

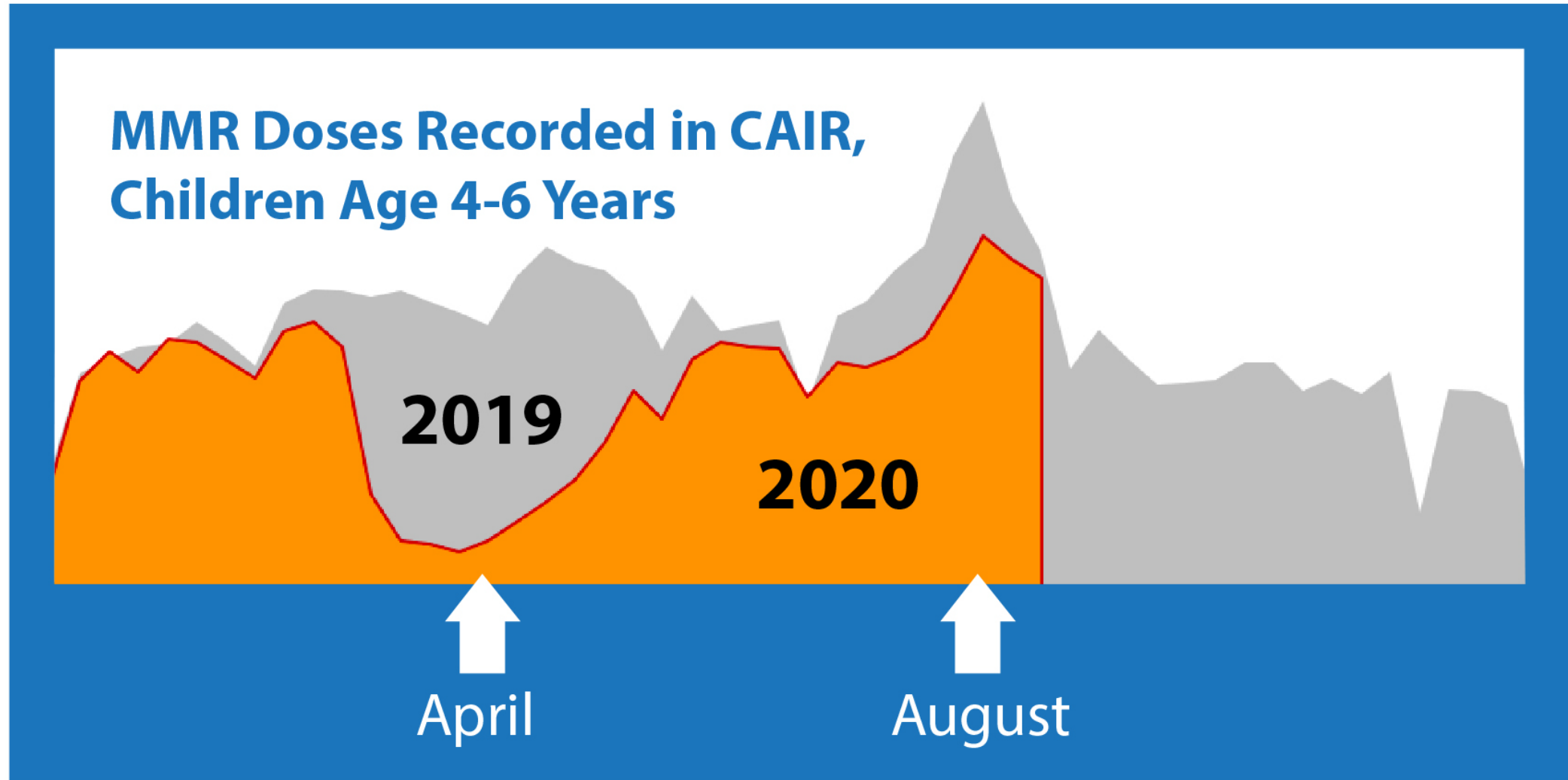
# Vision

- 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



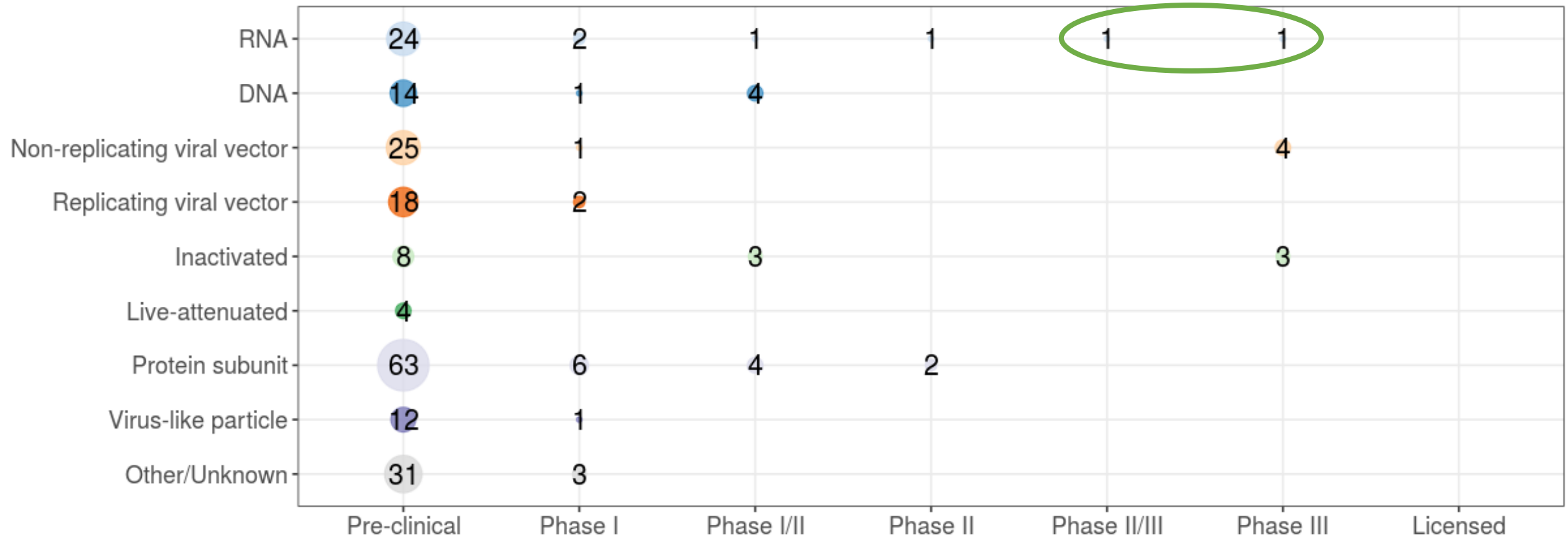
Data from the California Immunization Registry

# 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



# 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:  $-20^{\circ}\text{C}$  ( $-4^{\circ}\text{F}$ ) for up to 6 months.
  - May refrigerate at  $2-8^{\circ}\text{C}$  ( $36-46^{\circ}\text{F}$ ) 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:  $-70^{\circ}\text{C}$  ( $-94^{\circ}\text{F}$ ) 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  $2-8^{\circ}\text{C}$  ( $36-46^{\circ}\text{F}$ ) 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.

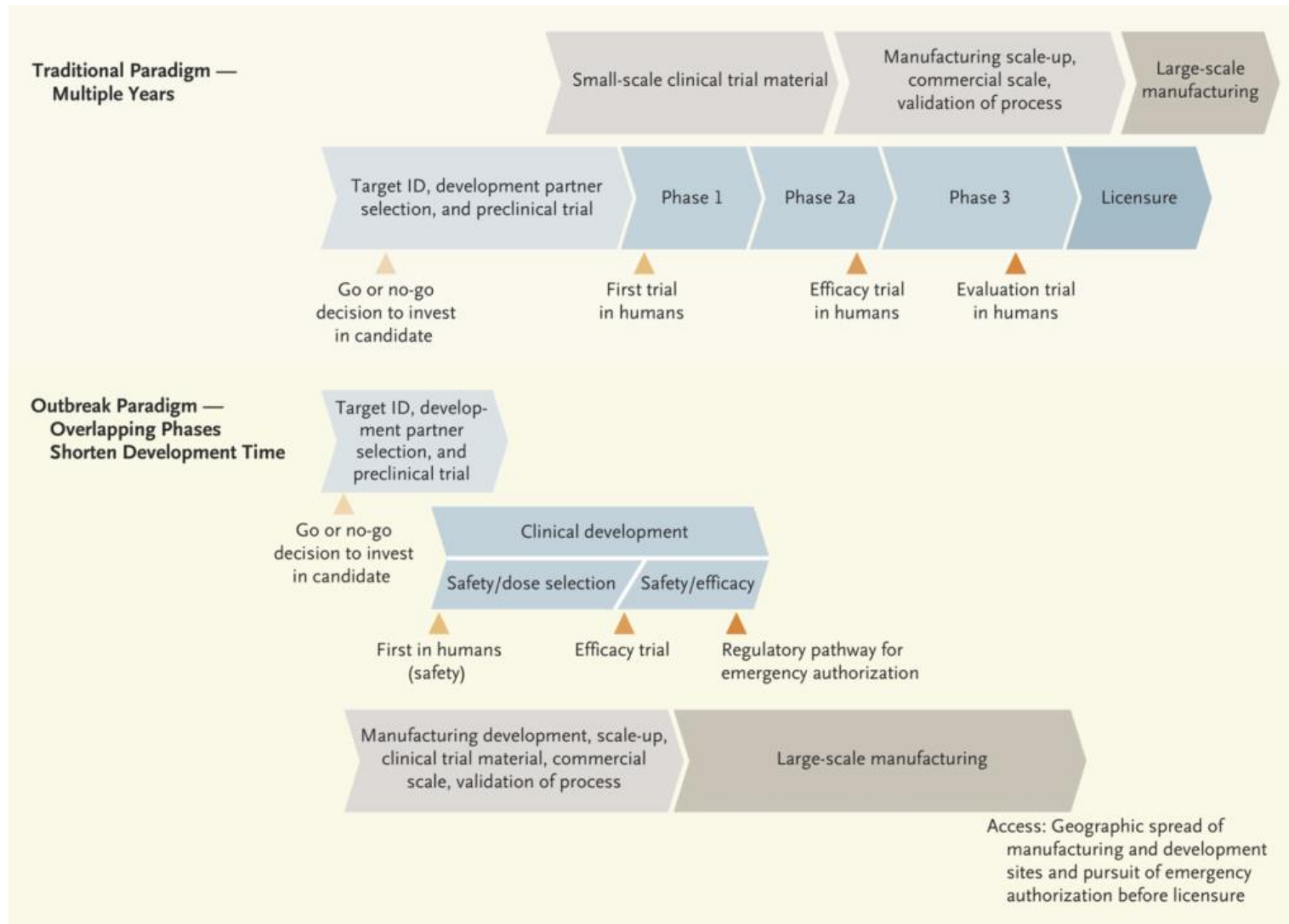
# Emergency Use Authorization (EUA)

- **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



Lurie, N, NELM 2020:  
<https://www.nejm.org/doi/full/10.1056/NEJMp2005630>

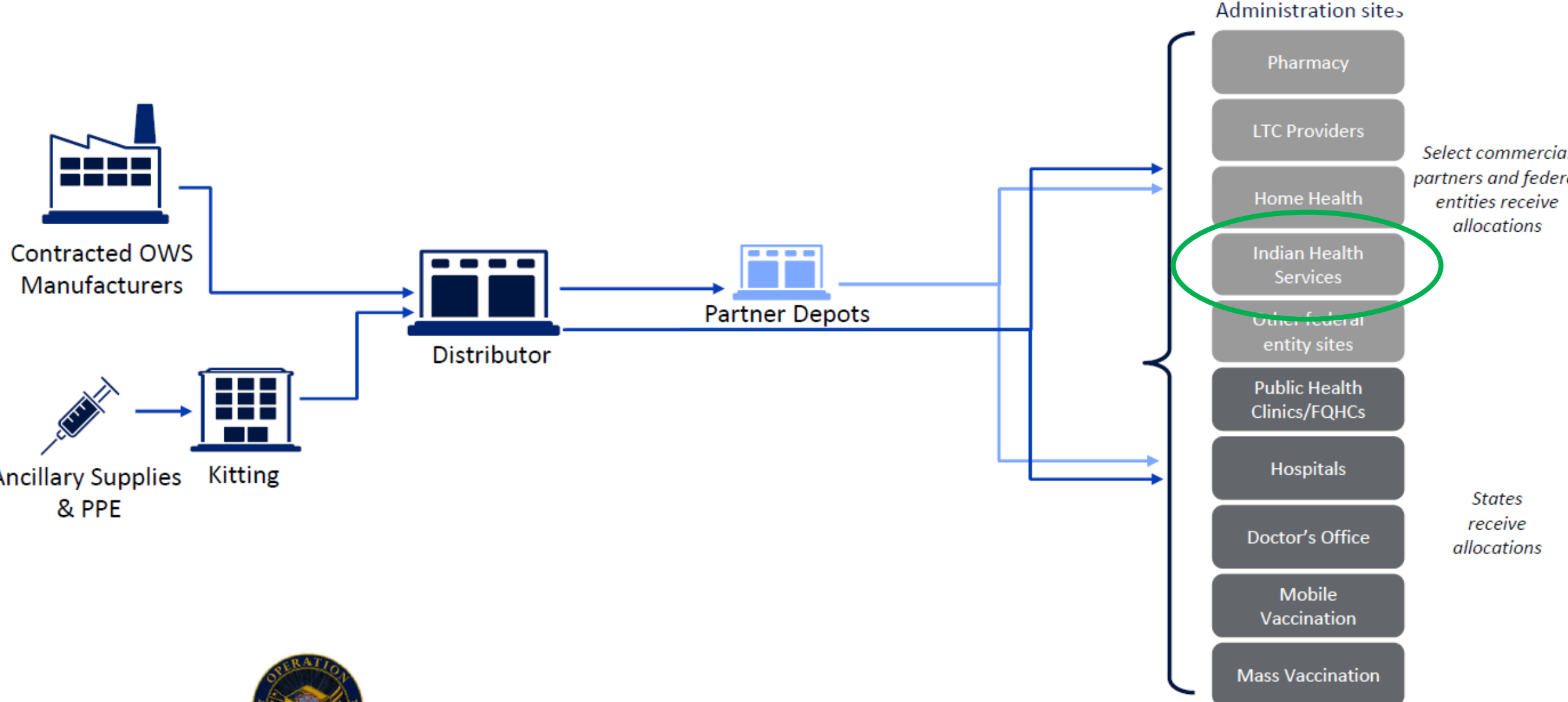
# Planning Under Uncertainty

# Planning Assumptions

based on information from CDC and past pandemics

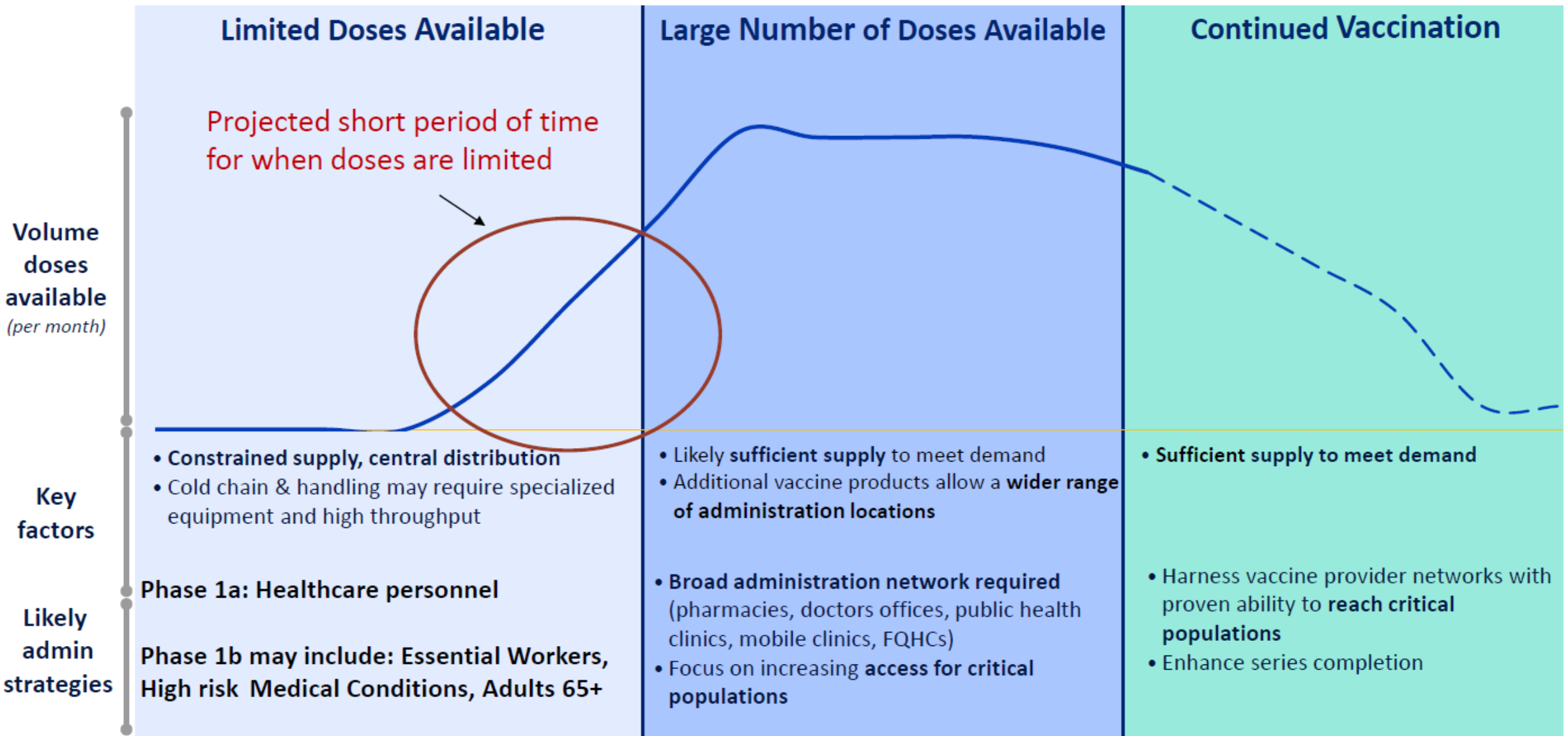
- Costs: For the initial year(s), USG pays for vaccine and ancillary supplies.
- Allocation to States: Proportional to population
  - Federal Government will also allocate directly to: active military, VA, IHS...
- Allocation plan within California: LHDs direct local allocations
  - CDPH allocates to 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

# Overview of Distribution and Administration



OWS coordination

# Administration of COVID-19 vaccine will require a phased approach



# 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

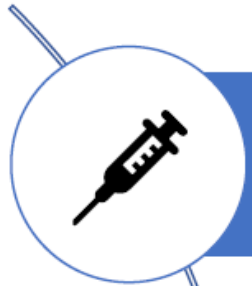
**DRAFT TABLE 2** Applying the Allocation Criteria to Specific Population Groups

<b>Phases</b>	<b>Population Group</b>	<b>Criterion 1: Risk of Acquiring Infection</b>	<b>Criterion 2: Risk of Severe Morbidity and Mortality</b>	<b>Criterion 3: Risk of Negative Societal Impact</b>	<b>Criterion 4: Risk of Transmitting Infection to Others</b>	<b>Mitigating Factors for Consideration</b>
1a	High risk workers in health care facilities	H	M	H	H	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.
1a	First responders	H	M	H	H	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.
1b	People with significant comorbid conditions	M	H	M	L	High risk of severe morbidity and mortality, but may be able to social distance and isolate.
1b	Older adults in congregate or overcrowded settings	H	H	L	L	High risk of acquiring infection due to lack of choice in setting.



# ACIP COVID-19 Vaccine Work Group: Proposed Guiding Principles

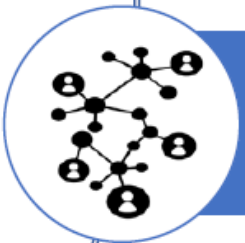
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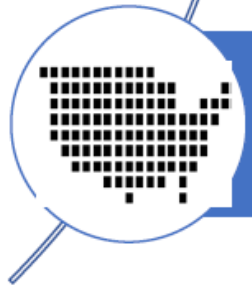
**Safety is paramount.** Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development or distribution



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

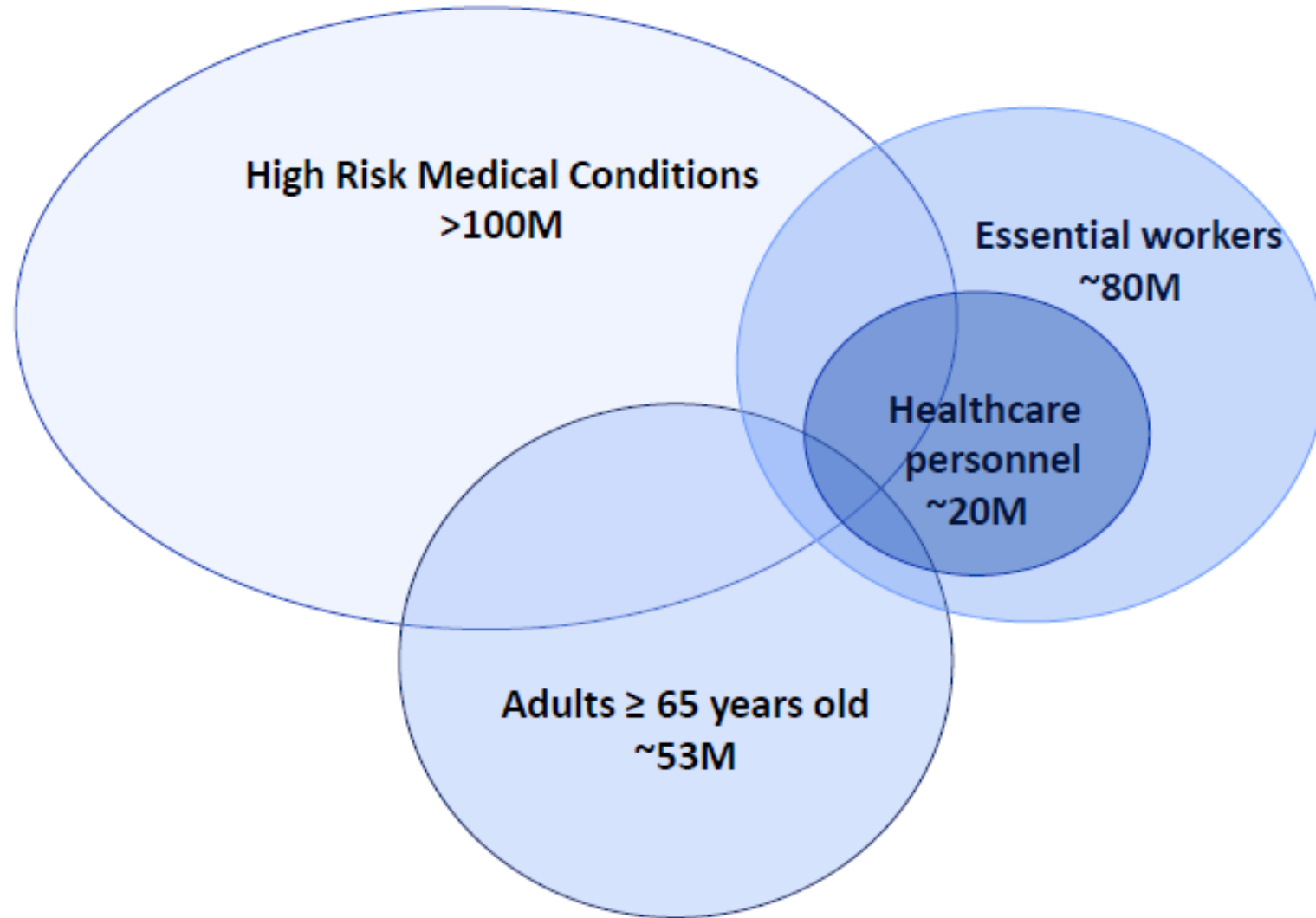


**Efficient Distribution.** During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical



**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



# 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 ( $\geq 2$  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

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# INDIAN HEALTH SERVICE (IHS) CALIFORNIA AREA OFFICE (CAO) COVID-19 VACCINATION PLANNING UPDATE

**OCTOBER 6, 2020**



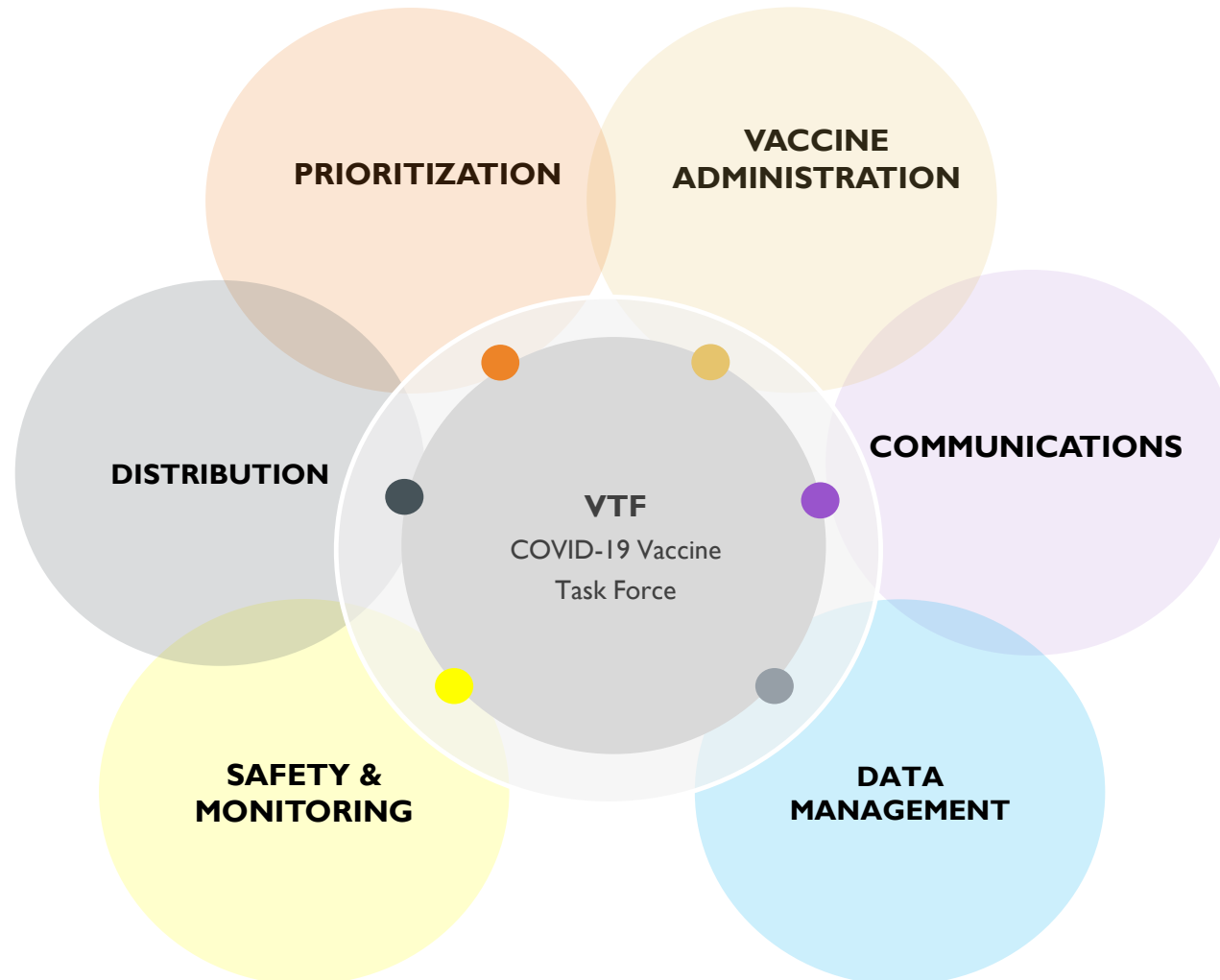
SUSAN DUCORE, DNP, MSN, RN, PHN  
AREA NURSE CONSULTANT  
CALIFORNIA AREA IHS



# 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 IHSVTF

- 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](mailto:Rachel.Harvey@ihs.gov)

## RESOURCES

- **IHS** - COVID-19 Vaccine Planning Website: <https://www.ihs.gov/coronavirus/vaccine/>
- **CDC** - COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations –released September 16, 2020: [https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim\\_Playbook.pdf](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf)
- **Operation Warp Speed** - Strategy for Distributing a COVID-19 Vaccine – released September 16, 2020: <https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf>
- **FDA** - Development and licensure of vaccines to prevent COVID-19 – released June, 30 2020: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>

# 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](mailto:Rachel.Harvey@ihs.gov) by October 7

- When distribution pathways are confirmed, information will be shared

# QUESTIONS/COMMENTS

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Area Nurse Consultant  
California Area Indian Health Service  
916-930-3981 extension 323  
[Susan.Ducore@ihs.gov](mailto:Susan.Ducore@ihs.gov)

**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](mailto:Rachel.Harvey@ihs.gov)

# CRIHB COVID-19 Meeting Notes

## ATTENDEES:

1. Rondi Johnson, Karuk Health & Human Services
2. Buck Ellingson
3. Maria Hunzeker, Feather River Tribal Health
4. Alinea Stevens
5. Silver
6. Kyle Desautel, Pit River Tribe
7. Joseph Mirelez, Torres Martinez Desert Cahuilla Indians
8. Barbara Hart
9. Rachel Harvey, CA IHS
10. Rob Schechter, CDPH
11. Carolyn Pumares
12. Tilford Denver
13. Loren Ellery
14. Terri Sue Canale-Dalman
15. Will Micklin, Ewiiapaayp Band
16. M Goodwin
17. Amy Groom, CDC
18. Liz Lara, UIHS
19. Susan Ducore, CA IHS
20. Jess Montoya, Riverside San Bernardino County Indian Health
21. Christine Brennan
22. Michael Bacoch III
23. Josefina Cortez
24. Vickey M
25. Diana Zamora
26. D. Miller
27. Marilyn Benck, Table Mountain Rancheria
28. Clara Stairs
29. M. Castello
30. Dennis Ickes
31. L. Davies
32. Jim Suennen, CHHS Agency Tribal Liaison
33. J. Coin
34. Jane Grey
35. Rachel Magoffin
36. Shirley Laos
37. Kori Novak
38. Will Micklin
39. Sorhna Li
40. Brandi G.
41. Kristal Raymond
42. Stratton King
43. Laura Quilter
44. Janna B.
45. R. Johnson
46. T. Blocher
47. Julie Rooney
48. Glen Hayward
49. E. Padilla
50. Loren Ellery
51. Selina De La Pena
52. Edgar Ednacot
53. Laura Wong
54. Gerard Jenkins
55. Amanda W.
56. E. Solis
57. Scott Black
58. Sonya Tetnowski
59. Phuoc Le
60. Karen T.
61. R. Sisson
62. Virginia Hendrick
63. Orvin Hanson
64. M. Benck
65. Inder Wadhwa
66. Trudy Raymundo

## CRIHB STAFF ATTENDEES:

Vanesscia Cresci, Rosario Arreola  
Pro, Dr. Thomas Kim, Aurimar  
Ayala, Kelley Milligan

**DATE: Tuesday, October 6, 2020 (3:30PM-4:30PM, PST)**

**HOST: CRIHB**

Meeting Recording:

[https://us02web.zoom.us/rec/share/V7jCL0Ro\\_hFh2XFqy6pXRp43DwrYE3tJa0keNxWJ7LUMansQV3\\_ZscrXkseQf7pn.WmDvriTMRUG1E9Vw](https://us02web.zoom.us/rec/share/V7jCL0Ro_hFh2XFqy6pXRp43DwrYE3tJa0keNxWJ7LUMansQV3_ZscrXkseQf7pn.WmDvriTMRUG1E9Vw) Passcode: 24W+drx+

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 Warp 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](mailto:Rachel.Harvey@ihs.gov)). As distribution information becomes available it will be shared.