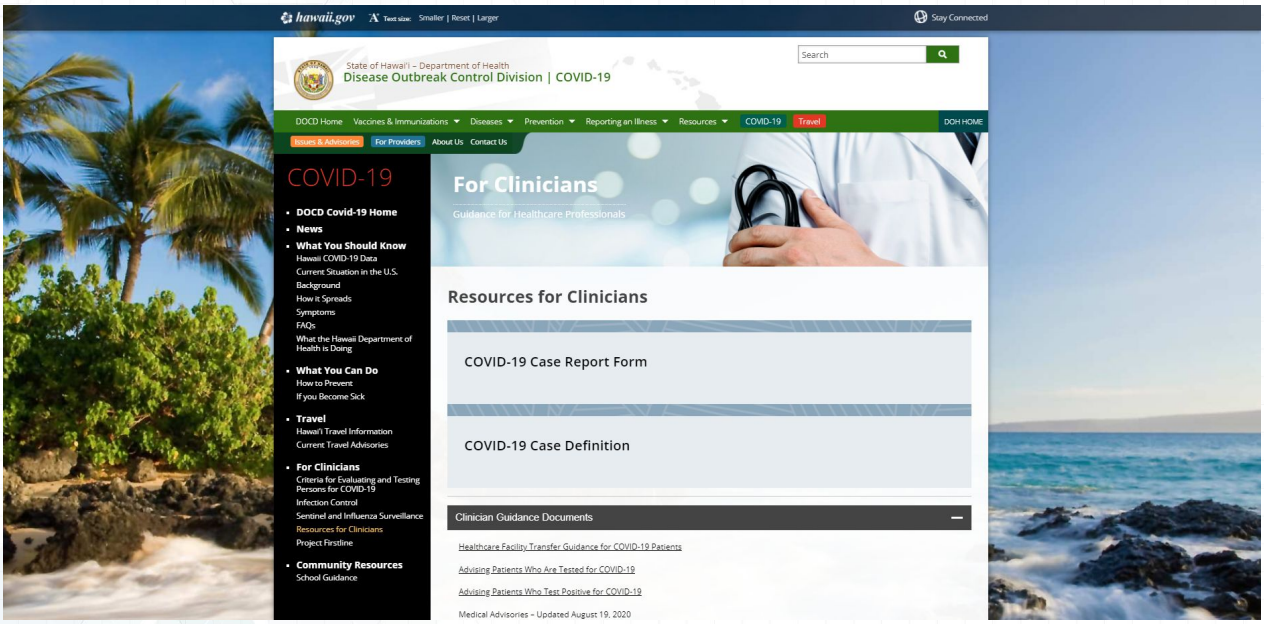
What To Do If You Have Been Tested for COVID-19

Caring for Someone with COVID-19 at Home

What To Do If You Have Tested Positive for COVID-19

What Contacts of Persons with COVID-19 Should Do

https://health.hawaii.gov/coronavirusdisease2019



Dr. Steven Hankins
DOH Medical Advisory Group Co-Chair

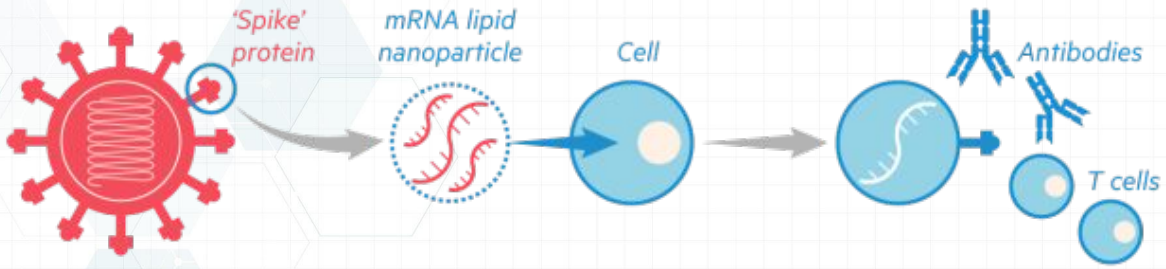
Dr. Sandra Chang
DOH Medical Advisory Group Co-Chair

Pfizer & Moderna COVID-19 Vaccines

- Vaccine Safety
- Vaccine Efficacy
- Follow-Up for Safety and Efficacy

How mRNA vaccines work

Genetic instructions are given to the immune system to recognise the virus



Scientists focus on the genetic sequence for the virus's 'spike' protein. This is used to synthesise an mRNA sequence – instructions that cells can use to make the 'spike' protein

The synthetic mRNA is packaged in a lipid nanoparticle that delivers the instructions to a cell

Once inside the cell, its cellular machinery follows the mRNA instructions to produce the viral protein. This is displayed on the surface of the cell and stimulates an immune system response

Source: Pfizer

Update on COVID-19 Vaccine Development

Pfizer/BioNTech BNT162b2 Vaccine

- mRNA COVID-19 vaccine
  - 2 dose injection, **21** days apart
- Phase 3 clinical trial began July 27, 2020
- Well-tolerated with most adverse effects resolving shortly after vaccination
- **95% effective** (170 confirmed COVID-19 cases)
  - 162 cases in placebo group
  - 8 cases in vaccine group
- FDA Advisory Committee voted in support of EUA: Dec. 10, 2020
- FDA BLA submission anticipated in Q2 2021

Moderna mRNA 1273 Vaccine

- mRNA COVID-19 vaccine
  - 2 dose injection, **28** days apart
- Phase 3 clinical trial began July 27, 2020
- Generally well-tolerated with majority of adverse effects mild to moderate
- **94.1% effective** (196 confirmed COVID-19 cases)
  - 185 cases in placebo group
  - 11 cases in vaccine group
- FDA EUA review: Dec. 17, 2020

Vaccine Trial Participant Diversity

- Vaccine Trials Included Individuals of Diverse Ethnicities and High-risk Age Groups

Ethnicity	Pfizer		Moderna
	US Only	Overall Study	US Study
Asian	6%	5%	4%
Black	10%	10%	10%
Hispanic/Latinx	13%	26%	20%
Native American	1%	1%	
White	70%	58%	63%
All Others			3%
Ages 56-85 y	45.4%	40.9%	
Age >=65 y			25%

Pfizer Phase 2/3 Trial Design

BNT162b2 mRNA vaccine, IM injection,
0 & 21 d
44,000 Study Participants:
266 children ages 12-15 y, **608 children ages 16-17 y, 43,518 adults 18 y**
50% vaccine, 50% placebo

Primary Efficacy Endpoint:
Confirmed COVID-19 7 d after second dose to end of study (2 y)
Without previous infection
With or without previous infection

Confirmed COVID-19: acute respiratory illness + positive NAAT for SARS-CoV 2
Primary Efficacy Endpoint: 164 cases of confirmed COVID-19 for true VE rate ≥ 60%

Pfizer Phase 2/3 Trial Design

Secondary Efficacy Endpoints

- Confirmed COVID-19 from 14 d after Dose 2
- Severe COVID-19 from 7 d or 14 d after Dose 2
- CDC-defined COVID-19 from 7 d or 14 d after Dose 2

Pfizer Vaccine Efficacy

Primary objective analysis

- Vaccine efficacy rate of 95% against confirmed COVID-19
  - Participants without prior COVID-19 infection 7 d after 2nd dose
  - Participants with and without prior COVID-19 infection 7 d after 2nd dose
- Vaccine efficacy rate over 94% in adults over 65 years of age
- Efficacy appears consistent across age, gender, race and ethnicity demographics
  - Continued collection of subgroup data needed over full, 2-year study period

Secondary objective analysis

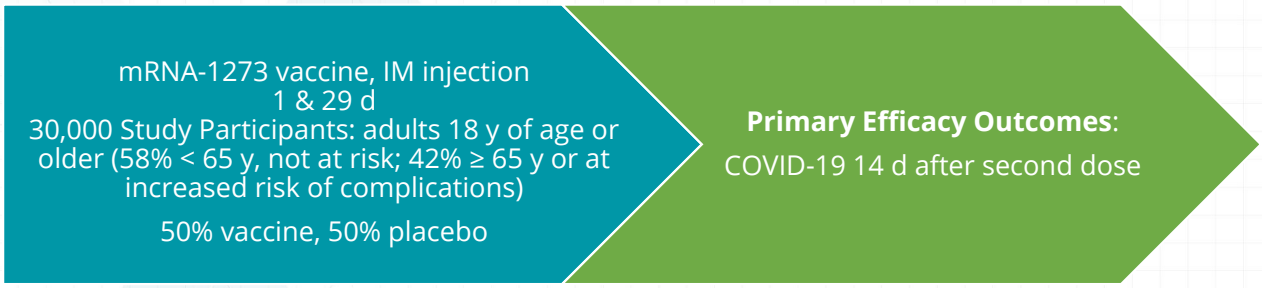
- Vaccine efficacy against severe COVID-19
  - 9 cases in placebo group vs. 1 case in vaccinated group
- Vaccine efficacy in preventing COVID-19 after first dose
- Vaccine efficacy in preventing COVID-19 in individuals with prior SARS-CoV-2 infection
- More data needed to firmly support these secondary objectives

Pfizer Vaccine Safety

- Participants followed for a median of 2 months following 2nd dose of vaccine:
  - Solicited safety data: randomized subset of 8,000 participants 18 years and older, ~100 children 12-15 years of age
  - Unsolicited safety data: 38,000 trial participants
- Vaccine well tolerated with most solicited adverse events (SAE) resolving shortly after vaccination (2-3 d)
  - Most common SAEs: injection site reactions, fatigue, headache, muscle pain, chills, joint pain, fever
  - Few Grade 3 SAEs greater than or equal to 2% in frequency that prevent daily routine activity: fatigue, headache
  - Older adults (<55 y) reported fewer and milder SAE following vaccination
  - Few cases of lymph adenopathy & Bell's Palsy requires further surveillance
  - Similar safety profile across age groups, genders, ethnic and racial groups, participants with or without medical comorbidities, participants with or without evidence of prior SARS-CoV-2 infection at enrollment
    - Will continue to collect subgroup data for remainder of 2-year study

US FDA safety milestones achieved for EUA

Moderna Phase 3 Trial Design



COVID-19 case definition:

- At least TWO of defined **systemic symptoms**, OR
- At least ONE of defined **respiratory signs/symptoms,** AND
- At least one **positive SARS-CoV-2 NAA test**

Primary Efficacy Endpoint: 151 cases of confirmed COVID-19 for true VE rate ≥ 60%

Moderna Phase 3 Trial Design

Secondary Efficacy Outcomes

- **Severe COVID-19**
- **Serologically confirmed SARS-CoV-2 infection or COVID-19** regardless of symptomatology or severity
- COVID-19 using a **secondary definition of symptoms**
- **Death** caused by COVID-19
- **COVID-19 after the first dose of vaccine**
- **Asymptomatic** SARS-CoV-2 infection

Moderna Vaccine Efficacy

Primary endpoint analysis

- Vaccine efficacy rate of 94.1% against confirmed COVID-19
  - Participants without history of prior COVID-19 infection 14 d after second dose
- Efficacy consistent across age, race, ethnicity, gender demographics

Secondary endpoint analysis

- Vaccine efficacy rate of 100% against severe COVID-19 cases
  - 30 cases of severe COVID-19 in placebo group (including 1 death)
  - No cases of severe COVID-19 in vaccinated group

Moderna Vaccine Safety

- Solicited adverse events indicate vaccine was well-tolerated
- Majority of adverse events mild or moderate in severity
- Grade 3 SAEs greater than or equal to 2%, generally short-lived (severe = prevents daily routine activity)
  - First dose – injection site pain
  - Second dose – fatigue, myalgia, arthralgia, headache, pain and erythema/redness at injection site

US FDA safety milestones achieved

Dr. Steven Hankins

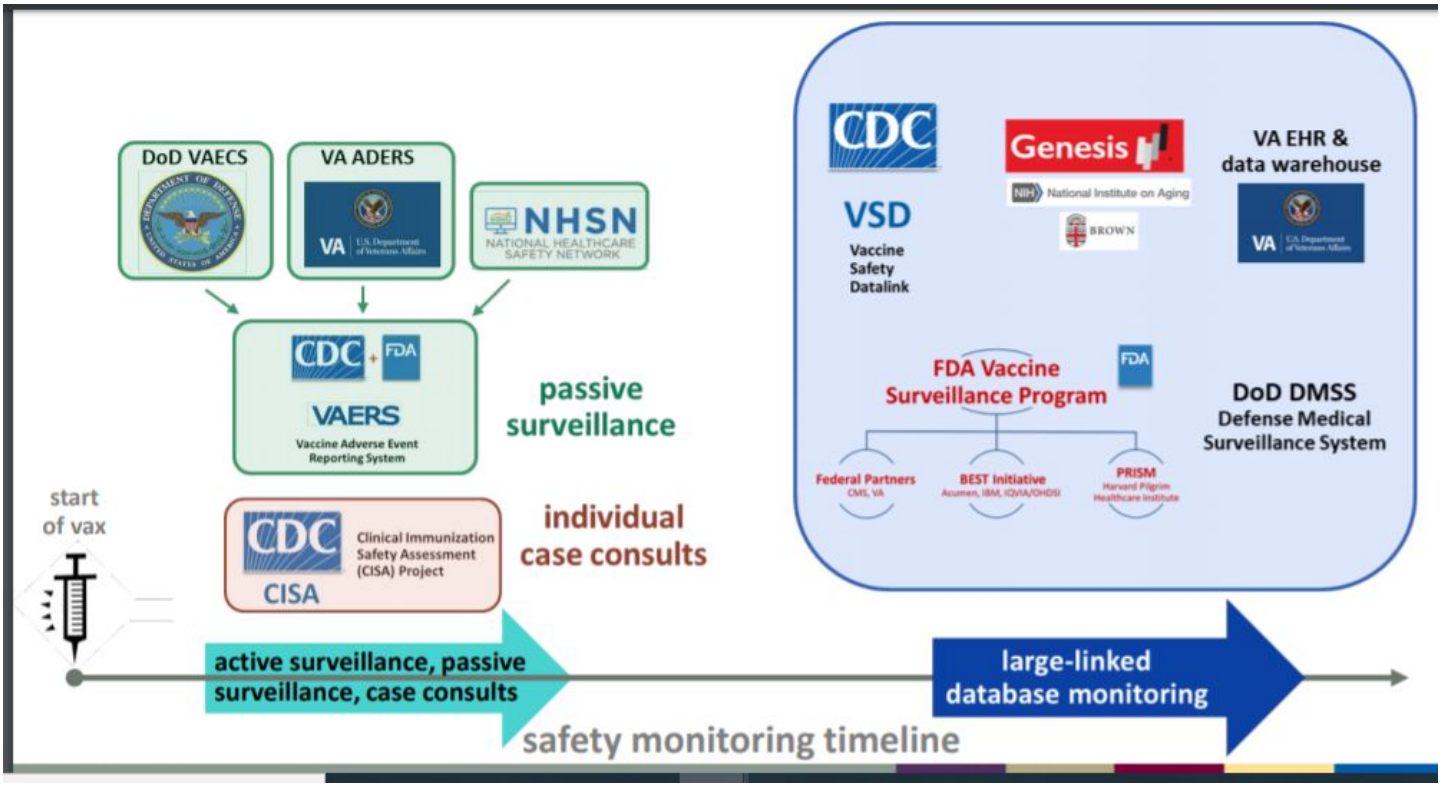
DOH Medical Advisory Group Co-Chair

Vaccine Safety & Efficacy Follow-up

- Both Pfizer and Moderna will continue safety and efficacy data analysis for 2 years after study initiation
- Follow-up in progress for 2 reports of anaphylaxis in UK
    - Only slight numerical imbalance in allergic reactions in Pfizer trial, none serious
- Questions to be answered with additional data from ongoing trials:
    - How long will the vaccine last (duration of protection)?
    - Will vaccination prevent asymptomatic SARS-CoV-2 infection?
    - Will vaccination reduce SARS-CoV-2 transmission?
    - Are two vaccine doses required for protection or can protection be achieved with a single vaccine dose?
    - Is the vaccine safe and effective in children 12-15 years of age?
- Bridging studies are under consideration to demonstrate safety/immunogenicity in children and pregnant women not included in current trials.

Vaccine Safety Follow-up

- Active Surveillance
  - V-Safe after vaccination health checker App
- Passive Surveillance
  - CDC/FDA Vaccine Adverse Event Reporting System (VAERS)
    - Long-standing, established vaccine safety monitoring system
- Individual Case Consults
  - CDC Clinical Immunization Safety Assessment Project
- CDC's ACIP Vaccine Safety Technical Sub-Group (VAST)
  - Central hub for post-authorization/approval safety monitoring
- Large-linked database monitoring



Monitoring systems and populations

	Monitoring systems	Population	Healthcare workers	LTCF residents
early	**VAERS** (CDC & FDA) VA ADERS DoD VAECS CDC NHSN	General U.S. population, VA and DoD patient populations, NHSN acute care and long-term care facilities	Yes	Yes
early	**V-safe** (CDC)	All COVID-19 vaccine recipients eligible	Yes	Limited
later	**VSD** (CDC)	Insured patients in VSD sites	Yes	Limited
later	**FDA-CMS**	Medicare recipients (90+% of 65 y/o in the U.S., including 650K LTCF residents)	Limited	Yes
later	**BEST & PRISM** (FDA)	Insured patients in BEST & PRISM sites	Yes	Limited
later	**VA EHR & data warehouse**	Enrolled VA patients	Limited	Yes
later	**DoD DMSS**	Active duty military (limited info on beneficiaries [i.e., family members, retirees])	Yes	Limited
later	**Genesis HealthCare** (Brown U. & NIH-NIA)	Long-term care facility residents (~35,000 long stay residents)	No	Yes

Your role

COVID-19 vaccine safety gets stronger with your participation

Public health partners

- Promote participation in **v-safe**
- Promote reporting to **VAERS**
- Communicate with your partners on vaccine safety

Healthcare providers

- Encourage patient participation in **v-safe**
- Report adverse events to **VAERS**
- Communicate with patients on vaccine safety

Resources

- Pfizer/BioNTech SARS-CoV-2 Vaccine Clinical Trial Protocol
- Pfizer Press Release on Final Efficacy Analysis of Phase 3 Study, 11/18/20
- FDA Briefing Document: Pfizer-BioNTech COVID-19 Vaccine, 12/8/20
- Moderna SARS-CoV-2 Vaccine Clinical Trial Protocol
- Moderna Press Release on First Interim Analysis of Phase 3 Study, 11/16/20
- Moderna Press Release on Final Efficacy Analysis of Phase 3 Study, 11/30/20
- ACIP Post-authorization safety monitoring update, 12/01/20

Dr. Steven Hankins
DOH Medical Advisory Group Co-Chair

Hilton Raethel
President & CEO, Healthcare Association of Hawaii

Who gets to get it first

- Prioritization philosophy
- Dispensing to priority groups
- Implementation to healthcare systems

Who gets it first?

Prioritization philosophy

Prioritization Framework

- **The Advisory Committee on Immunization Practices (ACIP)** advises CDC on population groups and circumstances for vaccine use.

- Informs policy decisions based on data regarding:
  - Vaccine candidates
  - Surveillance and mathematical modeling
  - Vaccine allocation literature from published and external expert committee reports

Ethical Considerations

- **Maximize benefits and minimize harms**
- **Mitigate health inequities**
- **Promote justice**
- **Promote transparency, encourage trust**
- **Ensure autonomy**

Prioritization Framework

Criteria 1: Risk of acquiring infection

Individuals have higher priority to the extent that they have a greater probability of being in settings where SARS-CoV-2 is circulating and of being exposed to a sufficient dose of the virus.

Criteria 2: Risk of severe morbidity and mortality

Individuals have higher priority to the extent that they have a greater probability of severe disease or death if they acquire infection.

Criteria 3: Risk of negative societal impact

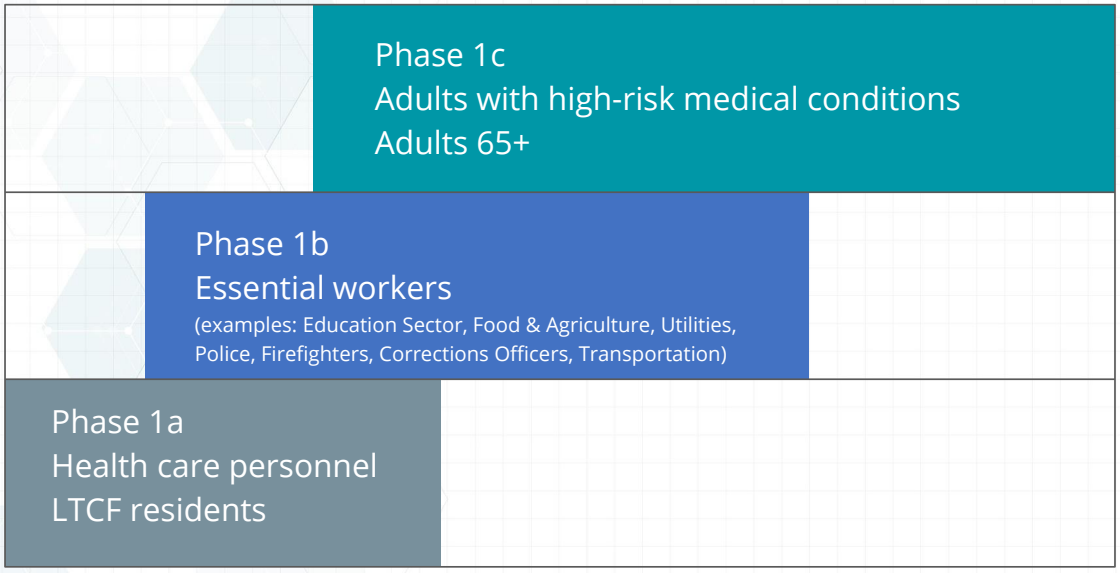
Individuals have higher priority to the extent that societal function and other individuals' lives and livelihood depend on them directly and would be imperiled if they fell ill.

Criteria 4: Risk of transmitting infection to others

Individuals have higher priority to the extent that they there is a higher probability of their transmitting the infection to others.

Source: National Academies: A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus, available at: https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus

Prioritization Framework



Source: ACIP

Prioritization Framework

Healthcare personnel

Paid and unpaid people serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials

Residents of long-term care facilities

Adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently

- Factors related to **Critical infrastructure** determined by the Department of Homeland Security Cybersecurity and Infrastructure Security Agency
- **Logistical considerations**

Sub-Prioritization

- We anticipate sufficient allocation to cover all healthcare workers by the end of the year
- There is a probability of insufficient doses in the first few weeks to reach the entire worker population at a single registered vaccination site
- Sub-prioritization will likely be necessary during Phase 1b, lc, and Phase 2
- DOH is developing sub-prioritization guidance based on Federal guidelines and the four risk criteria in the Prioritization Framework

Sample Sub-Prioritization Considerations

Risk of acquiring infection

□ Immune compromise
□ Aerosolizing procedures
□ Frequent contact with COVID + patients
□ Job cannot maintain 6' distance from many people/day
□ Prolonged contact with >10 people/day
□ Contact with persons who may refuse or are unable to wear a mask
□ Live or work in a congregate living setting
□ Exposure to bodily fluids

Risk of severe illness

□ Immune compromise
□ Age > 65
□ Underlying Medical Conditions
□ From a disportionately affected community
□ Smoker

Risk of societal impact

□ Direct patient care or critical support service
□ First responder with direct public contact or critical support function
□ Other critical worker in high risk
□ Live with someone who is a healthcare worker, first responder, or other critical worker
□ Sole income source for household

Risk of spread of COVID

□ Direct patient contact
□ First responder with direct public contact
□ Frequent contact where you cannot maintain 6' distance
□ Frequent prolonged contact (>15 minutes/person) < 6' distance
□ Live with more than 3 other individuals
□ Live with someone who has any of the risks for severe illness or mortality

Hilton Raethel

President & CEO, Healthcare Association of Hawaii

Immunity for Administering Vaccines

A vaccine for COVID-19 would be a "covered countermeasure" to which the Public Readiness and Emergency Preparedness or PREP Act immunity would apply provided that the other conditions are satisfied. The PREP Act authorizes the Secretary of Health and Human Services to issue a Declaration to provide liability immunity under federal and state law to certain individuals and entities against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, *administratio*n, or use of certain medical countermeasures, *e.g.,* a vaccine. The liability immunity extends to claims under both federal and state law. The liability immunity does not provide protection for death or serious injury caused by willful misconduct. The Secretary issued a PREP Declaration on March 10, 2020 with respect to COVID-19. The PREP Act provides that a person covered by this PREP Act immunity includes a physician or other health care professional who administers a vaccine within the scope of his or her practice under state law.

Post Acute Care

- Pharmacy Partnership for Long-Term Care Program
  - Federal program with CVS, Walgreens and selected pharmacies
- Pharmacies will provide end-to-end management of the COVID-19 vaccination process including:
  - Cold chain management
  - On-site vaccination
  - Fulfillment of reporting requirements
- Applies to Nursing Homes, Assisted Living Facilities and other large congregate settings for older adults
  - Includes hospice patients in these settings
- Program provided free of charge – but facilities required to register
- All Nursing Homes and Assisted Living Facilities in Hawaii have enrolled

Post Acute Care

- CVS and Walgreens will require signed consent
  - Fact sheet supplied
- Nursing Homes
  - 8,628 residents and staff
- Assisted Living facilities
  - 5,340 residents and staff
- ARCHs with 20 or more residents would be included
- Does not apply to:
  - Hospice providers
  - Home Health
  - 438 adult residential care homes
  - 1,223 community care foster homes

Post Acute Care

- Allocation for Nursing Homes comes from state allocation
- Hawaii has chosen Moderna for Pharmacy Partnership for Long-Term Care Program
- Pharmacies will provide 3 clinic dates to facilities, one week apart for the first dose
    - Staggered clinic dates maximize coverage of the facility's residents and staff, and to minimize impacts associated with side effects
- Pharmacies will follow up and provide a second dose 3 to 4 weeks later, depending on the vaccine
    - Moderna's second dose will be administered about 28 days, or 4 weeks after the first dose
- Nursing homes in first wave
- Assisted living facilities a month after 2nd dose for nursing facilities
    - Approx. March 2021

Post Acute Care

- Staffing challenge for CVS and Walgreens
- DOH and counties looking for same staff
- Low individual facility counts in Hawaii could impact availability of vaccine

Vaccine rollout: the feds, the state & the counties

Ron Balajadia
DOH Immunization Branch Chief

Jon Shear
ReadyZoneHQ

- Federal Guidance
  a. Project Background/Challenges
- State Operations
  a. Overview of Draft COVID-19 Vaccination Plan
- County Operations
  a. Phase 1 Concept of Operations (CONOPS)
- Handling Storage

Project Background

The CDC directed that all states provide a vaccination plan by 16 Oct 2020

HDOH developed and submitted the draft COVID-19 Vaccination Plan in less than 30 days

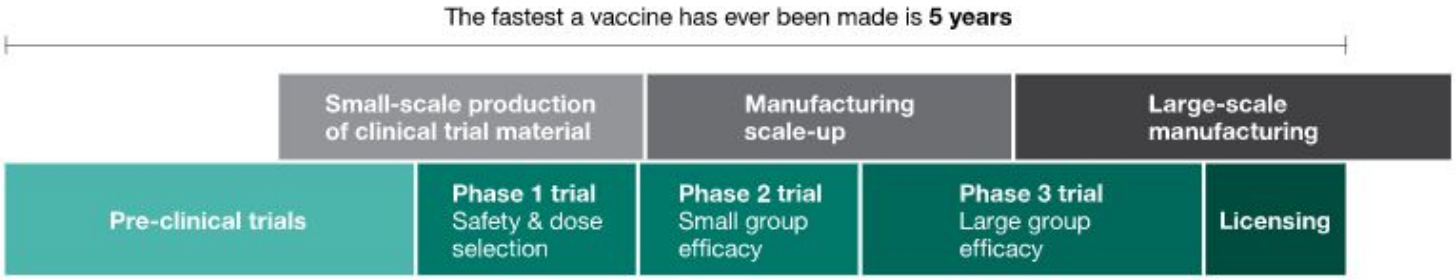
Currently working to implement the draft COVID-19 Vaccination Plan.

Project Background

"**At the end of the day, if we get a vaccine that's very fast, but we only can give it to 10 people**, that's not going to help us. And if we get a vaccine that we give to millions of people, but it takes us 10 years, that's also not the right solution."

Dr. Lynda Stuart,

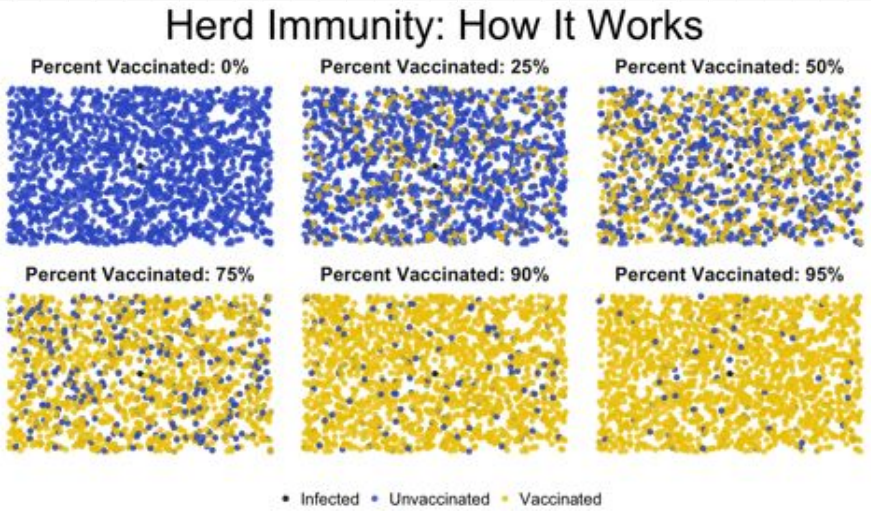
- Leading vaccine expert at the Bill & Melinda Gates Foundation.



Project Background

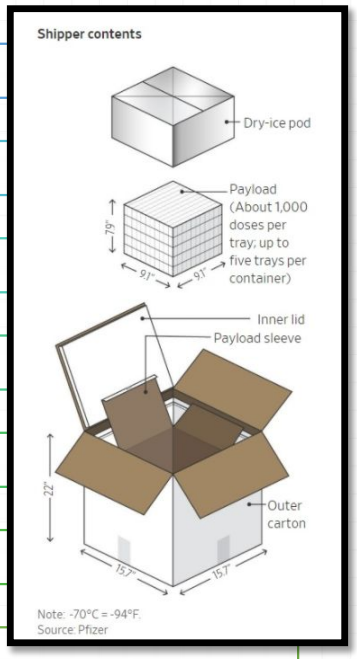
"In general, with a virus as contagious as SARS-CoV-2, around 60% of the population would need to be immunized to reach the herd immunity threshold"

- Dr. Amesh Adalja
  - Senior Scholar at the Johns Hopkins University Center for Health Security



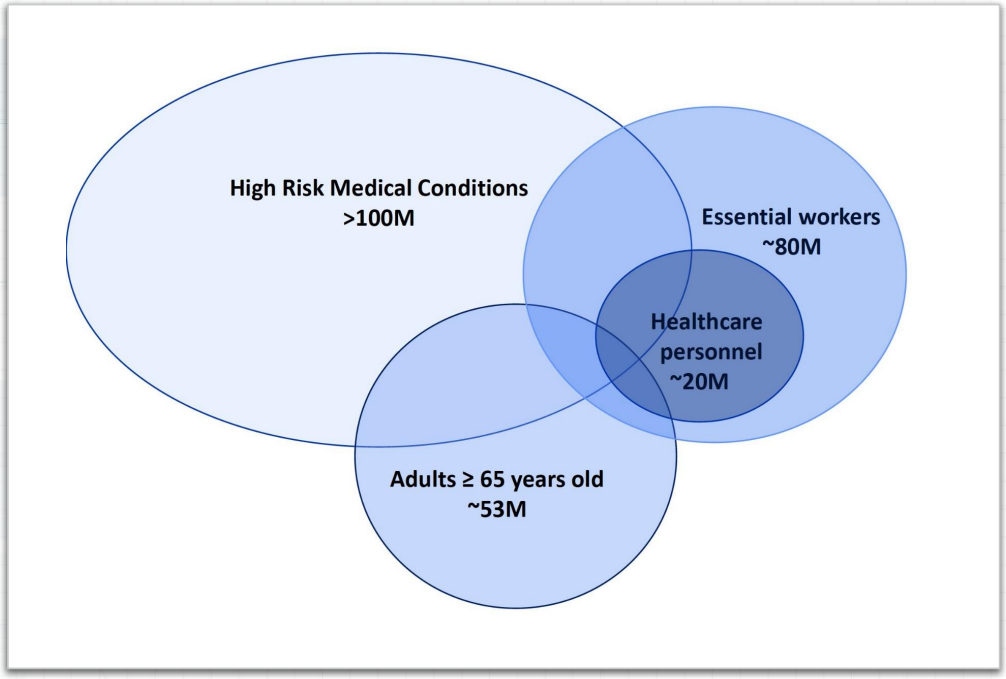
COVID-19 Vaccination Challenges

1. Need to Prioritize Critical Populations due to limited initial availability of COVID-19 vaccine
2. Simultaneous demand for vaccine supplies and equipment throughout the world
3. Potential need for Ultra-cold storage capacity/redistribution
4. Need to rapidly enroll vaccination providers
5. Limited staffing resources are available to conduct vaccinations
6. Potential requirement for second-doses
7. Vaccine Hesitancy



COVID-19 Vaccination Challenges

Need to Prioritize Critical Populations due to limited initial availability of COVID-19 vaccine



Update on Vaccine Rollout - Assumptions

November 20th	• Pfizer submits EUA application
November 30th	• Moderna submits EUA application
December 1st	• CDC Advisory Committee on Immunization Practices (ACIP) meets • U.K. Approves Pfizer Coronavirus Vaccine
December 8-10	• FDA's vaccine advisory committee meets to discuss COVID-19 vaccines • Could issue EUA approval at that time
December 11th or 12th	• CDC's ACIP meets to determine if everyone should get the vaccine, or if some people should be excluded. • OWS could begin shipping before ACIP guidance is issued; within 24 hours of EUA approval
December 13th	• Earliest anticipated arrival date of vaccines in Hawaii • Once ACIP issues its recommendations, vaccinations can be given
December 14th	• Earliest potential ability to begin vaccination

Overview of Draft COVID-19 Vaccination Plan

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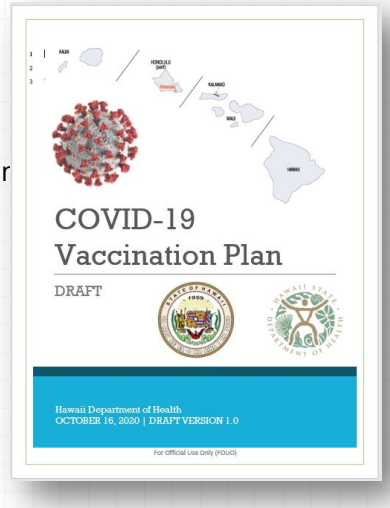
- K – References
- L – Plan Maintenance



Situation Overview

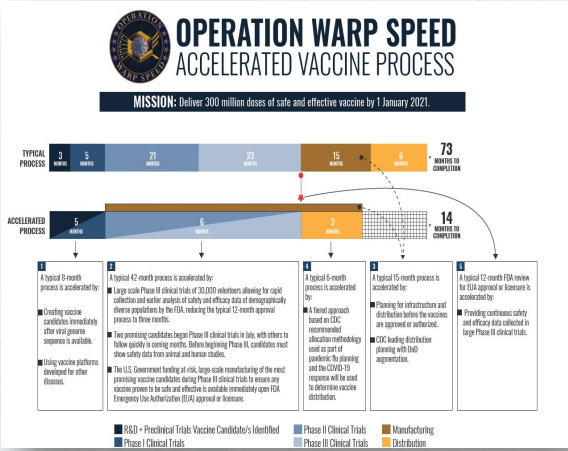
"Immunizing the U.S. population against COVID-19 will likely require the single largest vaccination campaign ever undertaken and require leaders from state public health, immunization, and emergency management systems to design and execute the vaccination operation."

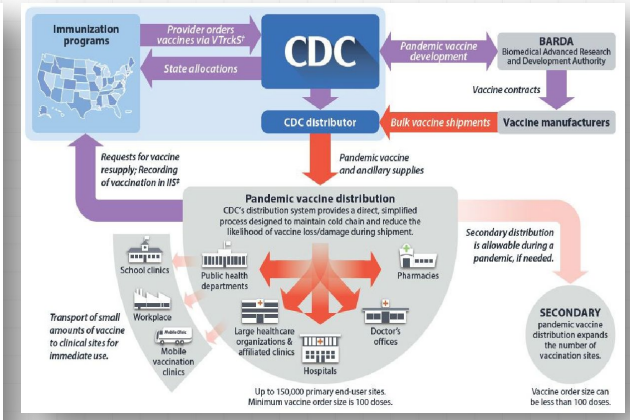
Situation Overview

"As with many COVID-19 activities, a "whole of government" response, with broad participation by health and human services, economic development, education, and public safety agencies, as well as private sector partners and the public, is crucial to success."

Situation Overview

“The challenge of vaccine development is matched by the challenge of vaccine distribution; once discovered and produced, it must be delivered and dispensed to the population writ large.”

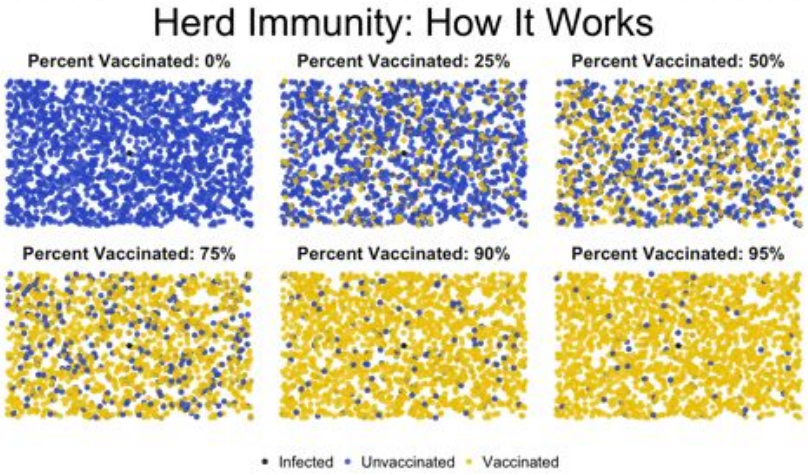




Achieving Herd Immunity

“In general, with a virus as contagious as SARS-CoV-2, around 60% of the population would need to be immunized to reach the herd immunity threshold”

- Dr. Amesh Adalja
  - Senior Scholar at the Johns Hopkins University Center for Health Security



Situation - Assumptions

Target Date	Number of Doses Provided by CDC Nationwide	Doses Allocated to Hawaii (.44% of Doses Available)	Total Number of People Vaccinated with 1st and 2nd Doses	Total Percentage of Population of Hawaii Age 18 and Older (1,116,000) Vaccinated
~~Nov 2020~~ Dec 2020	20,000,000	88,000?	44,000	4%
~~Dec 2020~~ Jan 2021	35,000,000	154,000	77,000	7%
~~Jan 2021~~ Mar 2021?	300,000,000	1,320,000	660,000	59%
Total	**355,000,000**	**1,562,000**	**781,000**	**70%**

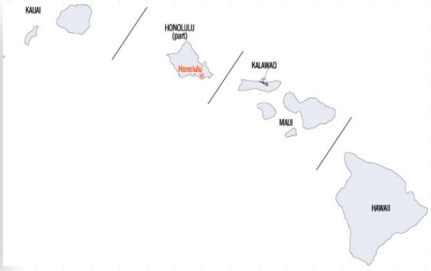
Situation - Assumptions

Delivery Schedule	Hawaii County	Maui	Molokai	Lanai	City and County of Honolulu	Kauai	Approximate number in group
March - Dose 1 (Group A – Stage 2)	29,738	23,265	995	456	125,566	10,594	190,627
April - Dose 2 (Group A – Stage 2)	29,738	23,265	995	456	125,566	10,594	190,627
April - Dose 1 (Group B – Stage 2)	29,738	23,265	995	456	125,566	10,594	190,627
May - Dose 2 (Group B – Stage 2)	29,738	23,265	995	456	125,566	10,594	190,627
May - Dose 1 (Group C – Stage 3)	29,738	23,265	995	456	125,566	10,594	190,627
June - Dose 2 (Group C – Stage 3)	29,738	23,265	995	456	125,566	10,594	190,627
Total doses needed	178,428	139,592	5,967	2,735	753,395	63,561	1,143,763
Daily Vaccination Target (Completing vaccinations in a 5-day period)	2,974	2,327	99	46	12,557	1,059	19,061

Need to be able to vaccinate approx. 19,000 people/day 5 days/week for 12 weeks

Mission Statement

The Hawaii State Department of Health (HDOH) will manage the rapid ordering and distribution of vaccine(s) to affected populations statewide in order to reduce COVID-19 related illness, hospitalizations, and death thereby establishing conditions for economic prosperity and societal normalcy.



Operational Phases

Phase 1

- Potentially Limited Doses Available

Phase 2

- Large Number of Doses Available, Supply Likely to Meet Demand

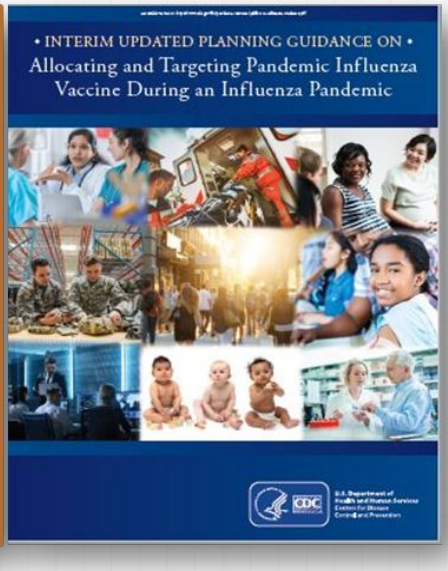
Phase 3

- Likely Sufficient Supply, Slowing Demand

Figure ES-5: Operational Phases

Planning Team Organization

"Guidance for allocating and targeting initial vaccination of certain groups includes a structure… that defines population groups in four broad categories that correspond with the objectives of a pandemic vaccination program – to protect people who
1) maintain homeland and national security,
2) provide health care and community support services,
3) maintain critical infrastructure, and
4) are in the general population."



COVID-19 Vaccination Program Organizational Structure with Working Groups

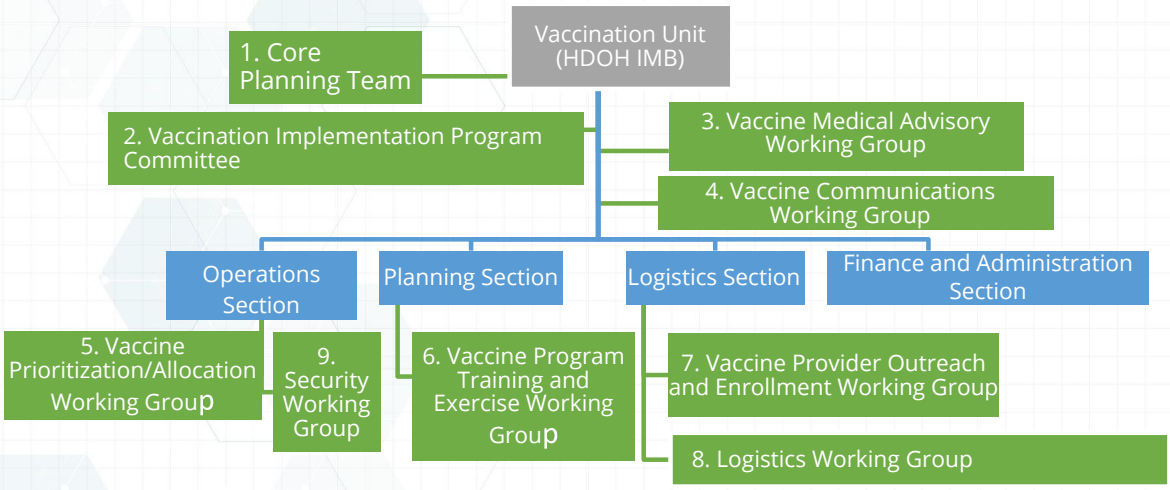
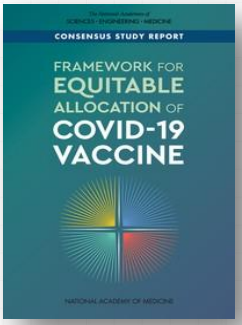


Figure A-2: COVID-19 Organizational Structure with Working Groups

Appendix C: Critical Populations
Vaccine Priority Groups by Allocation Stage

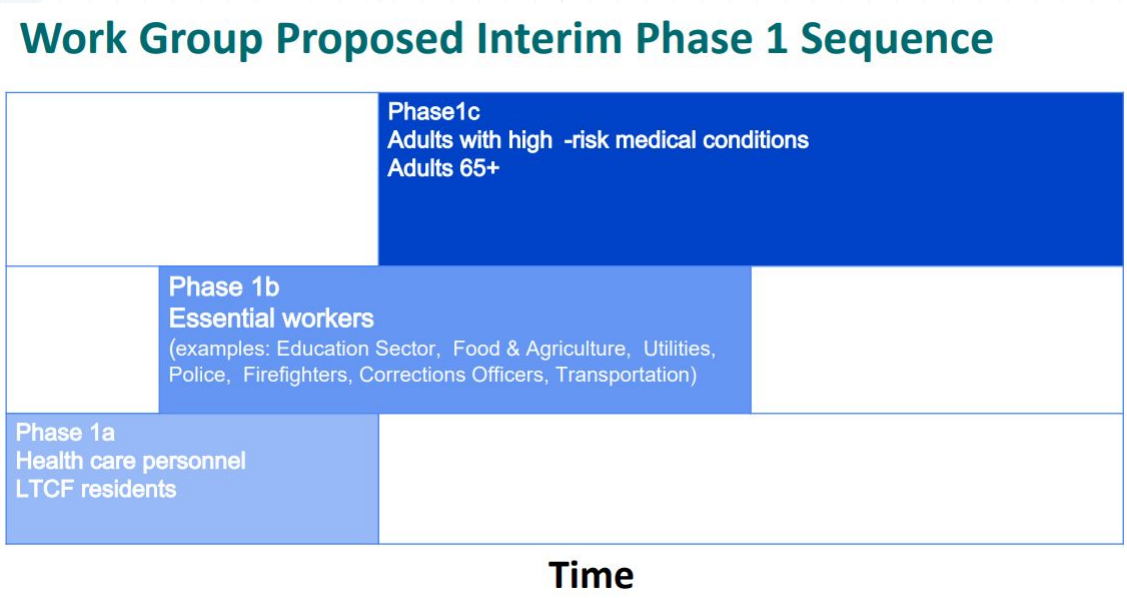
Allocation Stage	Population Group
Stage 1a	High-risk health workers (e.g., in hospitals or nursing homes, or providing home care)—these health professionals are involved in direct patient care. Also included are workers who provide transportation, environmental services, and other health care facility services and who risk exposure to bodily fluids or aerosols.
	First responders whose jobs put them at high risk of exposure to COVID-19
Stage 1b	People of all ages with comorbid and underlying conditions that put them at significantly higher risk
	Adults aged 65 and older living in congregate or overcrowded settings
Stage 2	K-12 teachers and school staff
	Critical risk workers in high-risk settings - workers who are both in industries essential to the functioning of society and at substantially high risk of exposure
	People of all ages with comorbid and underlying conditions that put them at moderately higher risk
	People in homeless shelters or group homes for individuals with physical or mental disabilities or in recovery and staff who work in those facilities
	People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings
	Adults aged 65 and older not included in Allocation Stage 1
Stage 3	Young Adults (18-22)
	Children (0-17)
	Workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Allocation Stages 1 or 2
Stage 4	Everyone residing in Hawaii who did not have access to the vaccine in previous allocation stages



ORIGINAL – THIS HAS BEEN REVISED as of 12/1

NOTE: When individuals within a group fall into multiple allocation stages, the higher allocation stage should take precedent. And, according to the NASEM framework, within each allocation stage, all groups have equal priority.

CDC Advisory Committee on Immunization Practices (ACIP)



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

ACIP Meeting – 1 Dec 2020

Proposed groups for Phase 1a vaccination

Health care Personnel[1,2] (HCP) (~21million)	Long-Term Care Facility (LTCF) Residents[3] (~3M)
Examples	
• Hospitals • Long-term care facilities • Outpatient clinics • Home health care • Pharmacies • Emergency medical services • Public health	• Skilled nursing facilities (~1.3 M beds) • Assisted living facilities (~0.8 M beds) • Other residential care (~0.9 M beds)

1. https://www.cdc.gov/infectioncontrol/guidelines/healthcare
2. personnel/index.htmlhttps://www.cisa.gov/publication/guidance -essential-critical-infrastructure-workforce
3. https://www.cdc.gov/longtermcare/index.html

Allocation Discussion – Stage 1a

Population Group	Hawaii County	Maui	Molokai	Lanai	C&C Honolulu	Kauai	Total
High-risk Health Workers	3312	1603	181	66	30245	887	36294
Number of Estimated Doses (70%)	2318	1122	127	46	21172	621	25406

Skilled nursing facilities				Other eligible facility types*		
# of facilities signed up	# of certified beds reported	Estimated allocation (# of certified beds x 2 [to account for staff])		# of facilities signed up	# of certified beds reported	Estimated allocation (# of certified beds x 2 [to account for staff])
46	4,314	8,628		31	2,670	5,340

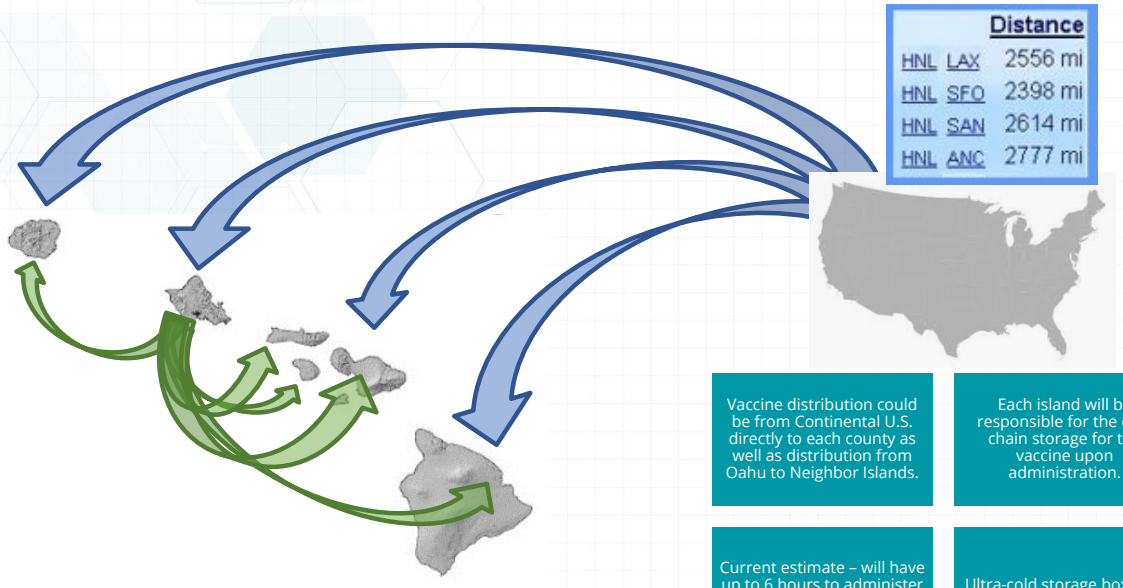
	Hawaii	Maui	Molokai	Lanai	Honolulu	Kauai	Total	
Older adults (≥65 years to 79 years)	29,561	19,727	1,118	485	116,511	10,305	177,711	Group accounts for approximately 80 percent of reported deaths related to COVID-19 (United States). Population-level COVID-19 mortality risk is estimated to be 16- to 52-fold higher (United States) and 30- to 100-fold higher (worldwide) for this group than for younger people.
Older adults (>80 years)	8,652	5,940	416	174	49,921	3,133	68,244	Group is experiencing a mortality rate 5-fold greater than average (United States). Group is experiencing an "overwhelming percentage" of severe outcomes due to COVID-19 (worldwide).
	38,213	25,667	1,534	659	166,432	13,438	245,955	

*Includes assisted living, CCRC, personal care homes, residential care, adult family home, adult foster home, IDD, HUD 202, Veteran's homes

Appendix D: Logistics

- Vaccine Allocation
- Vaccine Ordering
- Vaccine Distribution
- Vaccine Inventory Management
- Vaccine Recovery
- Strategies to Minimize Wastage of Vaccine, Constituent Products, and Ancillary Supplies
- Biomedical Waste Handling
  - Tab 1: Vaccine Administration Capacity
  - Tab 2: Vaccination Provider Recruitment and Enrollment
  - Tab 3: Satellite, Temporary, and Off-Site Clinics
  - Tab 4: Vaccine Storage and Handling
  - Tab 5: Vaccine Administration Documentation and Reporting
  - Tab 6: Requirements for Immunization Information Systems (IIS) or Other External Systems.

Appendix D: Logistics
Vaccination Supply Chain & Distribution



Transit time by air up to eight hours

Vaccine distribution could be from Continental U.S. directly to each county as well as distribution from Oahu to Neighbor Islands.

Each island will be responsible for the cold chain storage for the vaccine upon administration.

Current estimate – will have up to 6 hours to administer vaccine after reconstitution with diluent

Ultra-cold storage box – up to 10 days w/o dry ice refill

Concept of Operations for Phase 1

COVID-19 Vaccination Program

Phase 1 Focus

Distribution to Vaccination Providers – Stage 1a

- Stage 1a (High-risk health workers (e.g., in hospitals or nursing homes, or providing home care)—these health professionals are involved in direct patient care. Also included are workers who provide transportation, environmental services, and other health care facility services and who risk exposure to bodily fluids or aerosols.

Distribution to Long-Term Care Facilities – Stage 1a

- Federal pharmacy providers (Walgreens/CVS)

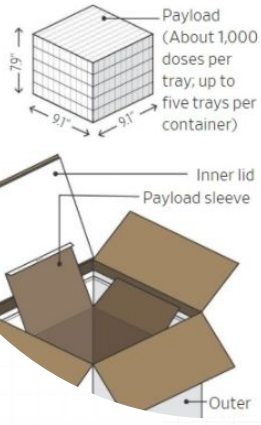
Distribution to Closed PODs – Stage 1a, Stage 1b

- Local and State First responders whose jobs put them at high risk of exposure to COVID-19

Distribution to Vaccination Providers

Vaccination provider site	Ordering assumptions			Operating assumptions				
	Order size	Storage conditions	Patient flow	Number of immunizers	Patients per immunizer	Hours per day	Vaccines per day	Shipment model
A – large outpatient center (mass vx)	1 tray (975 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	~500/day	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations	1 tray; 2-3 times per week
B – hospital or outpatient center	1 tray (975 doses)	Ultra-cold freezer, Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	4 immunizers	6 patients/hour (~10 min/Vx)	8 hours	192 vaccinations	1 tray; every week
C – large hospital with affiliated outpatient center	5 trays (4,875 doses)	Ultra-cold freezer, Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	7 immunizers (hospital outpatient clinic)	6 patients/hour (~10 min/Vx)	8 hours	340 vaccinations	1 tray; 1-2 times a week
D – outdoor parking lot vaccination hub at large retail pharmacy	1 tray (975 doses)	2-8C fridge, for product estimated at site (5 days)	~200/day	5 immunizers	6 patients/hour (~10 min/Vx)	N/A	240 vaccinations	1 tray; every week
E – mobile vaccination in targeted geographic areas	5 trays (4,875 doses)	2-8C fridge, for product estimated in mobile unit (5 days)	Variable	3 immunizers	6 patients/hour (~10 min/Vx)	Not specified	150 vaccinations	1 tray; every week
F – large indoor spaces not used during pandemic (convention hall)	(4,875 doses)	with dry ice, 2-8C fridge, for product estimated at site (5 days)			(~10 min/Vx)		vaccinations	every week
G – Drive-through vaccination clinic	3 trays (2,925 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations (by 7 days)	2-3 trays; very week

Figure 2: Vaccine A vaccination provider site archetypes for shipment timing and site planning



Distribution to Closed PODs

Distribution CONOPS

General Stations in a Vaccination Clinic

Station 1: COVID - 19 Screening

Pre Screen patients for symptoms; defer immunization of individuals who fail pandemic screening and refer them for other medical care as appropriate

Station 2: Registration

Greet and hand necessary registration forms to patient or guardian if not previously filled out online

Station 3: Medical Screening

Review patient immunization records and determine needed vaccines

Station 4: Vaccination Area

Deliver vaccinations to patients

Station 5: Post-Vaccination Waiting Area

Observe patients for 15 minutes to ensure no adverse reactions especially if driver was vaccinated

Station 6: Exit

Patients exit clinic through a different entrance to reduce contact between patients

POD Considerations

- Central location
- State/city-owned facility/location
- Anticipated quantity of doses
- Available restrooms for staff
- IT requirements
- Power/generator needs
- Available parking
- Security
- Availability on dates of both first dose and second dose

Estimated Staffing per Site

With 64 staff per site can process 325 people per day in approx. 2 hours

Requires 65 multi-dose vials (5 doses per vial) per location = 325 doses per location

Position	Number per Shift	Source of Stat (tent.)	Experience
Traffic control lead	1		Nonmedical
Traffic control	4		Nonmedical
Station 1: COVID-19 Screening	8		Nonmedical
Station 2: Registration	8		Nonmedical
Station 3: Medical Screeners	4	Coordinated by HDOH	Medical: nurse
Station 4: Vaccination Station (VS)	8	Coordinated by HDOH	RNs, LPN, others as dictated by state laws
Station 4: Vaccine Preparer/Supply to VS	8	Coordinated by HDOH	LPN, MT
Station 5: Post-Vaccination Waiting Area/Exit Review	4	Coordinated by HDOH	RN or public health person for questions/instruction/ observation and form verification
Medical Records/Data Entry Lead	1		Nonmedical (IT)
Medical Records/Data Entry	8		Nonmedical, vaccine info and doses administered data processed
Clinic Manager	1	HDOH	Medical Public Health Nurse (PHN)
Deputy Clinic Manager	1	HDOH	Medical Public Health Nurse (PHN)
Logistics Manager	1		Nonmedical
Deputy Logistics Manager	1		Nonmedical
Security	2		Nonmedical
Float Staff	2		Nonmedical
Float Staff	2	Coordinated by HDOH	RNs, LPN, others as dictated by state laws
Total Personnel (Medical)	28	Coordinated by HDOH	Medical
Total Personnel (Nonmedical)	36		Nonmedical
Total Personnel	64		

Translator (not counted in total clinic staffing estimates)	TBD	TBD	Language fluency with training

Discussion - Distribution to Long-Term Care Facilities

"With no vaccine, about 179,000 people may die in the first six months of 2021, Springborn says.

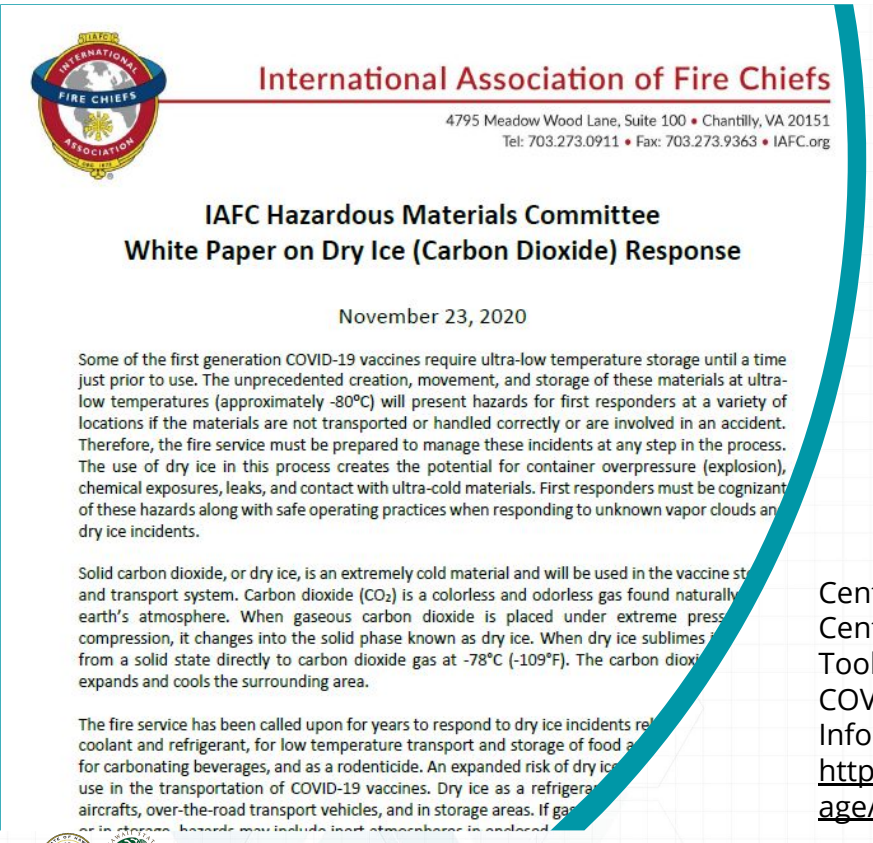
His team's model suggests that deaths could decline to about 88,000 if a vaccine were introduced gradually, given to 10% of the population each month, and distributed uniformly without prioritizing any groups.

But distributing vaccines in a targeted way, based on people's ages and whether they are essential workers, could save another 7,000 to 37,000 lives, depending on the situation."

https://www.technologyreview.com/2020/11/20/1012313/who-should-get-a-covid-19-vaccine-first/

Federal pharmacy partner will:

- Schedule and coordinate on-site clinic dates directly with each facility.
- Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
- Ensure cold chain management for vaccine.
- Provide on-site administration of vaccine to all residents and any staff not already vaccinated.
- Report required vaccination data to the local, state/territorial, and federal jurisdictions within 72 hours of administering each dose.
- Adhere to all applicable CMS COVID-19 testing requirements for LTCF staff.



International Association of Fire Chiefs

4795 Meadow Wood Lane, Suite 100 • Chantilly, VA 20151
Tel: 703.273.0911 • Fax: 703.273.9363 • IAFC.org

IAFC Hazardous Materials Committee
White Paper on Dry Ice (Carbon Dioxide) Response

November 23, 2020

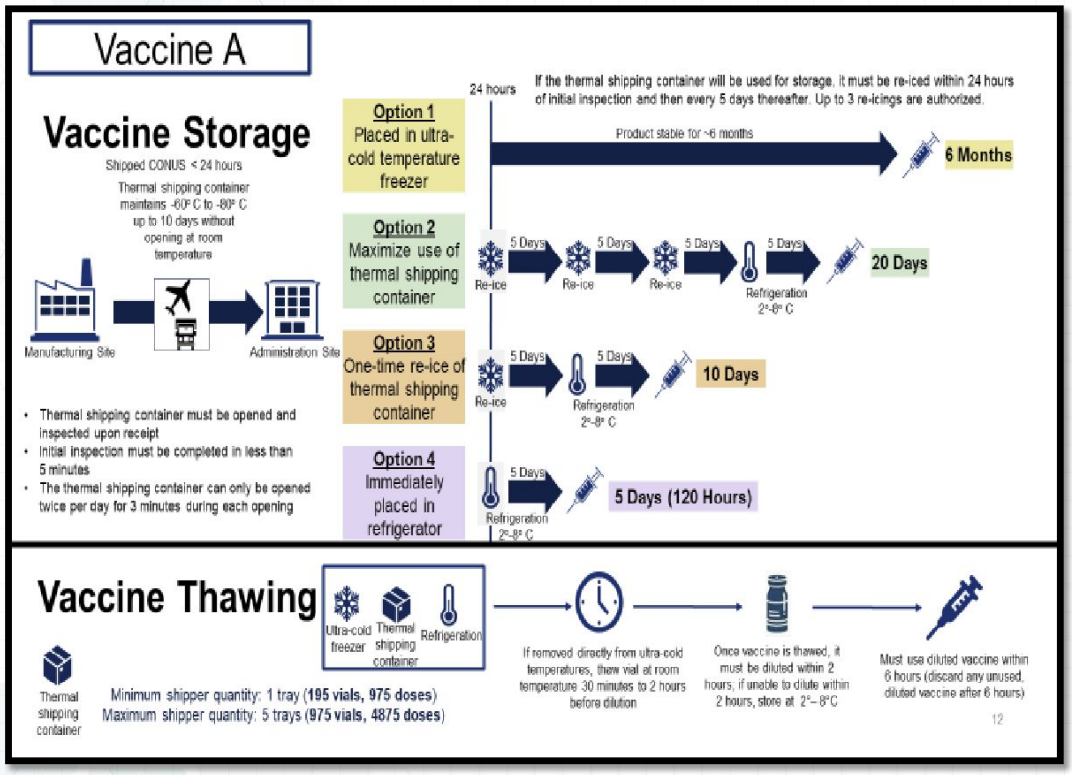
Some of the first generation COVID-19 vaccines require ultra-low temperature storage until a time just prior to use. The unprecedented creation, movement, and storage of these materials at ultra-low temperatures (approximately -80°C) will present hazards for first responders at a variety of locations if the materials are not transported or handled correctly or are involved in an accident. Therefore, the fire service must be prepared to manage these incidents at any step in the process. The use of dry ice in this process creates the potential for container overpressure (explosion), chemical exposures, leaks, and contact with ultra-cold materials. First responders must be cognizant of these hazards along with safe operating practices when responding to unknown vapor clouds an dry ice incidents.

Solid carbon dioxide, or dry ice, is an extremely cold material and will be used in the vaccine st and transport system. Carbon dioxide (CO_2) is a colorless and odorless gas found naturall earth's atmosphere. When gaseous carbon dioxide is placed under extreme press compression, it changes into the solid phase known as dry ice. When dry ice sublimes from a solid state directly to carbon dioxide gas at -78°C (-109°F). The carbon dioxi expands and cools the surrounding area.

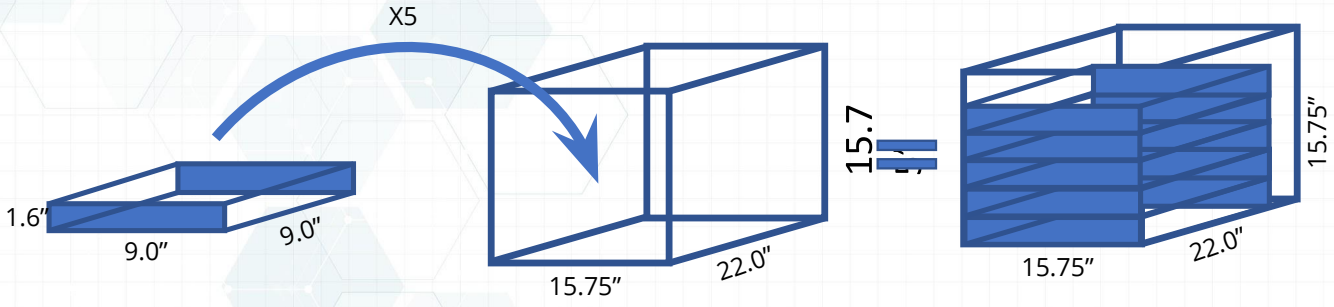
The fire service has been called upon for years to respond to dry ice incidents re coolant and refrigerant, for low temperature transport and storage of food a for carbonating beverages, and as a rodenticide. An expanded risk of dry ic use in the transportation of COVID-19 vaccines. Dry ice as a refrigera aircrafts, over-the-road transport vehicles, and in storage areas. If ga

Shipping and Handling

Centers for Disease Control and Prevention Center (CDC) Vaccine Storage and Handling Toolkit, Updated November 2020 (with COVID-19 Vaccine Storage and Handling Information), available at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html



Discussion on Logistical Requirements and Challenges COVID-19 Vaccination Scenarios for Jurisdictional Planning—Phase 1, Q4 2020



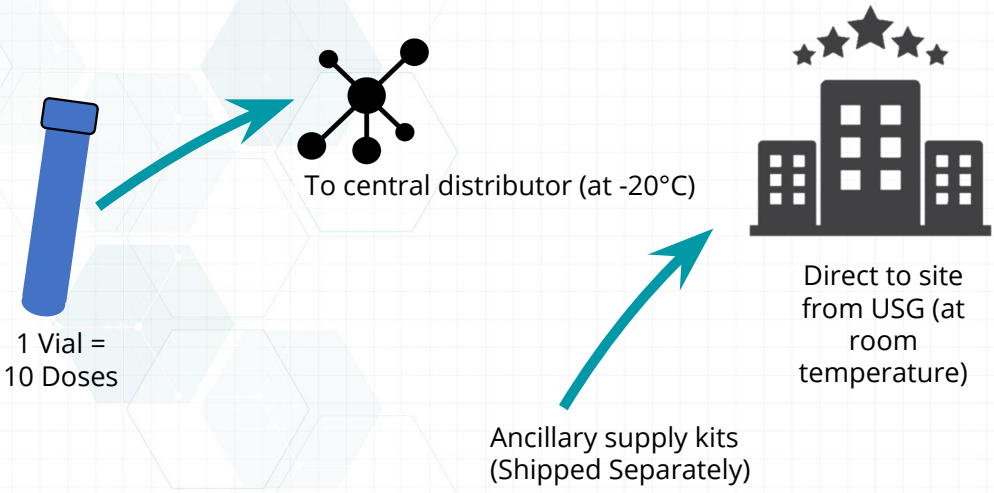
Tray
"Pizza Box"

Thermal shipper

Each shipper can hold up to 5 trays, and each tray will hold up to 195 vials (975 Doses).

Vaccine A = Pfizer

Discussion on Logistical Requirements and Challenges COVID-19 Vaccination Scenarios for Jurisdictional Planning—Phase 1, Q4 2020



Vaccine B = Moderna

Additional Q&A/Wrap Up

Ron Balajadia, Department of Health Immunization Branch chief

Dr. Sandra Chang, DOH Medical Advisory Group Co-Chair

Dr. Josh Green, Lieutenant Governor

Dr. Steven Hankins, DOH Medical Advisory Group Co-Chair, Facilitator

LTC Jon Ishikawa, HING

Dr. Sarah Kemble, DOH State Epidemiologist

Hilton Raethel, President & CEO, Healthcare Association of Hawaii

Jon Shear, ReadyZoneHQ