

County of Humboldt

COVID-19 Vaccine Distribution Concept of Operations (CONOPS)



February 5, 2021



This Concept of Operations (CONOPS) was developed in partnership between the Humboldt County Operational Area Emergency Operations Center (EOC), Humboldt County Sheriff's Office (HCSO), Humboldt County Department of Health and Human Services, Public Health Branch. The contents of this CONOPS incorporate lessons learned from H1N1, best practices provided by the County of San Mateo, and protocols detailed in the Humboldt County Public Health Branch (HCPHB) Medical Countermeasures (MCM) Emergency Response Plan.

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Introduction

As of January 15, 2021, the COVID-19 pandemic has infected 2,263 and killed 24 people in Humboldt County. COVID-19 is the disease caused by the SARS-CoV-2 virus.

This Concept of Operations (CONOPS) outlines the strategic goals and mission areas of vaccine distribution and administration, and also provides the operational detail necessary to implement such a response. It also serves to inform Humboldt County communities of initial COVID-19 vaccination efforts to distribute COVID-19 vaccine. The CONOPS consolidates as much of the County's vaccine allocation and distribution strategy in one place as succinctly as possible in order to answer stakeholder and community questions about the process. It will be updated as additional vaccine candidates are allocated to the County and as additional population subgroups are targeted for the distribution.

Two COVID-19 vaccines have been the first to be distributed in the U.S. and in Humboldt County: one made by Pfizer/BioNTech, and one made by Moderna. Several other pharmaceutical companies, including AstraZeneca and Janssen, are developing COVID-19 vaccine candidates which may become available in Humboldt County at a later date. The table below details some of the clinical attributes and key storage metrics for the vaccines:

Pfizer BIONTECH		moderna		Other Vaccine Candidates	
Name	BNT162B2	Name	MRNA-1273	Companies	Janssen, Novavax, AstraZeneca, Merck
Type	mRNA	Type	mRNA	Types	Viral vector, Antigen, Vector, Replicating Viral Vector
EUA Granted	December 11, 2020	EUA Granted	December 18, 2020	EUA Granted	
Efficacy	95.0%	Efficacy	94.5%	Efficacy	
Number of Doses	2 doses, 21 days apart	Number of Doses	2 doses, 28 days apart	Number of Doses	2 doses, 28 days apart (AstraZeneca), 1 dose (Janssen)
Side Effects	Fever, soreness at injection site, headache, fatigue, chills	Side Effects	Muscle aches, mild fever, fatigue, chills	Side Effects	
Ultra Low Storage	-80°C to -60°C (-112°F to -76°F), 6 months	Ultra Low Storage	-25°C to -15°C (-13°F to 5°F), 6 months	Ultra Low Storage	
Regular Cold Storage	2°C to 8°C (36°F to 46°F), 5 days	Regular Cold Storage	2°C to 8°C (36°F to 46°F), 30 days	Regular Cold Storage	
Room Temp Storage	2 hours (before dilution) 6 hours (after dilution)	Room Temp Storage	12 hours (unopened) 6 hours (after withdrawing 1 st dose)	Room Temp Storage	

Emergency Use Authorization (EUA) is a mechanism that the U.S. Food and Drug Administration (FDA) uses in order to quickly and efficiently authorize medical countermeasures, such as vaccines, for use during a public health emergency such as a global pandemic.

EUA is granted following a thorough review and determination by the FDA that the known and potential benefits of a vaccine or other pharmaceutical product outweigh the potential risks.



Given the high efficacy of vaccines as indicated by clinical trials, it is estimated that 70% of the population must receive a vaccine in to achieve herd immunity, which occurs when a disease no longer spreads because enough of the population is immune. It will be especially important for healthy adults over the age of 18 to get the COVID-19 vaccine to reach this proportion, since it has not yet been well studied in children and many individuals who are immunocompromised cannot be vaccinated.

An important fact regarding vaccination is that most of the vaccines mentioned above require two (2) doses given several weeks apart in order to reach their desired effectiveness in preventing disease. This means that given Humboldt County's population of 135,000, herd immunity will not be achieved until approximately 70% of Humboldt County adults have been vaccinated (roughly 76,000 adult Humboldt County residents). This will be a massive, unprecedented undertaking that requires collaboration, cooperation, sacrifice, patience, and understanding.

The good news is that beginning the distribution of COVID-19 vaccines marks a major milestone in the fight against the pandemic. Due to the amount of time required to distribute the vaccine, and unknowns about the degree to which vaccinated persons may spread the disease, it is important to emphasize the continued importance of following non-pharmaceutical interventions such as masking and social distancing to protect oneself and others. Even after receiving a vaccine, individuals must continue to follow these measures to mitigate the spread of the virus.

The rest of this CONOPS outlines the guidelines Humboldt County is using to allocate the vaccine to across the county, detail the logistics behind distributing the vaccine, explain the distribution process, and elaborate on how the distribution of the vaccine will be reported and tracked.

Allocation Guidelines

Principles of Allocating Supplies of COVID-19 Vaccine

Humboldt County is utilizing guidance and recommendations for the allocation of COVID-19 vaccine from reputable, reliable sources, including:

- Center for Disease Control (CDC)
- Advisory Committee on Immunization Practices (ACIP)
- California Department of Public Health (CDPH)

The most current "Priority group" vaccination allocation guidance information is available from CDPH at: <https://covid19.ca.gov/vaccines/> .

Humboldt County is making equitable distribution a part of decisions related to vaccine distribution. Vaccination decisions include consideration of a variety of factors, including:

- Maximize benefit and minimize harms
- Promote justice
- Promote transparency
- Flexibility
- Timely and efficient distribution and conservation



Maximize Benefits and Minimize Harms

Allocation of COVID-19 vaccine maximizes the benefits of vaccination to both individual recipients and the overall population. In identifying population subgroups prioritized for vaccination, consideration is given to those at highest risk of, and from, infection. Additional factors, such as the importance of healthy first responders and frontline healthcare workers, are considered.

Promote Justice

The principle of promoting justice is an obligation to protect and advance opportunity for all persons to receive the vaccine. Allocation of the COVID-19 vaccine promotes justice by intentionally ensuring that all persons have equal opportunity to be vaccinated, both within population subgroups recommended for early vaccination, and as the vaccine becomes more widely available. In promoting this principle, we are committed to removing unfair, unjust, and unavoidable barriers to vaccination that disproportionately affect marginalized groups.

Promote Transparency

This relates to the decision-making process surrounding allocation of initial COVID-19 vaccines. Transparency is an essential principle to building and maintaining trust with our partners and the community we serve. In alignment with this principle, all decision making processes and plans for COVID-19 vaccine allocation are evidence-based, understandable, and pertinent information is made publicly available. As the disease and response evolve, we are committed to providing new information as it becomes available, and seek to deliver clear explanations about changes to the recommendations and response.

Flexibility

Humboldt County may adjust prioritization and allocations for a variety of reasons including to reflect changing guidance, vaccine availability, and/or available vaccine characteristics.

Timely and Efficient Distribution and Conservation

Humboldt County endeavors to never waste vaccine and to ensure that all doses are preserved and administered in a timely and efficient fashion. Despite advance planning and coordination, immunization will be accepted by some but not all to whom it is offered, and some doses will be left over and at risk of spoilage. This CONOPS empowers licensed vaccinators faced with the spoilage of vaccine to make reasonable efforts to vaccinate others with such vaccine, preferably vaccinating those in prioritized population subgroups. Conversely, Humboldt County analyzes the need and timing for second doses of vaccinations and conserve vaccine for that purpose in the best judgment of the Humboldt County Health Officer. The State of California has committed to allocating an equal amount of second doses to match the first dose allocation while allowing for 50% of second doses to be used as first doses if reserving second doses slows the distribution of vaccine. The hope is that conservation of supply is not necessary in order to provide a full round of vaccination to each individual receiving an initial dose.



Vaccination Delivery Resources and Approaches

Humboldt County utilizes the following resources to deliver vaccinations:

Public Health Nurse Vaccination Delivery (Limited):

- As first doses arrive in Humboldt County, limited amounts of vaccine have been administered by licensed staff members of Humboldt County Public Health Branch (HCPHB).
- Use of HCPHB staff in vaccination roles is not sustainable in any large-scale way, because it takes them away from other critical daily tasks related to disease testing, contact tracing, vaccination planning efforts, and other important efforts to mitigate the pandemic.
- In certain limited situations, HCPHB may determine that vaccination of a certain population subgroup is of such critical urgency that staff may be temporarily reassigned to carry out the vaccinations. An example is the deployment of several HCPHB staff to vaccinate at-risk staff of congregate living facilities such as skilled nursing homes, assisted living facilities, and residential care sites.
- CDPH's plan for vaccine delivery includes the public health system as a whole, to include not only Local Health Jurisdictions (LHJs), but also Multi-County Entities (MCEs) such as hospital systems that cross multiple counties, Federally Qualified Health Centers (FQHCs) and others.
 - Due to the nature of such a large-scale venture, LHJs are not the sole vaccinators in a countywide vaccination effort.
- The intent of the EOC and HCPHB is to rely on County-sponsored vaccine clinics as well as other community resources to administer vaccinations, as described below:

Hospitals and clinics (Expanding):

- HCPHB helps coordinate the delivery of vaccine and provide technical assistance to CaIVAX-enrolled healthcare facilities that employ licensed staff authorized for administering vaccine. HCPHB empowers these sites to provide vaccinations to populations in line with federal, state, and local allocation guidance.
- The sites prioritized to receive vaccine are determined by Public Health utilizing several factors including but not limited to: the Allocation Guidelines mentioned earlier in this CONOPS; perceived risk and consequence of the site's staff being infected; the number of site staff perceived to be at risk of exposure; and, the site's ability to provide additional vaccination services, including capacity to handle vaccination reservations and screening, to other population subgroups as designated and authorized.
- In coordination with HCPHB and the Emergency Operations Center, selected hospitals and clinics are encouraged to publicize, manage, and deliver vaccinations to targeted population subgroups beyond their own staff, in accordance with current vaccination phases and tiers. An example is Mad River Community Hospital vaccinating EMT/Paramedics from Arcata Fire and Humboldt Bay Fire during Phase 1A, Tier One.
- Healthcare workers in large systems were vaccinated as part of Phase 1A; once this was complete, healthcare providers transitioned into vaccinating individuals outside of their systems and/or established patients.



- The intent of utilizing hospitals and clinics is that the skilled and licensed staff at these sites will quickly build efficiency and independence and will continue to deliver vaccinations to designated population subgroups as the response evolves.
- Providence St. Joseph's is a multi-county entity (MCE) that the state provides a direct COVID-19 vaccine allocation to. These allocations may be used to support community-based vaccination clinics.

Pharmacy Partnerships (Expanding):

- HCPHB is following Governor Newsom's direction to utilize the federal "COVID-19 Pharmacy Partnership" program. The Partnership program is continuing to evolve, but in early January 2021 it enabled licensed employees of CVS and Walgreens drug stores to vaccinate at-risk residents of congregate living facilities such as skilled nursing homes, assisted living facilities, and residential care sites.
- The pharmacies prioritized to receive and administer vaccine will be determined by a variety of factors including state and federal program guidelines, store chain policies, capacity to handle vaccination reservations and screening, and the availability of licensed staff to vaccinate population subgroups.
- In coordination with HCPHB and the Emergency Operations Center, selected CalVAX-enrolled pharmacies are encouraged to publicize, manage, and deliver vaccinations to targeted population subgroups in accordance with current vaccination phases and tiers.
- The intent of utilizing pharmacies is that the skilled and licensed staff at these sites will quickly build efficiency and independence and will continue to deliver vaccinations to designated population subgroups as the response evolves.

Public Vaccination Site Clinics (Government + Volunteer Partnerships):

- In order to vaccinate 70% of Humboldt County adults in a timely way, high-throughput temporary "Vaccination Clinics" must be planned, staffed, and operated. These may be walk-up or drive-through models, located around the county.
- When developing, publicizing, and operating Public Vaccination Site Clinics, consideration should be given to the Allocation Guidelines described earlier in this CONOPS. This includes the need to promote justice and create equal opportunity.
- Vaccination Clinics are coordinated and managed by a combination of paid employees from HCPHB and the Humboldt County EOC.
- Vaccination Clinics are staffed primarily by volunteers. "Volunteers" includes: unaffiliated citizen volunteers and medically-licensed volunteers, recruited and sworn in for the COVID-19 pandemic as Disaster Health Volunteers (DHVs); established trained volunteers who are already sworn and affiliated (e.g., American Red Cross or CERT members); and, skilled/licensed paid employees of other entities whose salary/work time is donated by their employer (e.g., paid paramedics of Humboldt Bay Fire administering vaccinations).
- At each Vaccination Clinic, the ratio of HCPHB paid/licensed employees to volunteers is approximately 1:20. This means that a large Vaccination Clinic will require three (3) medically licensed HCPHB employees and 50-60 volunteers, to include volunteers with medical licensure to assist in overseeing clinical operations under the supervision of Public Health Nurses.



- Recruiting, screening, selecting, managing, scheduling large numbers of volunteers is very challenging, especially given the months of operation required and the realities of managing volunteer groups.
- Every site chosen for a temporary “Vaccination Clinic” requires advance visits, resource requests, and a signed Memorandum of Understanding (MOU) with the County EOC for the use of the site by the County.
- Every agency or entity that provides its paid staff or volunteers to assist the County at a Vaccination Clinic must have a signed MOU for their staff/volunteers.
- There are additional logistics and expenses that must be managed for each Vaccination Clinic. Examples include, but are not limited to, signage, cones and traffic control devices, an ambulance to be on-site in some cases.
- HCPHB may utilize its Medical Health Operational Area Coordinator (MHOAC) Program to seek mutual aid assistance from the region and/or state if local vaccination clinics cannot be sufficiently staffed with existing volunteer resources.

Allocation of COVID-19 Vaccine (Phases/Tiers of Implementation)

Humboldt County allocates COVID-19 vaccines in general alignment with current Phases/Tiers as promulgated by California Department of Public Health. When CDPH modifies State Orders and recommendations, Humboldt County will consider the new guidance and make modifications as deemed appropriate by County Public Health.

As of mid-January 2021, Humboldt County is allocating vaccine as follows:

TABLE: From CDPH Report “Local Vaccination Plans”

PHASE	TIER	DESCRIPTION	PLAN FOR VACCINATION	HOW WILL THEY BE NOTIFIED TO BE VACCINATED?	PROJECTED START DATE
<i>Phase 1a</i>	<i>Tier 1</i>	Acute care, psychiatric and correctional facility hospitals	Done in acute care hospital settings.	Through POC at each facility	Finishing 2nd doses
		Skilled nursing facilities, assisted living facilities, and similar settings for older or medically vulnerable individuals	CDC-pharmacy partnership	Through POC at each facility	Finishing 2nd doses
		Paramedics, EMTs and others providing emergency medical services	Coordinated by PH	Through POC at each facility	Finishing 2nd doses

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PHASE	TIER	DESCRIPTION	PLAN FOR VACCINATION	HOW WILL THEY BE NOTIFIED TO BE VACCINATED?	PROJECTED START DATE
Phase 1a	Tier 1	Dialysis centers	Coordinated by PH	Through POC at each facility	Finishing 2nd doses
	Tier 2	Intermediate care facilities for persons who need non- continuous nursing supervision and supportive care	CDC-pharmacy partnership and coordinated by PH	Through POC at each facility	Finishing 2nd doses
		Home health care and in-home supportive services	Coordinated by PH	Through POC at each facility, group, organization	Currently Vaccinating
		Community health workers, including promotoras	Coordinated by PH	Through POC at each facility, group, organization	Currently Vaccinating
		Public health field staff	Coordinated by PH	Through POC at facility, group, or organization	Currently Vaccinating
		Primary Care clinics, including Federally Qualified Health Centers, Rural Health Centers, correctional facility clinics, and urgent care clinics	Coordinated by PH	Through POC at facility, group, or organization	Currently Vaccinating
Phase 1a	Tier 3	Other settings and health care workers	Coordinated by PH	Through POC at facility, group, or organization	Currently Vaccinating
		Specialty clinics	Coordinated by PH	Through POC at facility, group, or organization	Currently Vaccinating

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PHASE	TIER	DESCRIPTION	PLAN FOR VACCINATION	HOW WILL THEY BE NOTIFIED TO BE VACCINATED?	PROJECTED START DATE
		Laboratory workers	Coordinated by PH	Through POC at facility, group, or organization	Currently Vaccinating
		Dental and other oral health clinics	Coordinated by PH	Through POC at facility, group, or organization	Currently Vaccinating
		Pharmacy staff not working in settings at higher tiers	Coordinated by PH	Through POC at facility, group, or organization	Currently Vaccinating
Phase 1b	Tier 1	75+	Coordinated by PH and medical providers in our community.	Through primary clinic or invitation to PH mass vaccination effort. Media release and County website interest form.	Currently Vaccinating
		Food and Agriculture	Coordination by PH	TBD	Tentative – Late February/ Early March
		Education and Childcare	Coordination by PH	Through POC at facility, group, or organization.	Beginning Late February – Early March
		Emergency Services	Coordination by PH	Through POC at facility, group, or organization.	Beginning week of February 1 – mid/late February
Phase 1b	Tier 2	65-74 years with underlying medical conditions/ disabilities that place them at high risk for severe COVID-19 illness and death	Coordinated by PH and medical providers in our community.	Through primary clinic or invitation to PH mass vaccination effort.	TBD - Dependent on vaccine supply
		Incarcerated Individuals - jails and prisons	Coordination by PH	Through POC at facility, group, or organization.	TBD - Dependent on vaccine supply

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PHASE	TIER	DESCRIPTION	PLAN FOR VACCINATION	HOW WILL THEY BE NOTIFIED TO BE VACCINATED?	PROJECTED START DATE
	Tier 2	Homeless/Unhoused	Coordination by PH	Through outreach at facility, group, or organization.	TBD - Dependent on vaccine supply
		Transportation and Logistics	Coordination by PH	Through POC at facility, group, or organization.	TBD - Dependent on vaccine supply
		Industrial, Residential, Commercial	Coordination by PH	Through POC at facility, group, or organization.	TBD - Dependent on vaccine supply
		Critical Manufacturing	Coordination by PH	Through POC at facility, group, or organization.	TBD - Dependent on vaccine supply
Phase 1c	Tier 1	65-74 years	Coordinated by PH and medical providers in our community.	Through primary clinic or invitation to PH mass vaccination effort.	TBD - Dependent on vaccine supply
		16-64 years with underlying medical conditions/ disabilities that place them at high risk for severe COVID-19 illness and death	Coordinated by PH and medical providers in our community.	Through primary clinic or invitation to PH mass vaccination effort.	TBD - Dependent on vaccine supply
Phase 1c	Tier 1	Water and Waste Management, Defense, Energy, Chemical and Hazardous, Communication and IT, Financial Services	Coordination by PH	Through POC at facility, group, or organization.	TBD - Dependent on vaccine supply
		Government Operations/Community Services	Coordination by PH	Through POC at facility, group, or organization.	TBD - Dependent on vaccine supply

* "Coordination by PH" indicates that HCPHB is either hosting clinics for the specified group, working with a partner agency to hold clinics, or directing vaccination guidelines in settings such as clinics, pharmacies, hospitals, and/or FQHCs.

Table found at: <https://humboldt.gov/DocumentCenter/View/92365/Humboldt-County-COVID-19-Vaccination-Plans>



Coordination, Publicity, and Public Information

Role of County Public Health Branch (HCPHB)

The County Health Officer or designee is the primary authority overseeing the type and location of different vaccination sites and providers around Humboldt County, with the total number of approved sites being determined by the State of California. Staff members of HCPHB may offer assistance and support to these entities as resources allow, appropriate and practicable to do so. HCPHB programs house the technical expertise to support mass vaccination efforts in Humboldt County.

Role of County Emergency Operations Center (EOC)

The County EOC supports and coordinates key parts of the response in partnership with HCPHB and other entities. Planning, coordination, financial tracking, and reporting consistent with the Standardized Emergency Management System (SEMS) and National Incident Management System (NIMS) are examples of the EOC's involvement. The County EOC's Logistics Section helps plan for and support the operation of public "Vaccination Clinics". The County EOC's Operations Section houses the Vaccination Branch which completes the bulk of outreach to population subgroups and clinic coordination/implementation. Staff members of HCPHB, including the Immunization Clinic and Emergency Preparedness Program, are assigned to work within the Humboldt County EOC's Operations Section, under the clinical direction of HCPHB. The County EOC Director oversees the Joint Information Center (JIC) which coordinates public messaging and incident related information.

Role of County Joint Information Center (JIC)

Located within the County EOC, the JIC produces many different public information products and handles hundreds of phone calls and emails from the public each week. As the response has evolved, inquiries about vaccine availability have skyrocketed; over 80% of calls received in late January have been about vaccination. This includes persons wishing to be vaccinated and possible volunteers offering to help. The JIC has proven to be a reliable and trustworthy source of information for the public, but it cannot maintain this status unless all vaccination program information including dates/times/places of vaccine availability are shared with the JIC. The JIC will also support vaccination efforts by acquiring additional staff to assist with vaccine appointment registration.

Logistics

Receipt and Distribution of Vaccine Allotments

The State of California (CDPH) is the ultimate authority determining the shipping destination(s) for vaccine allotments sent to Humboldt County. As the response evolves, CDPH may modify the destination(s) and/or the quantities and types of vaccine allotments shipped. There are many factors influencing the type, quantity, and shipping destinations, including but not limited to inventory, supply chains, and the needs and abilities of various sites and counties to securely store and vaccinate. Currently, the following entities have been directly receiving vaccine allocations shipped into Humboldt County:

- Humboldt County Public Health Branch
- Designated pharmacies
- Hospitals, including Multi-County Entities (MCE's)
- Designated community health centers



The vaccine arrives in two separate components: the vaccine, and the ancillary supply kit. Some COVID-19 vaccines require reconstitution, in which case a diluent is shipped as a third component. Diluent and ancillary supplies are properly proportioned to match the amount of vaccine allotted to the site. The diluent is provided at room temperature. For COVID-19 vaccines that require reconstitution with dilutant or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies are also included.

COVID-19 vaccine, dilutant, and ancillary kits are shipped to vaccination provider sites enrolled by the jurisdiction's immunization program within 48 hours of order approval. Because of cold chain requirements, ancillary supply kits (and diluent, if applicable) are shipped separately from vaccine but should arrive before or on the same day as vaccine. Each distributing facility must have an official designated point of contact for receiving the vaccine shipment and confirmation of receipt, reported within one (1) hour of receipt. The point of contact is referred to as the **Vaccine Coordinator**.

Ancillary supplies are packaged in kits and are automatically ordered in amounts to match vaccine orders. Each kit contains supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit
- For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will also be included.

Ancillary supply kits do not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may also be needed depending on vaccination provider site needs, as ancillary supplies only include a limited number of face shields and surgical masks. Some entities may need to be prepared to provide these supplies for vaccination efforts. A centralized location may be established where Humboldt County pre-hospital providers could send couriers to pick up the vaccine from the location receiving direct shipments. Couriers and distributors should use the [Chain of Custody Form](#) included in Appendix B of this document to keep records of all exchanges of vaccine.

Vaccine Storage

Proper vaccine storage and handling is important from the moment the vaccine arrives at the site. All staff are trained to notify the Vaccine Coordinator or alternate (back-up) coordinator when a vaccine delivery has arrived.

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness. HCPHB staff works with the Vaccine Coordinator at each distributing facility to ensure appropriate vaccine storage and handling procedures are established and followed. The COVID-19 vaccines have a hold time at room temperature of less than 6 hours.



There are 3 separate options for vaccine storage at the point of vaccination: an Ultra-Low Temperature Freezer, the thermal shipper designed for temporary storage that the vials were sent in, and a 2 to 8°C (36 to 46°F) refrigerator. For a reliable cold chain, three elements must be in place: a well-trained staff, reliable storage and temperature monitoring equipment, and accurate vaccine inventory management.

To minimize opportunities for breaks in the cold chain, most COVID-19 vaccines are delivered from CDC's centralized distributor directly to the location where the vaccine is stored and administered, although some vaccine may be delivered to secondary depots for redistribution.

Dispensing

Decentralization of Vaccination Efforts

Hospitals, clinics, and pharmacies with licensed personnel qualified to administer their own vaccinations are encouraged to organize and train staff to dispense the COVID-19 vaccine to their own critical personnel. Humboldt County may have trained staff to offer, however they will be in high demand and potentially short supply as vaccination efforts expand. Each entity will be encouraged to pre-assign and train vaccine dispensing staff to cover their own critical personnel. If entities agree to assist with vaccine administration, they will be responsible for ensuring that all vaccine administrators are properly credentialed and qualified. If assistance is needed, entities may partner with county sponsored vaccination clinics, utilizing the EOC's infrastructure/logistics to support their vaccination efforts (e.g., entities may provide staff to a county sponsored clinic and set up a separate lane to vaccinate their personnel).

COVID-19 Vaccination Provider Staffing & Training

Hospitals, clinics, and pharmacies with licensed personnel are encouraged to designate pre-assigned vaccination dispensing staff. These staff may include a team consisting of vaccinators, couriers, and data entry people who would set up at a centralized vaccine clinic site where persons to be vaccinated should be scheduled to receive the vaccine. Agency partners are welcome to add and supplement existing positions in accordance with setting up and running vaccine clinics and/or POD sites.

Training of COVID-19 vaccination providers is vital to ensure the success of the COVID-19 Vaccination Program. The CDC has many educational resources available for use (even some for co-branding), Online videos may be particularly useful for convenient access and standardization of instruction. Each vaccine manufacturer is also developing educational training resources for its individual vaccine candidates which will likely be available. The Fact Sheet for Healthcare Providers Administering Vaccine for the Pfizer/BioNTech COVID-19 vaccine may be found at: <https://www.fda.gov/media/144413/download>.

All COVID-19 vaccination providers should be trained and understand the following:

- ACIP COVID-19 vaccine recommendations, when available
- How to order and receive COVID-19 vaccine
- COVID-19 vaccine storage and handling (including transport requirements)
- How to administer vaccine, including mixing with diluent, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
- How to document and report vaccine administration via California Immunization Registry (CAIR) or other system approved by the Humboldt County DHHS Public Health Branch.



- How to manage vaccine inventory, including accessing and managing product expiration dates
- How to report vaccine inventory
- How to manage temperature excursions
- How to document and report vaccine wastage/spoilage
- Procedures for reporting adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets to vaccine recipients
- How to track daily vaccine inventory to report to CDC's VaccineFinder. Vaccine couriers must sign out and sign in vaccine supply with the pickup location and should keep documentation of those exchanges using the [Chain of Custody Form](#) to promote accountability.

Administration Best Practices

CDC recommends following 5 best practices for COVID-19 administration regardless of the vaccine scenario as outlined below:

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Always follow the manufacturer's instructions for preparing vaccine.
- Only prepare vaccines when you are ready to administer them.
- Always check expiration dates. If your facility stocks multiple vaccine products, always confirm you have selected the correct vaccine.
- Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration. Pre-drawing vaccine can result in waste when more is drawn up than needed. In the rare instances when it is necessary to pre-draw vaccines, it is important to follow recommended guidance to avoid compromising and wasting vaccine and to maintain the cold chain. Carefully follow the toolkit best practices for pre-drawing vaccine as well as any manufacturer guidance.

Vaccine Reconstitution

Vaccine preparation is the final step in the cold chain before administration. Handling vaccines with care is equally as important as storing them properly. It is important to follow vaccine preparation instructions provided in the vaccine product's EUA Fact Sheet for Healthcare Providers or the vaccine package insert. The following are vaccine reconstitution guidelines for the available vaccines:

Pfizer - BioNTech	Moderna
<ul style="list-style-type: none"> • Require on-site mixing • Must be diluted with diluent prior to administration • Five doses per 2mL vial • Must be administered within 6 hours of dilution • Remainder of diluted vaccine should be discarded • Diluent provided as part of ancillary kits 	<ul style="list-style-type: none"> • No dilution required • Vial must be thawed before use • Swirl <i>gently</i> prior to withdrawing dose and administering • Must be administered within 6 hours of withdrawing first dose • Do not shake • Do not return thawed vial to the freezer



Administering the Vaccine Before Administering

- All patients must be given any applicable vaccine Fact Sheets prior to the administration of any vaccine.
- If there are limited Fact Sheet hard copies available, Fact Sheets could be provided on a computer monitor, tablet, or some other video display. They could also be downloaded on an electronic device if a link or QR code is provided to each parent/patient.
- The EUA Fact Sheet for Recipients for the Pfizer/BioNTech vaccine can be downloaded from the FDA at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>.
- The EUA Fact Sheet for Recipients for the Pfizer/BioNTech vaccine can be downloaded from the FDA at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine>
- Ensure that patients have a chance to have their questions answered. Give parents/patients a phone number to call in case of any questions or unexpected symptoms after receiving a vaccine.
- When possible, provide the Fact Sheet in the person's native or preferred language.
- Always double check the expiration date on vaccines and diluents before administering the vaccine.
- Keep the dispensing or vaccination station areas clean to avoid any contamination.
- Perform proper hand hygiene prior to preparing the vaccine.
- It is not recommended to pre-draw numerous doses of these vaccines as this can create wasted doses.

Administering the Vaccine

For more resources on vaccine administration see [ACIP General Best Guidance for Immunization: Vaccine Administration](#).

- Welcome the patient to establish rapport.
- Explain what vaccine will be given and what type of injection will be done.
- Identify any language barriers and connect with translation as needed (this should also be done at Registration).
- Confirm that the patient has reviewed the Vaccine Fact Sheet and ask if they have any questions.
- Double check that the appropriate forms have been completed and contain an accurate record of the patient and the vaccine lot number being given, as well as staff name/initials.
- Position the patient.
- Use a separate, sterile needle and syringe for each injection.
- Draw up the vaccine immediately before administration only.
- Identify the injection site, prepare with an alcohol wipe, and administer the vaccine at the proper angle.
- Use steady pressure while injecting the vaccine.
- Apply pressure to injection site for several seconds using a gauze pad or adhesive bandage.
- Properly dispose of the needle and syringe in a sharps container.
- Reassure the patient to help reduce anxiety and/or pain from the injection.
- Properly dispose of the vaccine vial.



After Administration

- Report any needlestick injury and maintain a sharp injury log.
- Direct the patient to wait in the observation area for a minimum of 15 minutes¹ with emergency supplies nearby to treat anaphylaxis emergency, and to immediately report any vaccine reactions, such as the following:
 - Soreness, redness, itching, or swelling at the injection site;
 - Slight or continuous bleeding;
 - Skin and mucosal symptoms such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes;
 - Respiratory symptoms such as nasal congestion, change in voice, sensation of throat closing, stridor, shortness of breath, wheezing, coughing, etc.;
 - Gastrointestinal symptoms such as nausea, vomiting, diarrhea, cramping, etc.;
 - Cardiovascular symptoms such as collapse, dizziness, tachycardia, or hypotension;
 - Any loss of consciousness.

It is not uncommon for patients to develop symptoms such as fever, fatigue, headache, chills, and myalgia following COVID-19 vaccination. These signs and symptoms may be challenging to distinguish from signs and symptoms of COVID-19 infection. To manage post-vaccination systemic signs and symptoms and prevent unnecessary work restrictions to vaccinated healthcare providers, the CDC has provided recommended strategies to evaluating and managing post-vaccination signs and symptoms which can be found here:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html>.

Additional guidance for medical management of vaccine reactions can be found at <https://www.immunize.org/catg.d/p3082a.pdf>.

Reporting

What is CAIR?

The California Immunization Registry (CAIR) is a secure, confidential, statewide computerized immunization information and reporting system for California residents. The CAIR system consists of 10 regional affiliates that cover the state. Each registry is accessed online to help providers and other authorized users track patient immunization records and help fully immunize Californians of all ages.

CAIR can only be used by authorized medical office staff, hospitals, and public health departments for the purposes of evaluating vaccine records, sending reminders, and protecting public health.

For the purpose of mass vaccination, centralized vaccine administration sites for pre-hospital providers may use CAIR to enter vaccine data and information for patients receiving COVID-19 vaccinations. These agencies and public health will work to make vaccinations accessible to their staff in order to help reduce the spread of COVID-19.

¹ 30 Minutes for persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy or a history of anaphylaxis due to any cause.



What Information Can Be Shared in a Registry?

- Patient's name, sex, and birthdate
- Parents' or guardians' names
- Limited information to identify patients
- Details about a patient's vaccinations

What's entered in the registry is treated like other private medical information. Misuse of the registry can be punished by law. Under California law, only an individuals' doctor's office, health plan, or public health department may see an individuals' address and phone number. Public health officials have access to the CAIR system in order to help prevent and respond to public health emergencies.

CAIR Mass Vaccination Module

For a basic overview of CAIR features and functionality please visit the [California Immunization Registry Training Video: Accessing CAIR](#).

Free CAIR training is available for pre-hospital provider staff. For local CAIR user support, including training options or local issue resolution please contact the [Local CAIR Representative \(LCR\) or Data Exchange Specialists](#).

To login go to: <https://massvac.cdph.ca.gov/>

For more information contact the CAIR Help Desk at 800-578-7889, or, CAIRHelpDesk@cdph.ca.gov.

Authorized Organizations entering information into CAIR are encouraged to organize all information before beginning to input information into the CAIR system. **PLEASE NOTE: You cannot save information without submitting it.** Remember to make a note of where you stopped so that you can start your data entry where you left off.

CAIR Standard Disclosure Policy

Per California Law ([Health and Safety Code, Section 120440](#)), all patients must receive proper disclosure before patient information can be entered into and shared through CAIR. Entry into and sharing of patient information through CAIR is understood to include any and all vaccine doses received by the patient, regardless of when the doses occurred relative to the date of disclosure. Patients also have the right to decline to have their information in CAIR shared with other participating organizations.

Please see the [CAIR Standard Disclosure Policy](#) for more information.

Each patient has the right to review their record for accuracy. Please see the [Immunization Registry Notice to Patients and Parents](#).

Translations of the 'CAIR Notice' into other languages is available at the [CAIR Forms page](#).

A patient may decline to have their child's information in CAIR shared, or 'locked', from other authorized organizations that use CAIR while maintaining access so that only the patient's medical care provider and public health authorities will be able to view records. A record may be requested to be 'unlocked' at any time by the patient to allow other authorized CAIR users to view the patient record.



To request that a record in CAIR be 'locked' or 'unlocked' visit the [CAIR Forms page](#).

Dose Scheduling, Reminders, and Tracking

For most COVID-19 vaccine products, two doses of vaccine, separated by 21 or 28 days, are needed. Because different COVID-19 vaccine products are not interchangeable, the second dose must be from the same manufacturer as the first dose.

Second dose reminders for vaccine recipients are critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness.

Vaccination providers must fill out a line list with accurate vaccine information (e.g., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give guidance to each patient who receives vaccine on when and how to schedule their second dose. It is essential that vaccination record and report data in a timely manner to ensure reporting to CDPH is accurate.

If vaccine recipients have a smartphone, they may consider documenting their vaccine administration with a photo of their vaccination record and entering the date the next vaccine dose is due on their electronic calendar. Additionally, the CDC is offering [VaxText](#), a free text messaging second dose reminder resource. By texting ENROLL to 1-833-VaxText (829-8398) vaccine recipients can opt in to receive a weekly text reminder for their second dose of COVID-19 vaccine in English and in Spanish. VaxText offers the added benefit of reminding patients/parents/guardians to sign up for the CDC's active safety monitoring system, called V-SAFE.

Vaccine Safety Monitoring and Reporting

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national system co-managed by the CDC and the Food and Drug Administration (FDA) to collect reports from healthcare professionals, vaccine manufacturers, and the public of adverse events that happen after vaccination. Anyone can submit a report to VAERS, including parents and patients.

[VAERS online reporting](#) is strongly encouraged, or, download the [Writable PDF Form](#). Please report clinically important adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event. A VAERS report does not mean that the vaccine caused the health problem, only that symptoms occurred after vaccination.

VAERS accepts all reports, including reports of vaccination errors. [Guidance on reporting vaccination errors](#) is available if you have additional questions.

Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

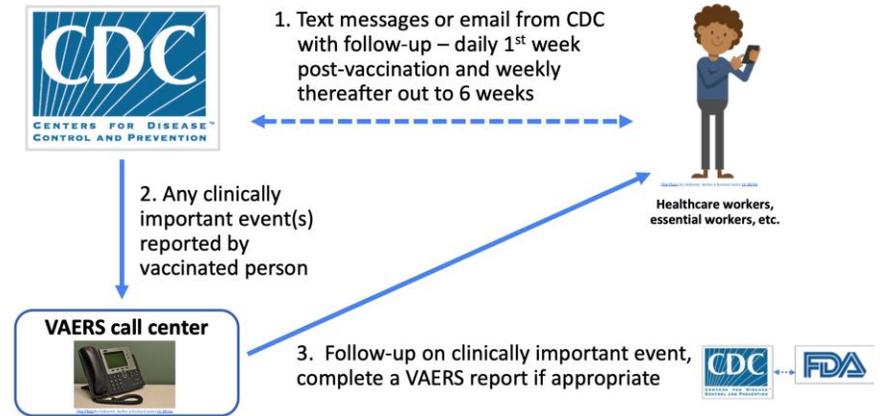


Vaccine Safety Assessment For Essential Workers (V-SAFE)

V-SAFE is a smartphone-based text, and text-to-web after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE uses text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination via text message and email.

The system will also provide telephone follow-up to anyone who reports medically significant (important) adverse events connected to the VAERS system.

Vaccine safety assessment for essential workers (V-SAFE)



DRAFT



GLOSSARY OF ACRONYMS

ACIP	Advisory Committee on Immunization Practices
CAIR	California Immunization Registry
CalVAX	CalVax is a vaccine management system created by CDPH
CDPH	California Department of Public Health
CERT	Community Emergency Response Team
CONOPS	Concept of Operations
DHV	Disaster Healthcare Volunteer
EOC	Emergency Operations Center
EUA	Emergency Use Authorization
EMS	Emergency Medical Services
EOC	Emergency Operations Center
FDA	Food and Drug Administration
HCSO	Humboldt County Sheriff's Office
HCPHB	Humboldt County Public Health Branch
IT	Information Technology
LHJ	Local Health Jurisdiction
MCE	Multi-County Entity
MCM	Medical Countermeasures



Appendix A: Acceptance/Declination Form

COVID-19 ACCEPTANCE / DECLINATION FORM

The Advisory Committee on Immunization Practices (ACIP) recommended that both 1) health care personnel and 2) residents of long-term care facilities be offered COVID-19 vaccine in the initial phase of the **COVID-19** vaccination program.

(Please choose one and sign)

_____ **I have chosen to receive the COVID-19 vaccination series.**

I have read the Emergency Use Authorization information (EUA) for Recipients and Caregivers on COVID-19 virus and vaccine and been given the opportunity to ask questions to understand the risks and benefits.

I also understand that I will continue to be required to wear appropriate PPE and practice social distancing. This vaccine will be provided to me free of charge.

_____ **I DECLINE COVID-19 vaccination at this time.**

I understand that due to my occupational exposure to COVID-19 I am identified as a health care worker at risk for contracting or transmitting COVID-19 virus.

I have read the EUA info on **COVID-19** and **COVID-19 vaccine** and been given the opportunity to ask questions to understand the risks and benefits. I have been given the opportunity to be vaccinated with **COVID-19 vaccine**, at no cost to myself. I understand that by declining the **COVID-19 vaccine**, I continue to be at risk for contracting and transmitting the COVID-19 virus, and if I want to be vaccinated with **COVID-19 vaccination** at a later date, I can receive the COVID-19 vaccination at no cost to me.

PRINTED NAME - _____ DATE - _____

SIGNATURE - _____

<https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm>

<https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>



Appendix B: Resource List

The County of Humboldt Emergency Operations Center recommends the following resources for additional information on the COVID-19 response in Humboldt County and on recommendations for the COVID-19 vaccine distribution process:

ACIP General Best Guidance for Immunization – Vaccine Administration	https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.pdf
California Immunization Registry Training Video – Accessing CAIR	https://www.youtube.com/watch?v=UoJ9iUX2isg&ab_channel=CAIR2
CDC COVID-19 Vaccine Training Module	https://www2.cdc.gov/vaccines/ed/covid19/
CDC Guidance on Post Vaccine Considerations for Healthcare Personnel	https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html
CDC Vaccine Storage and Handling Toolkit	https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
Pfizer/BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers	https://www.fda.gov/media/144413/download
Pfizer/BioNTech COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers	https://www.fda.gov/media/144414/download
Humboldt County COVID-19 Resources page	https://humboldt.gov.org/
Humboldt County COVID-19 Vaccination Plan	https://humboldt.gov.org/DocumentCenter/View/92365/Humboldt-County-COVID-19-Vaccination-Plans
Humboldt County COVID-19 Vaccination Information page	https://humboldt.gov.org/2872/Vaccine-Info