Vision

• Most of ~40M Californians will have equitably received safe and effective COVID-19 vaccines

• Severe COVID-19 illness minimized
  • Transmission of SARS CoV-2 reduced?

• Normalization of daily life
California’s Immunization Infrastructure

• ~19 Million influenza vaccine doses given in 2018-2019 season
  • Most of these given in a 3-4 months
• Tens of millions of other routine vaccine doses given per year
  • High immunization rates for children, lower for adults
• Most doses administered in clinical settings
  • >90% of doses given in clinics, hospitals, pharmacies...
• Local health departments (LHDs) key safety net
  • <10% of seasonal influenza doses
  • Surge capacity during pandemics, outbreaks, other urgencies
    • Double the routine doses in the 2009-10 H1N1 pandemic
Delayed Immunizations During the Pandemic

MMR Doses Recorded in CAIR, Children Age 4-6 Years

2019

2020

April

August

Data from the California Immunization Registry
Urgency of Influenza Vaccination in the Pandemic

• Reduce stress on the health care and public health system
  • Decrease medical visits, hospitalizations, outbreaks
  • Reduce diagnostic testing - Illnesses have similar symptoms

• Adults at high risk from both COVID-19 and influenza
  • Older age
    • Staff and residents of long-term care facilities; senior living facilities
  • Adults with underlying illnesses
  • African-American, Latinx and AI/NA populations
  • Essential workers/critical infrastructure workers
  • (Children have lower risk of COVID-19, but key transmitters of influenza)
Vaccine Development and Deployment
9/7/20: 239 COVID-19 vaccine candidates worldwide
40 undergoing clinical trials

https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/
Advanced Candidates
mRNA vaccines in US Phase III trials

**Moderna (mRNA-1273)**
- **Dosage:** 100 mcg
- **Administration:** 2 doses IM, 28 days apart
- **Doses per vial:** 10
- **Preservative:** None
- **Diluent:** None
- **Storage:**
  - Shipped, stored: –20°C (–4°F) for up to 6 months.
  - May refrigerate at 2-8°C (36-46°F) for up to 7 days.
  - Once the vial has been punctured, discard any doses unused after 6 hours.

**Pfizer/BioNTech (BNT162b2)**
- **Dosage:** 30 mcg
- **Administration:** 2 doses IM, 21 days apart
- **Doses per vial:** 5
  - Minimum 195 vials (975 doses) per shipment
- **Preservative:** None
- **Diluent:** Yes
- **Storage:**
  - Shipped, stored: –70°C (–94°F) for up to 6 months
  - If storing in special shipping container
    - Up to 10 days, if unopened.
    - Up to 6 months, if dry ice is replenished upon receipt and every 5 days, and if container openings are limited per instructions.
  - May refrigerate at 2-8°C (36-46°F) for up to 24 hours
  - May store at room temperature for up to 2 hours after thawing.
  - After mixing with diluent, use within 6 hours.
Emergency Use Authorization (EUA)

• Qualifying Criteria:
  – Declaration by HHS Secretary of emergency situation leading to serious or life-threatening disease or condition
  – Evidence of effectiveness for product intended to address emergency
    • EUA standard: “may be effective”
  – Known and potential benefits of the product outweigh the known and potential risks of the product
    • Intended use (e.g., number of individuals to be treated) and risk uncertainties impact application of EUA effectiveness standard
  – No adequate, approved, and available alternative
Operation Warp Speed
Subsidized large-scale manufacture, concurrent with trials

Planning Under Uncertainty
Planning Assumptions
based on information from CDC and past pandemics

- **Costs:** For the initial year(s), USG pays for vaccine and ancillary supplies.
- **Allocation to States:** Proportional to population
  - Federal Government will also allocate directly to: active military, VA, IHS...
- **Allocation plan within California:** LHDs direct local allocations
  - CDPH allocates to State facilities and perhaps other multicounty entities
- **Number of Doses:** Many vaccines will require 2 doses given over 3-4 weeks
- **Registration:** vaccinators into CDPH system; vaccinated into CAIR
- **Ordering system:** Modification of current CDPH systems
- **Distribution:** Feds to fund distributor (similar to VFC)
  - Distributor or Manufacturer ships directly to vaccinators based on LHD’s selections
- **Education, communication, media:** National campaign and materials from CDC and supplemented by CDPH
Administration of COVID-19 vaccine will require a phased approach

**Limited Doses Available**
- Projected short period of time for when doses are limited
- Constrained supply, central distribution
  - Cold chain & handling may require specialized equipment and high throughput

**Large Number of Doses Available**
- Likely sufficient supply to meet demand
- Additional vaccine products allow a wider range of administration locations
- Broad administration network required
  - Pharmacies, doctors offices, public health clinics, mobile clinics, FQHCs
  - Focus on increasing access for critical populations

**Continued Vaccination**
- Sufficient supply to meet demand
  - Harness vaccine provider networks with proven ability to reach critical populations
  - Enhance series completion

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**Phase 1a: Healthcare personnel**

**Phase 1b may include: Essential Workers, High risk Medical Conditions, Adults 65+**
Critical Unknowns about COVID-19 vaccines

- **Timing**: ETAs range from late 2020 to 2021 or later
- **Volume**: OWS accelerating production; goal of 100M+ courses in 2021
- **FDA status** of initial and later vaccines: First EUA, then licensure?
- **Effectiveness**: if elderly, comorbidity, or receipt of partial series?
- **National prioritization guidelines**
  - Currently under discussion by ACIP, NAS
  - UK preliminary guidelines: medically at risk, frontline health or social workers
  - Where will certain risk groups (e.g., LTCF staff, meat packers) be immunized?
- **Public acceptance** once available: Polling suggests 25% might not accept vaccine.
Priority Groups?
## NAM Committee – Prioritization

**DRAFT TABLE 2** Applying the Allocation Criteria to Specific Population Groups

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<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>High risk workers in health care facilities</td>
<td>H</td>
<td>M</td>
<td>H</td>
<td>H</td>
<td>High risk of acquiring infection due to no choice in setting but may have access to personal protective equipment. Essential to protecting the health care system.</td>
</tr>
<tr>
<td>1a</td>
<td>First responders</td>
<td>H</td>
<td>M</td>
<td>H</td>
<td>H</td>
<td>High risk of acquiring infection due to no choice in setting but may have access to personal protective equipment. Essential to protecting the health care system.</td>
</tr>
<tr>
<td>1b</td>
<td>People with significant comorbid conditions</td>
<td>M</td>
<td>H</td>
<td>M</td>
<td>L</td>
<td>High risk of severe morbidity and mortality, but may be able to social distance and isolate.</td>
</tr>
<tr>
<td>1b</td>
<td>Older adults in congregate or overcrowded settings</td>
<td>H</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>High risk of acquiring infection due to lack of choice in setting.</td>
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</table>
ACIP COVID-19 Vaccine Work Group: Proposed Guiding Principles

Safety is paramount. Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development or distribution.

Inclusive clinical trials. Study participants should reflect groups at risk for COVID-19 to ensure safety and efficacy data are generalizable.

Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical.

Flexibility. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand.
Possible groups for Phase 1 vaccination

- High Risk Medical Conditions >100M
- Essential workers ~80M
- Healthcare personnel ~20M
- Adults ≥ 65 years old ~53M
Phase 1a: High-risk HCW – ~15M in US

• Front line health care workers (in hospitals, nursing homes, or providing home care) who either:
  • work in situations where risk of SARS-CoV-2 transmission is high, or
  • are at an elevated risk of transmitting the infection to patients at high risk of mortality and severe morbidity
Front line HCW

• Clinicians
  • e.g., nurses, physicians, respiratory technicians, dentists, hygienists

• Workers in HC settings who meet the Phase 1a risk criteria
  • e.g., nursing assistants, environmental services staff, assisted living home staff, LTCF staff, group home staff, and home caregivers
  • Settings of COVID-19 patient: care; environmental cleaning, and performing procedures with high risk of aerosolization

• Morticians and funeral home workers
Planning scenarios for initial doses

- CA could receive doses* to immunize:
  - 0.6-1.8 million people in November
  - 0.9-2.7 million people in December
- Initial priority groups?
  - Healthcare workers (>2 million in CA?)
  - First Responders (>250K in CA?)
- Coverage of Priority groups?
  - Demand from group members?

*If CA receives 12% of the US allocation, and each person needs 2 doses. See CDC COVID 19 Vaccination Scenarios for Jurisdictional Planning, Phase 1, q4 2020; also Dooling presentation to ACIP 8/26/20
INDIAN HEALTH SERVICE (IHS) CALIFORNIA AREA OFFICE (CAO) COVID-19 VACCINATION PLANNING UPDATE

OCTOBER 6, 2020

SUSAN DUCORE, DNP, MSN, RN, PHN
AREA NURSE CONSULTANT
CALIFORNIA AREA IHS
IMPORTANCE OF PARTNERSHIPS AND ENGAGEMENT

- IHS is in constant communication with CDC and other operating divisions across the Department of Health and Human Services (DHHS) and other federal, state, Tribal and local jurisdictions.
- IHS holds **weekly** conference calls with Tribal and urban Indian health organization leaders.
- DHHS, through CDC and IHS, initiated Regional Consultation for Tribal Leaders feedback on COVID-19 Vaccination planning in Indian Country - week of September 28, 2020.
- On **Thursday, October 8, 2020**, the National Council of Urban Indian Health (NCUIH) will hold a virtual listening session with the IHS and CDC for urban Indian organizations to discuss vaccine planning and distribution.
- IHS/CAO is committed to providing ongoing technical assistance and support to California Tribal and urban Indian healthcare programs with regard to COVID-19 vaccine allocation, distribution, administration and data management.
- IHS/CAO will **continue** to engage with federal, state, Tribal and local partners to address barriers to and facilitate equitable access to safe and effective COVID-19 vaccines.
IHS COVID-19 VACCINE TASK FORCE (VTF)
CALIFORNIA AREA IHS VTF

- Carolyn Garcia, MSPH, REHS, Director, Division of Environmental Health Services
- CDR Carolyn Pumares, PharmD, Area Pharmacy Consultant
- Charles Magruder, MD, Area Chief Medical Officer
- Christine Brennan, MPH, Associate Director, Office of Public Health
- Mark Espinosa, MHCA, Health Systems Administrator/Area Urban Coordinator
- Robert Gemmell, MSIM, Associate Director, Office of Information Technology
- Susan Ducore, DNP, MSN, RN, PHN, Area Nurse Consultant/Immunization Coordinator
- Rachel Harvey, MPS, Public Health Analyst – Point of Contact: Rachel.Harvey@ihs.gov
**RESOURCES**

- **IHS** - COVID-19 Vaccine Planning Website: [https://www.ihs.gov/coronavirus/vaccine/](https://www.ihs.gov/coronavirus/vaccine/)


CONSIDERATIONS AND NEXT STEPS

- If vaccine is allocated to IHS:
  - Consider the best model for COVID-19 vaccine distribution - IHS or state/local jurisdiction
  - Communicate decision to IHS and state

  Pre-planning Tool (Excel Spreadsheet) distributed to all California Program Directors on October 1 – Due back to Rachel.Harvey@ihs.gov by October 7

- When distribution pathways are confirmed, information will be shared
QUESTIONS/COMMENTS

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California Area IHS VTF POC:
Rachel Harvey, MPS
Public Health Analyst
California Area Indian Health Service
916-930-3981, extension 361
Rachel.Harvey@ihs.gov
DATE: Tuesday, October 6, 2020 (3:30PM-4:30PM, PST)
HOST: CRIHB

Meeting Recording: https://us02web.zoom.us/rec/share/V7jClORo_hFh2XYq6pXRp43DwrYEtJa0keNwW7LUMa
wQV3_2scxKkseOf7pm.WmDvrtMRRG1E9TvW Passcode: 24W+dxr+
Note: audio not available for some portions of recording

COVID-19 Vaccine Information
Vaccine Development and Deployment
- Currently four vaccines in Phase III trials in the United States. Two popular ones are both mRNA vaccines; Moderna and Pfizer.
- Operation Ward Speed is a plan for the government subsidized large-scale manufacture of vaccine doses, concurrent with trials

Planning Under Uncertainty
- Planning assumptions for cost, vaccine allocation, number of doses, registration, ordering system, distribution, education, communication, and media are based on CDC info and past pandemics.
- California THPs will have two options to receive vaccines. Either through federal allocation or through local health departments.
- Critical unknowns about COVID-19 vaccines include; timing, volume, FDA status, effectiveness, national prioritization guidelines, and public acceptance.

Priority Groups
- Numerous organizations have come up with priority groups. Possible groups for Phase 1 vaccination include; high risk medical conditions, essential workers, healthcare personnel, and adults 65 or older.

IHS California Area Office COVID-19 Vaccination Planning Update
- IHS continues to work with CDC, DHHS, and other federal, state, Tribal and local jurisdictions to facilitate access to COVID-19 vaccines. IHS has created a CA area Vaccine Task Force (VTF), point of contact Rachel Harvey (Rachel.Harvey@ihs.gov). As distribution information becomes available it will be shared.