

**California Health and Human
Services Agency (CHHS)
California Department of Public
Health (CDPH)**

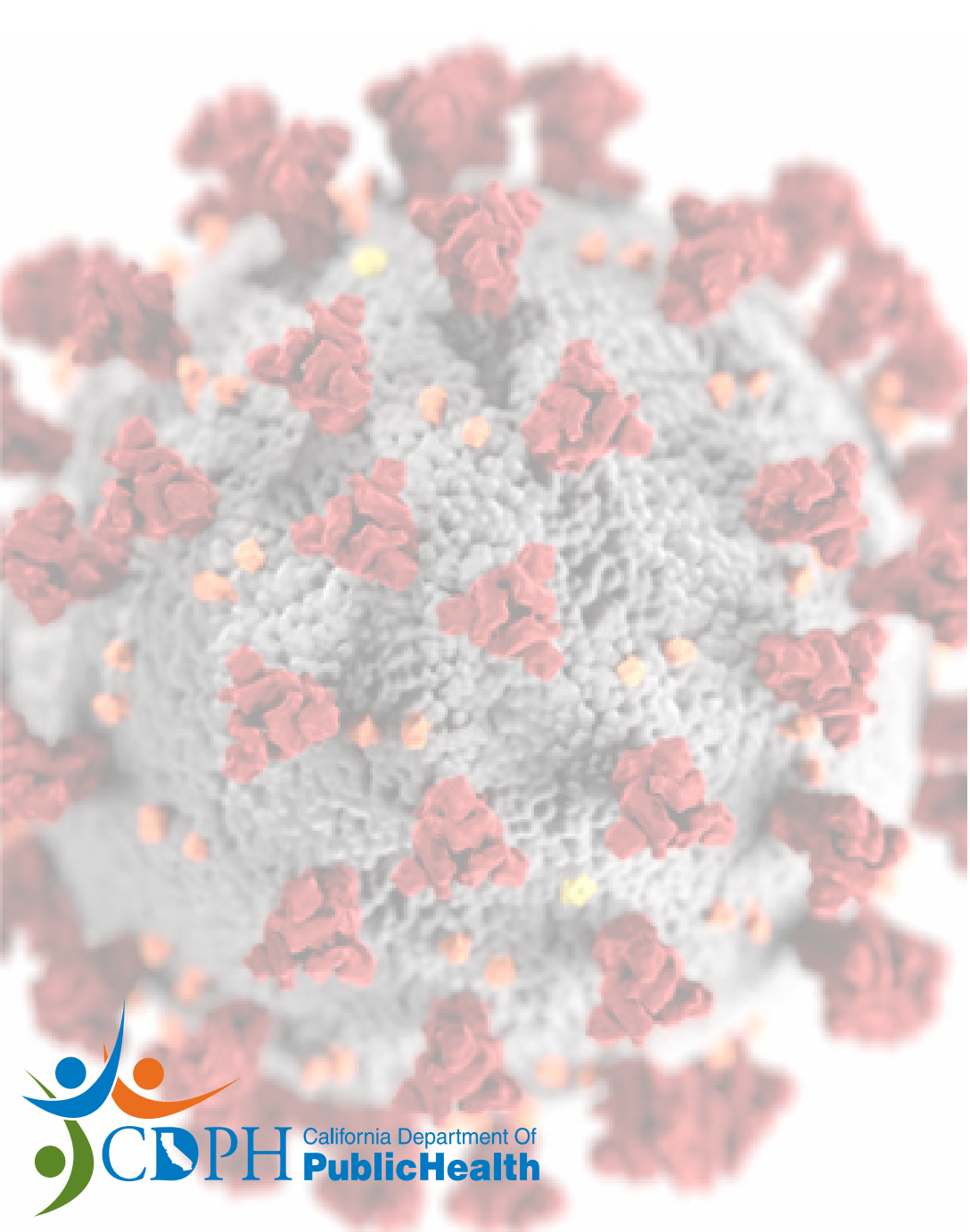
**COMMUNITY VACCINE ADVISORY
COMMITTEE**

MEETING #1

November 25, 2020

10:00 AM – 1:00 PM





WELCOME TO THE COMMUNITY VACCINE ADVISORY COMMITTEE

*Erica Pan, MD, MPH,
Acting State Health Officer, Co-Chair*

*Nadine Burke Harris, MD, MPH, Surgeon General,
Co-Chair*



Meeting Process

- All meetings will be virtual and interactive; cameras on; mute until ready to speak
- Use hand raise icon when you are ready to make comments/ask questions
- Consistent attendance by members; no delegates or substitutes
- Website - <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Community-Vaccine-Advisory-Committee.aspx>
- Public in listen-in mode via telephone at each meeting
- Public comment via written comments; will be summarized and discussed with Committee at subsequent meetings
- Technical issues with Zoom – put questions in chat





Community Vaccine Advisory Committee Overview

- Role, Timeline and Expectations of Community Vaccine Advisory Committee
- Relationship to Scientific Safety Review Workgroup/Drafting Guidelines Workgroup
- Challenges Ahead

Role, Timeline, and Expectations

1. Urgency of Timeline and Meetings
2. Role of Community Vaccine Advisory Committee beyond initial vaccine allocation period
3. Diversity of Membership
4. Connection between Workgroups and Community Vaccine Advisory Committee
5. Advisory Role of Community Vaccine Advisory Committee
6. Trusted Messengers & Trusted Listeners – A Reciprocal “Two-Way” Street
7. Challenges Ahead
8. Discussion with members



Vaccine Planning Overview

- History of CDPH's Work on Vaccine Planning and Prioritization



Vaccine Planning Overview

- California COVID-19 Governor's Vaccine Task Force



Community Vaccine Advisory Committee

- Advises the Vaccine Task Force on the direction of Task Force workgroups
- Committee Members Will Be Key Resources and Communicators to Your Organization's Membership
- Over 70 members representing diverse organizations from across California
- For transparency, all meetings are public



Scientific Safety Review Workgroup

- Eleven member workgroup of vaccine experts
- Charge: review vaccine clinical trial data to put California “seal of approval” on vaccine safety and effectiveness
- Workgroup has met twice
- Workgroup is on call ready to immediately review data



Drafting Guidelines Workgroup

- Charge is to develop allocation guidance for local health departments to determine who will receive vaccine when there is limited supply
- Sixteen-member workgroup has met three times and for nine hours
- Presently working on allocation for Phase 1a
- Next meeting: November 27, 2020



Vaccine Task Force Infrastructure

- Communications
- Information Management
- Logistics
- Administration, Budgets, Legal



Vaccine Planning Overview

- Scientific Safety Review Workgroup Update

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?
- Pandemic blunted, perhaps controlled
 - Contributes to normalization



California's Immunization Infrastructure

- ~19 Million influenza vaccine doses given in 2019-2020 season
 - Most of these given in ~3 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, etc.
- Local health departments (LHDs) are a key safety net
 - Surge capacity during pandemics, outbreaks, other urgencies
 - Double the routine doses in the 2009-10 H1N1 pandemic

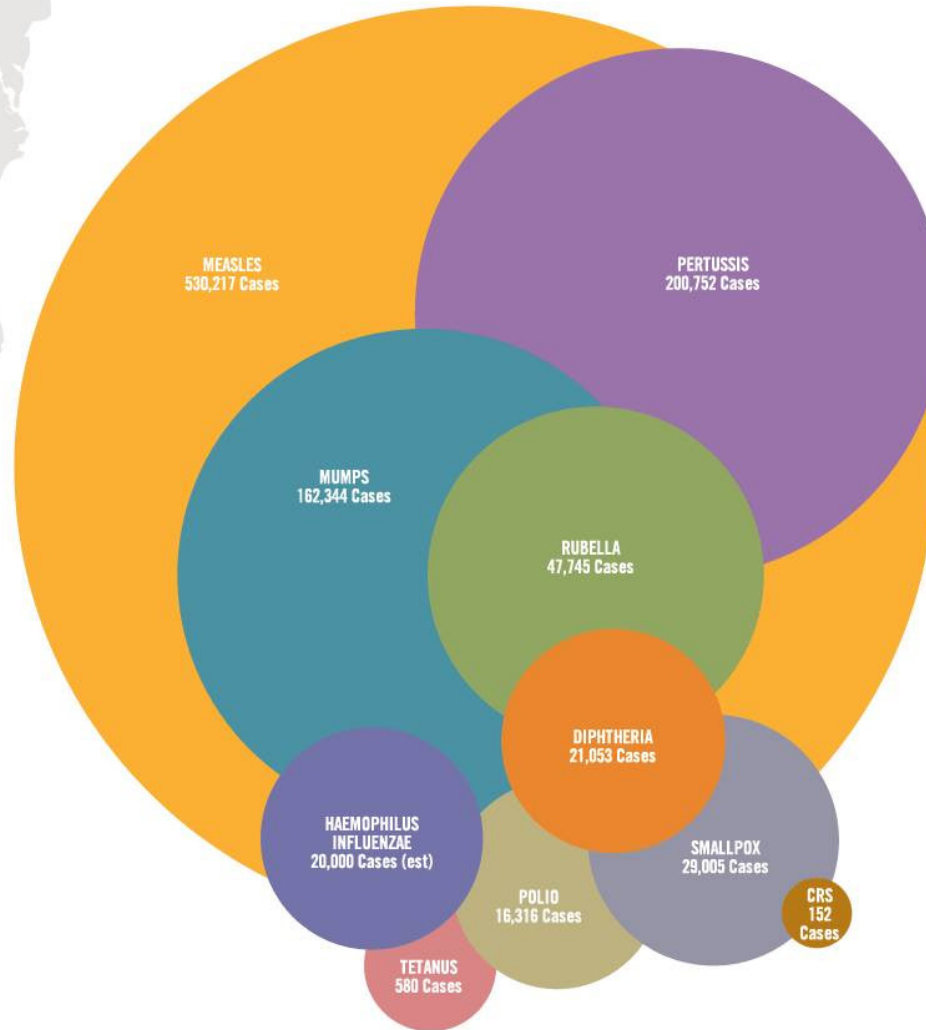


VACCINES WORK

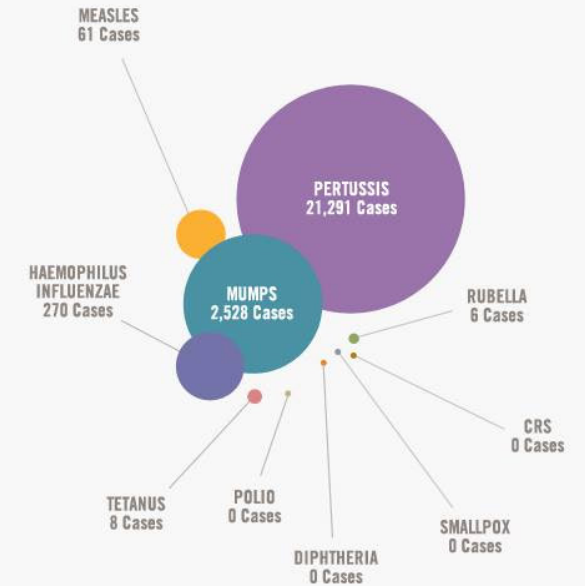
These bubbles are sized according to the annual number of disease cases in the US during the 1900s versus 2010. We've come so far. It's a reminder that while disease rates are low, most diseases haven't disappeared. This is why we continue to vaccinate.

SMALLPOX	THEN 29,005 NOW 0	MEASLES	THEN 530,217 NOW 61
DIPHTHERIA	THEN 21,053 NOW 0	MUMPS	THEN 162,344 NOW 2,528
PERTUSSIS	THEN 200,752 NOW 21,291	RUBELLA	THEN 47,745 NOW 6
TETANUS	THEN 580 NOW 8	CRS	THEN 152 NOW 0
POLIO	THEN 16,316 NOW 0	HAEMOPHILUS INFLUENZAE	THEN 20,000 NOW 270

THEN
Annual US disease cases in the 1900s



NOW
US disease cases in 2010

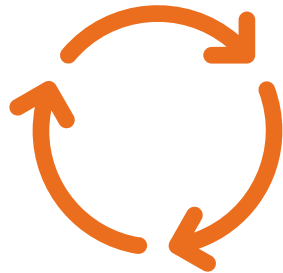


⁹ Centers for Disease Control and Prevention (CDC). Parents Guide to Childhood Immunizations. <http://www.cdc.gov/vaccines/pubs/parents-guide/default.htm>. Accessed August 15, 2011.

¹⁰ CDC. Impact of Vaccines in the 20th & 21st Centuries. <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/G/impact-of-vaccines.pdf>. Updated January 2011. Accessed August 15, 2011.

Vaccine Development and Deployment

FDA Review Cycle



Investigational New Drug (IND) Application

- Pre-Clinical Studies
- Phase I, II, or III (or combination phase) trials

Authorization Options after FDA Review

- Licensure
- Emergency Use Authorization (EUA)
- (Expanded Use Access IND [*Men B vaccine, NJ outbreak*])

Continued Oversight After Authorization

The Vaccine Life Cycle

safety at every phase

GUIDE

ACIP

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

BLA

BIOLOGICS LICENSE APPLICATION

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

FDA

FOOD AND DRUG ADMINISTRATION

IND

INVESTIGATIONAL NEW DRUG APPLICATION

VACCINE DEVELOPMENT

safety is a priority during vaccine development + approval

safety continues with CDC + FDA safety monitoring

PHASE 1 safety
PHASE 2 effectiveness
PHASE 3 safety + effectiveness

PHASE 4 safety monitoring for serious, unexpected adverse events

BASIC RESEARCH
DISCOVERY
PRE-CLINICAL STUDIES

CLINICAL STUDIES / TRIALS

FDA REVIEW

ACIP REVIEW

POST-APPROVAL MONITORING + RESEARCH

IND SUBMITTED

BLA SUBMITTED

FDA APPROVAL OF 1 NEW VACCINE

ACIP RECOMMENDATION



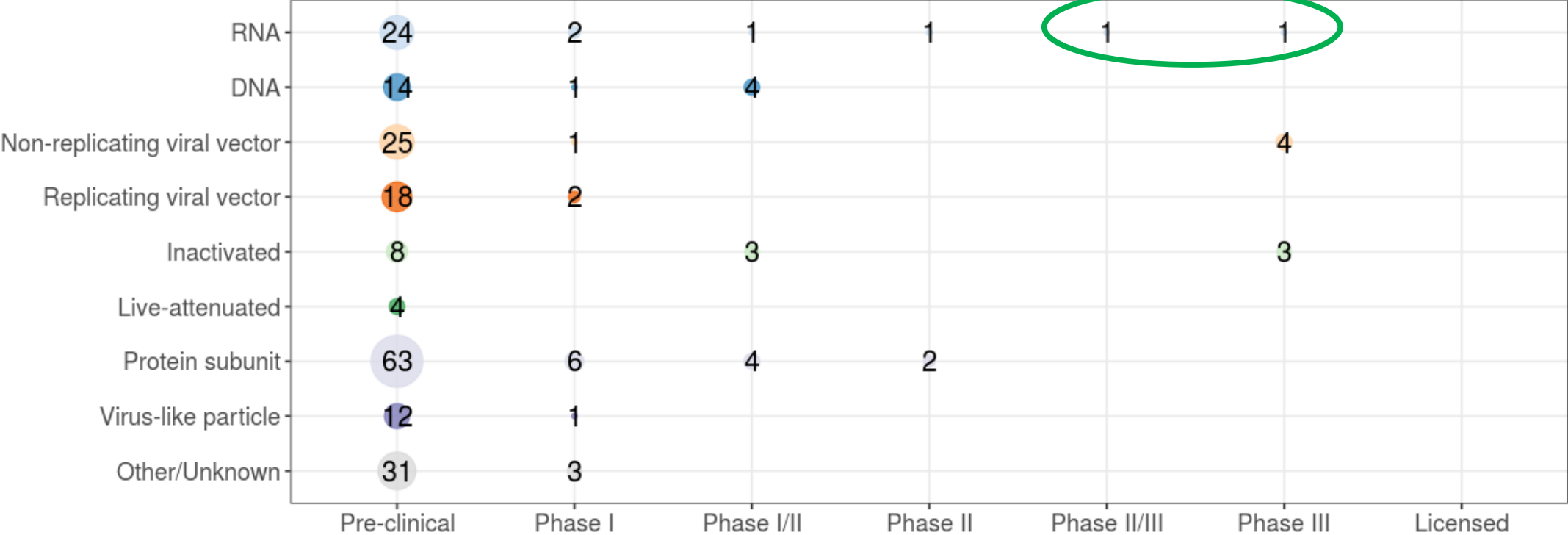
LEARN MORE

[FDA VACCINE DEVELOPMENT + APPROVAL PROCESS](http://go.usa.gov/xvvNd)
[CDC VACCINE SAFETY MONITORING + RESEARCH](http://go.usa.gov/xvvNe)



Vaccine Candidates & Clinical Trials

261 COVID-19 vaccine candidates worldwide
58 undergoing clinical trials



https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/

Candidates in Phase III trials

Vaccine Platform	Vaccine	# of doses	Trial Locations	Warp Speed Funding?
mRNA	Moderna mRNA-1273	2	USA	Yes
	Pfizer/BioNTech BNT162	2	USA, Argentina, Brazil, Turkey	Yes
Non-replicating adenovirus vector	Oxford ChAdOx1-S	1 or 2	UK, Brazil, South Africa, US	Yes
	Cansino Ad5-nCoV	1	Pakistan	
	Gamaleya Gam-COVID-Vac	2	Russia - "Sputnik V"	
	Janssen Ad26COVS1	1	USA, Brazil, Chile, others	Yes
Spike protein (nanoparticle)	Novavax NVX-CoV2373	2	UK	Yes
Inactivated (1st candidates from China)	Wuhan IBP vaccine	2	UAE, Bahrain	
	BIBP/Sinopharm BBIBP-CorV	2	UAE	
	Sinovac CoronaVac	2	Brazil, Indonesia	

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 $2-8^{\circ}\text{C}$ ($36-46^{\circ}\text{F}$) 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°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 $2-8^{\circ}\text{C}$ ($36-46^{\circ}\text{F}$) 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.

Updates - Press Releases

Moderna:

- COVID-19 cases VE 94.5%
90 in placebo group, 5 in vaccine group
- 65+ years 15 cases
- Severe Disease 11 in placebo group, 0 in vaccine group
- DSMB No serious safety concerns
- EUA submittal "Coming weeks"
- Storage (FDA review) 2-8 degrees C for up to 30 days

Pfizer

- COVID-19 cases VE 95%
162 in placebo group, 8 in vaccine group
- 65+ years VE 94%
- Severe Disease 9 in placebo group, 1 in vaccine group
- DSMB No serious safety concerns
- EUA submittal "Within days" (11/20?)
- Storage (FDA review) (No changes)



<https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy>
<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine>

Will We Know...?

Will we know from initial Phase III trial data whether immunization reduces...?

- | | |
|--|----------------------|
| 1. Milder COVID-19 disease ? | Yes |
| 2. Severe COVID-19 disease <ul style="list-style-type: none">- Hospitalization?- Death? | Maybe
Less likely |
| 3. Transmission of disease? | Less likely |



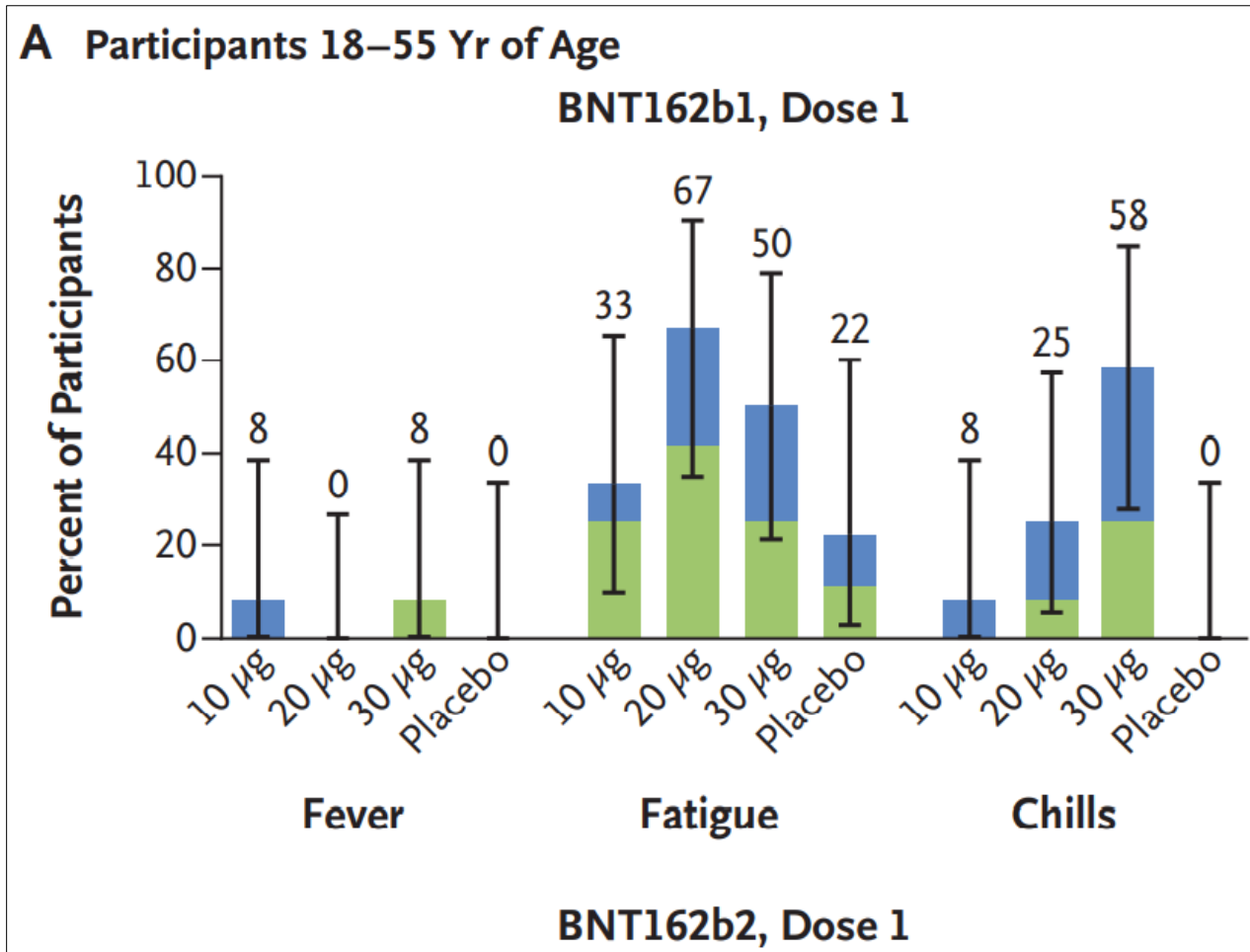
Sequence for a successful candidate...

- ✓ **Phase III Trial Data submitted** to US Health and Human Services
 - Review by FDA, CDC and its Advisory Committees over weeks

- FDA VRBPAC** meets: Recommend authorization?
- FDA review** completed: Authorize use?
- ACIP** meets: Recommend use?
- CA NV OR WA Committee** reviews: [Endorses or other term]?

- CDC** standing by to allocate available doses nationwide

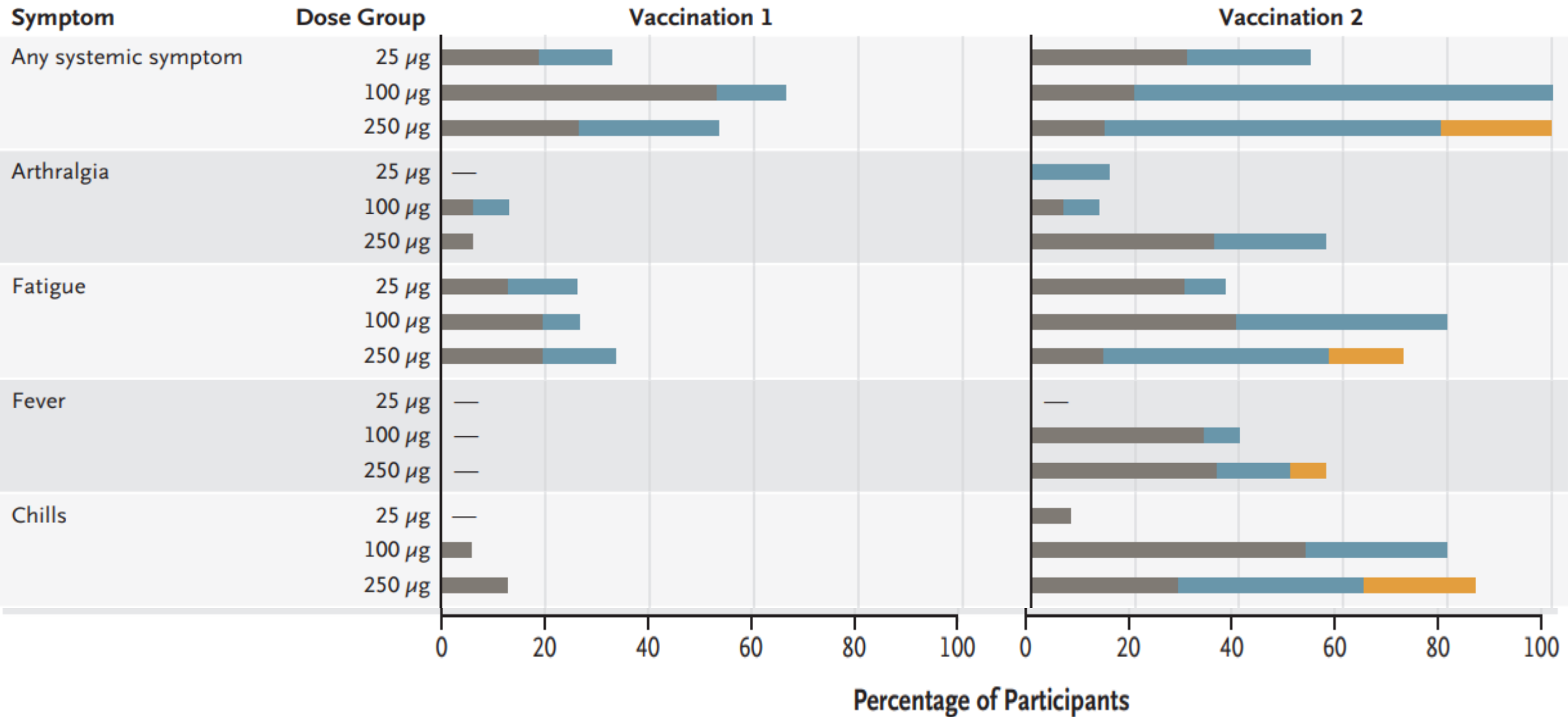
Safety Evaluation – Pfizer candidate



Systemic events: ■ Mild ■ Moderate ■ Severe
 Fever: ■ 38.0°C–38.4°C ■ >38.4°C–38.9°C ■ >38.9°C–40.0°C

Safety Evaluation – Moderna candidate

■ Mild ■ Moderate ■ Severe



FDA Surveillance of COVID-19 Vaccines

DRAFT Working List of Possible Adverse Event Outcomes

Subject to Change

- Guillane-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/
- meningoencephalitis/meningitis/
- encephalopathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint point
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease



Vaccine Planning Overview

- Vaccine Storage and Handling
- Pfizer & Moderna Vaccines

Pfizer Vaccine

- Pfizer-BioNTech
- 2 doses, 21 days apart
- Requires ultra-low temperature (ULT) storage (-80°C)
- Shipped from Pfizer to administration/storage sites
- May be the first vaccine distributed (~December)



Pfizer Vaccine Packaging

- Packaged in Pfizer's Ultra-Low Temperature Thermal Shipper
- Up to five trays (pizza boxes) per shipper
- Tray and vial quantities:
 - One vial = 5 doses
 - One tray = 195 vials
 - 975 doses per tray: the minimum order
 - Five trays = 4,875 doses: the maximum per shipper



Storage Options

- Store in the shipper
 - Dry ice distribution may become very complex
 - Dry ice distribution may prove to be expensive over the months
- ULT Freezers
- Refrigerate immediately and use in 5 days



Storing in the Shipper

- Dry ice PPE
 - Dry ice gloves and eye protection
- Use a metal scoop



Overcoming Pfizer Vaccine Challenges

- CDPH ordered 16 ULT storage freezers distributed across the state.
- Dry ice master contract.
- Initial shipment will come with first dry ice re-supply.
- Survey of local health departments and hospitals.
- Cross jurisdictional partnerships (mutual aid).



Moderna Vaccine

- Two doses, 28 days apart
- Requires frozen storage (-20° C)
 - The range (-25° to -15° C) is narrower than other frozen vaccines
- Shipped to administration/storage sites from McKesson
- Ancillary supplies shipped by USG
- Expected to be released closely behind Pfizer



Moderna Shipping/Storage/Use

- Shipping and storage temperature: -20°C
- Refrigerated Storage: (2°C - 8°C) for 7 days
- Multidose vials (10 per/vial)
- 100 dose minimum order
- Thaw times
 - 2 hours in the refrigerator, then 15 minutes at room temperature
 - 1 hour at room temperature



Vaccine Planning Overview

- Allocation Framework Development Update

Sample LHD Allocation

		Vaccine A				Vaccine B			
		Total Doses Available:		20,000	Total Doses Available:		10,000		
		Doses Allocated:		0	Doses Allocated:		0		
		Doses Remaining:		20,000	Doses Remaining:		10,000		
County	Provider	Estimated Staff/Need	Doses shipped to date	Staff - doses to date	Doses Assigned to Provider	Estimated Staff/Need	Doses shipped to date	Staff - doses to date	Doses Assigned to Provider
ALAMEDA	Local Health Department	15,000	6,000	9,000		15,000	6,000	9,000	
ALAMEDA	Hospital A	20	0	20		30	0	30	
ALAMEDA	Clinic	100	30	70		500	300	200	
ALAMEDA	Hospital B	80	20	60		60	40	20	
ALAMEDA	Long Term Care	100	30	70		1480	400	1080	
ALAMEDA	Dialysis Center	210	30	180		210	100	110	
ALAMEDA	Prison Clinic	410	100	310		280	160	120	
ALAMEDA	Hospital C	2000	300	1700		5000	1500	3500	
ALAMEDA	Hospital D	240	60	180		500	400	100	
ALAMEDA	Clinic	20	10	10		500	300	200	
ALAMEDA	Clinic	70	10	60		90	30	60	
ALAMEDA	Clinic	60	30	30		100	100	0	



Develop Guidance Given Limited Supply

- Important to review existing recommendations
- Need to ensure equity by carefully defining the groups of individuals who will be eligible for vaccine as additional supply arrives
- Because vaccine supply will be limited at first and increase over time, we must make determinations about allocation
- Some of these determinations will be based on risk factors, but should we take into account other considerations such as vaccine characteristics?



Vaccine Allocation Equity Principles

Foundational

Benefiting people and
limiting harm

Prioritizing equity

Equal concern

Procedural

Transparency

(Evidence-based)



National Academy of Science (NASEM)

- Goal: “Reduce severe morbidity and mortality and negative societal impact due to the transmission of SARS-CoV-2.”
- Allocation criteria: risk-based
 - Groups are prioritized by risk of members’
 - acquiring infection
 - severe sickness and death
 - negative societal impact
 - spreading disease



National Academy of Sciences Prioritization

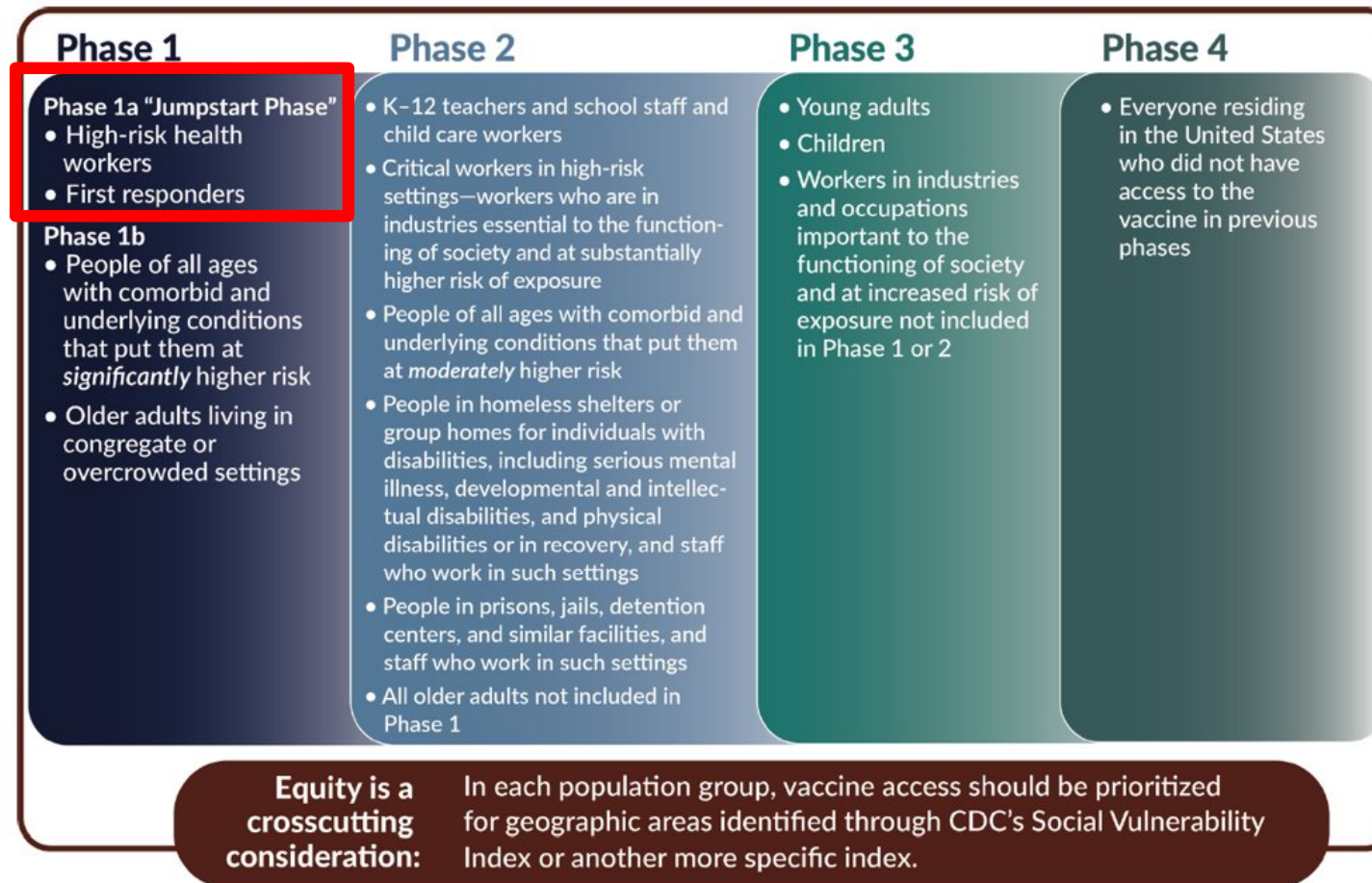
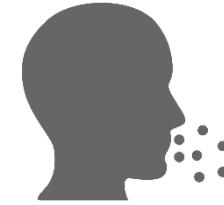


FIGURE S-2 A phased approach to vaccine allocation for COVID-19.

Definition of Healthcare Worker



“Health professionals who are involved in **direct patient care**, as well as those working in transport, environmental services, or other health care facility services—**who risk exposure to bodily fluids or aerosols.**”

- National Academy of Science

Definition of Phase 1a Medical First Responder

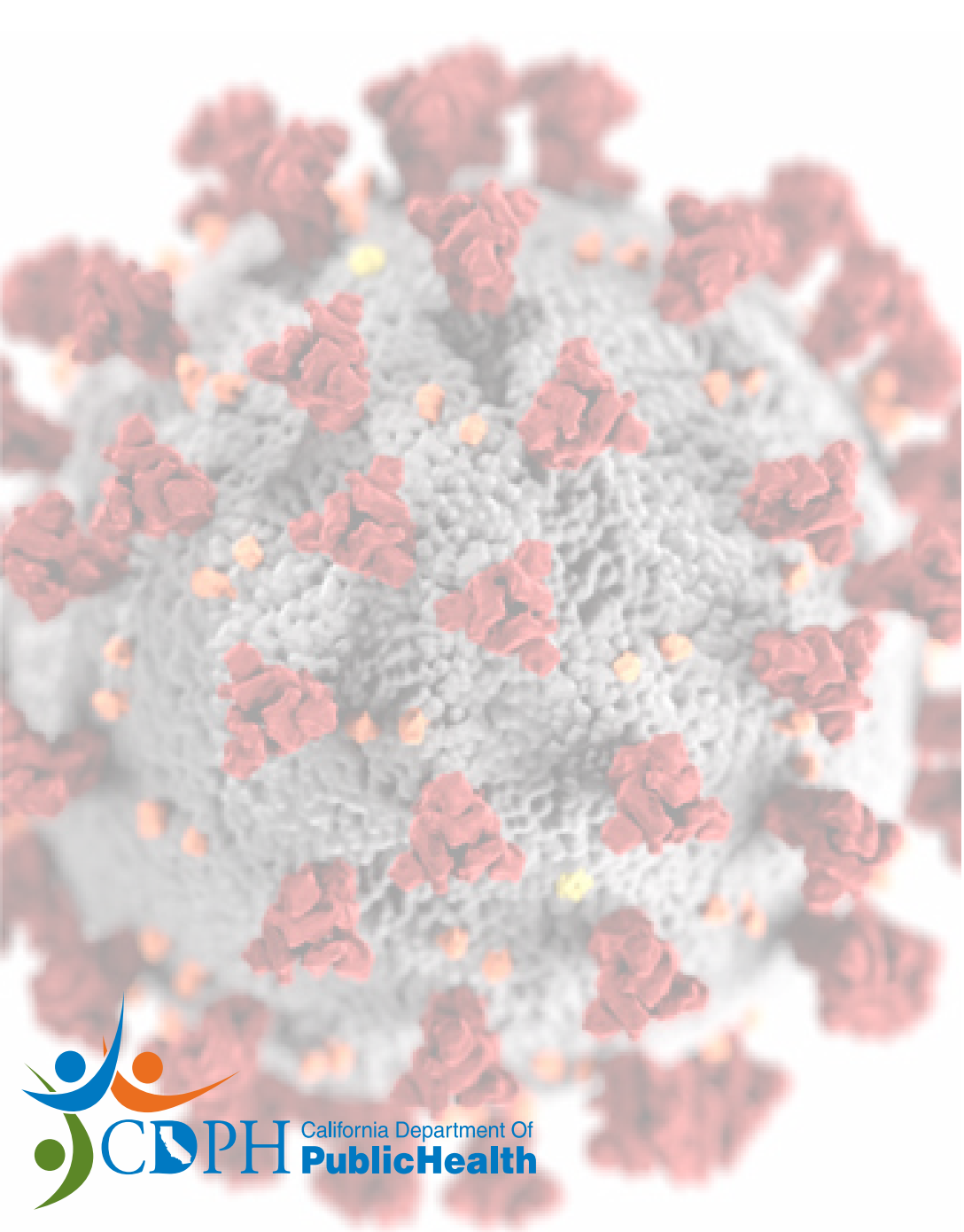
- Advisory Committee on Immunization Practices (ACIP) separated first responders into health care workers such as EMTs and paramedics and other essential workers including fire (those who are not EMTs or paramedics) and law enforcement
- EMTs, Paramedics are medical first responders.



Vaccine Planning Overview

- Questions and Answers

Break



Introduction of Data Related to Phase 1a and Review of Phase 1a Recommendations by Drafting Guidelines Workgroup



Potential Criteria to Subprioritize, Phase 1a

- Type of Facility
- Location of Facility
- Attributes of Individual Healthcare Workers



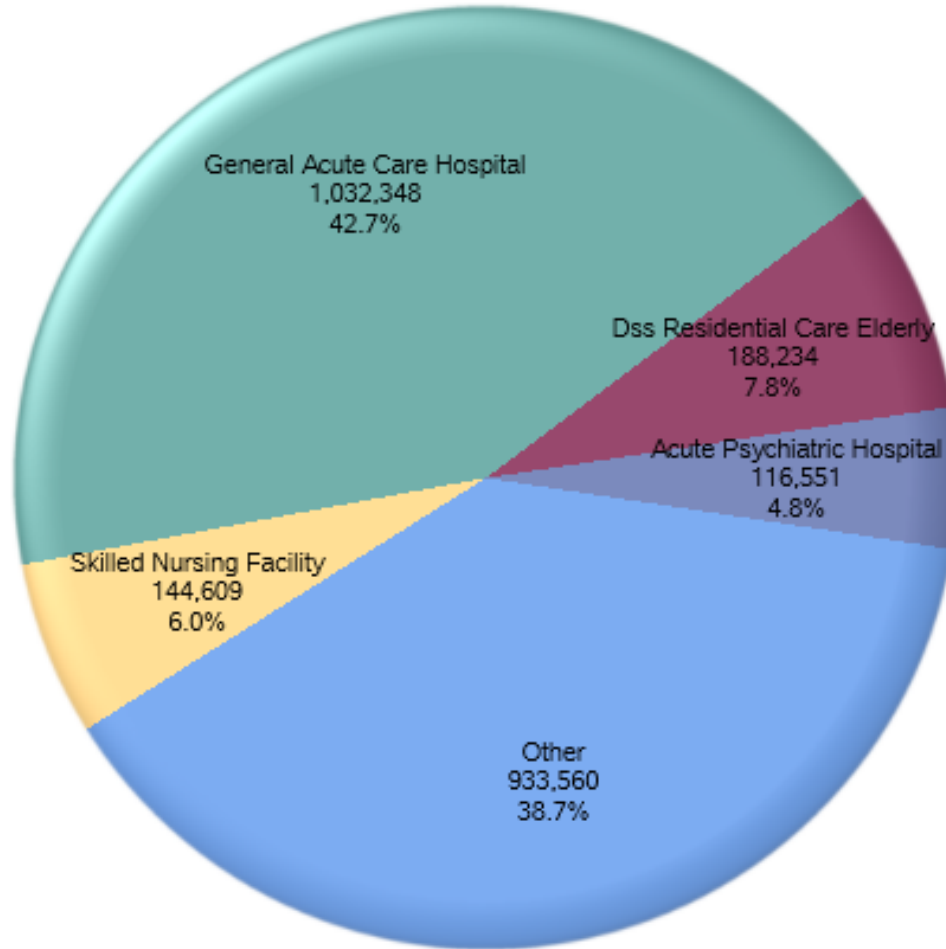
Type of Healthcare Facility

- When vaccine is initially limited in Phase 1a, which facilities should first receive vaccine to vaccinate health care workers?
- Possible tiered approach
 - First tier might include hospitals, congregate care settings and EMS personnel.
 - Second tier might include primary care clinics, home health, community health workers, and public health staff.
 - Third tier might include other facilities.



Healthcare Workers by Facility Type

Healthcare Total Number Working by Facility Type
Healthcare Total Number Working : 2,415,302



Source: Dataset 2: Licensed Healthcare Workforce by Facility Estimation

Healthcare Workers by Facility Type

Examples

Facility Type	Health Care Total Number Working
General Acute Care Hospital	1,032,348
Dss Residential Care Elderly	188,234
Skilled Nursing Facility	144,609
Acute Psychiatric Hospital	116,551
Dental Office	95,481
Dds Other In-Home Services	89,507
Dss Adult Residential	85,035
Ca Emergency Medical Services Auth	63,335
Dds Supported Living Services (Sls)	46,295
Local Health Department	42,854
Dss Adult Day Program	39,477
Vageneral Medical And Surgical Hospitals	36,415
Dss Home Care	35,904
Dss Rcf-Continuing Care Retirement Communit	33,949
Dss Short Term Residential Therapeutic Progr	31,333
Home Health Agency	26,068
Dr Offices From Medical Board	25,248
Primary Care Clinic	22,594
Veterinary Office	22,570

Facility Type	Health Care Total Number Working
Intermediate Care Facility-Dd/H/N/Cn/lid	9,899
Adult Day Health Care	9,240
Dss Adult Residential Facility For Persons W Intermediate Care Facility	9,180
Chemical Dependency Recovery Hospital	8,030
Surgical Clinic	7,161
Tribal Health Clinics	5,864
Vaother Outpatient Care Centers	5,076
Dss Temp Shelter Care Facility	4,200
Dds Family Home Agency	3,605
Dds Regional Resource Center	3,417
Dss Enhanced Behavioral Supports Home - Arf	3,366
Narcotic Treatment Programs (Ntp)	3,100
Congregate Living Health Facility	2,655
Other	2,098
Mental Health Rehabilitation Center (Mhrc)	1,484
Department Of Social Services	1,413
Rehabilitation Clinic	1,064
	991



Location of Healthcare Facility

- In Phase 1a when vaccine is initially limited, does the location of the facility matter as a prioritization factor?
- Use California Healthy Places Index in counties or similar information on vulnerability



Dataset 2

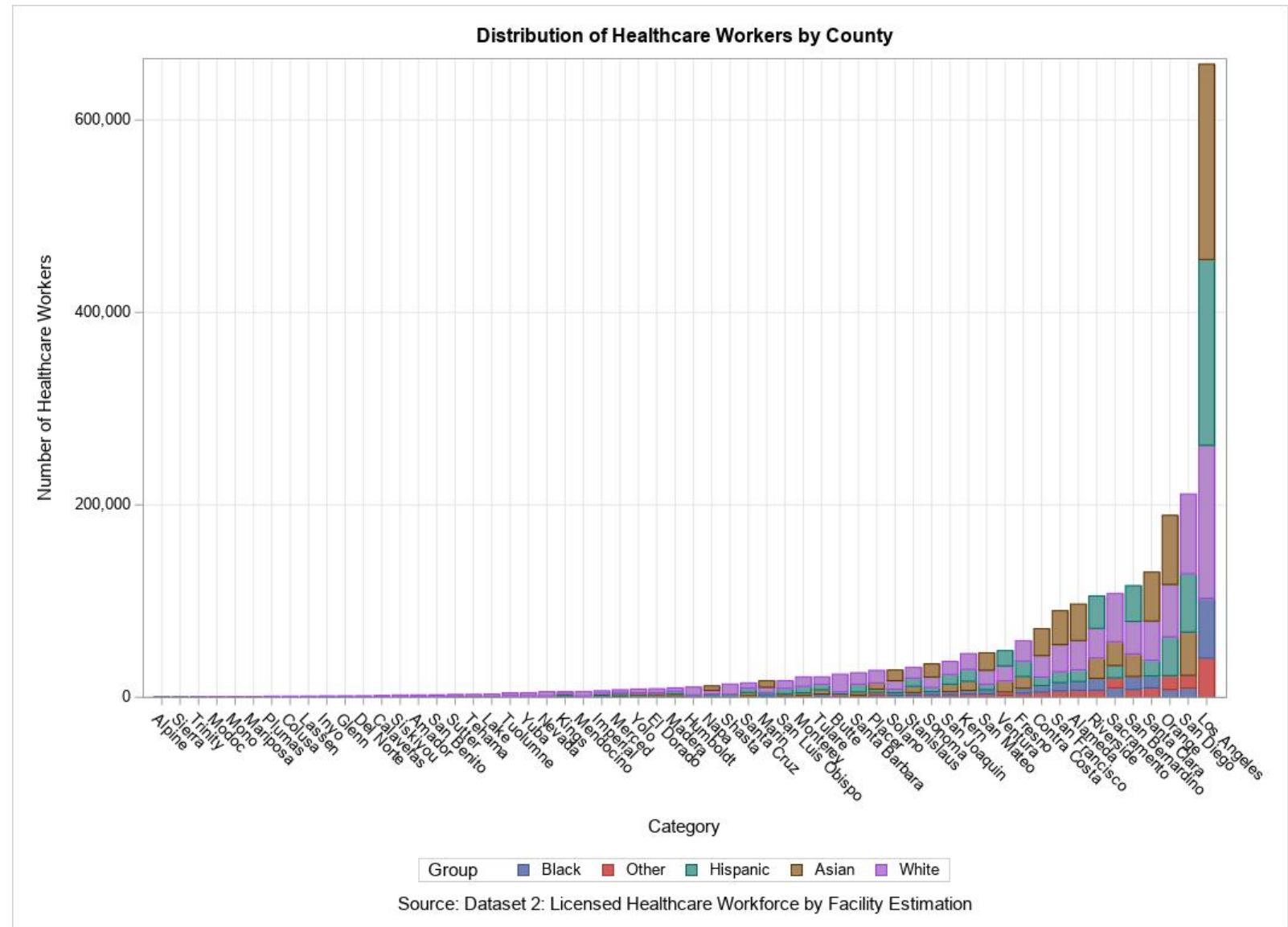
Healthcare Workforce by Healthcare Facility

Estimate of Total Healthcare Workforce by County
Total Statewide Healthcare Workforce= 2,415,302
Source: Dataset 2: Healthcare Workforce Estimates by Facility



Dataset 2

Healthcare Workforce by Healthcare Facility



Source: Dataset 2: Licensed Healthcare Workforce by Facility Estimation



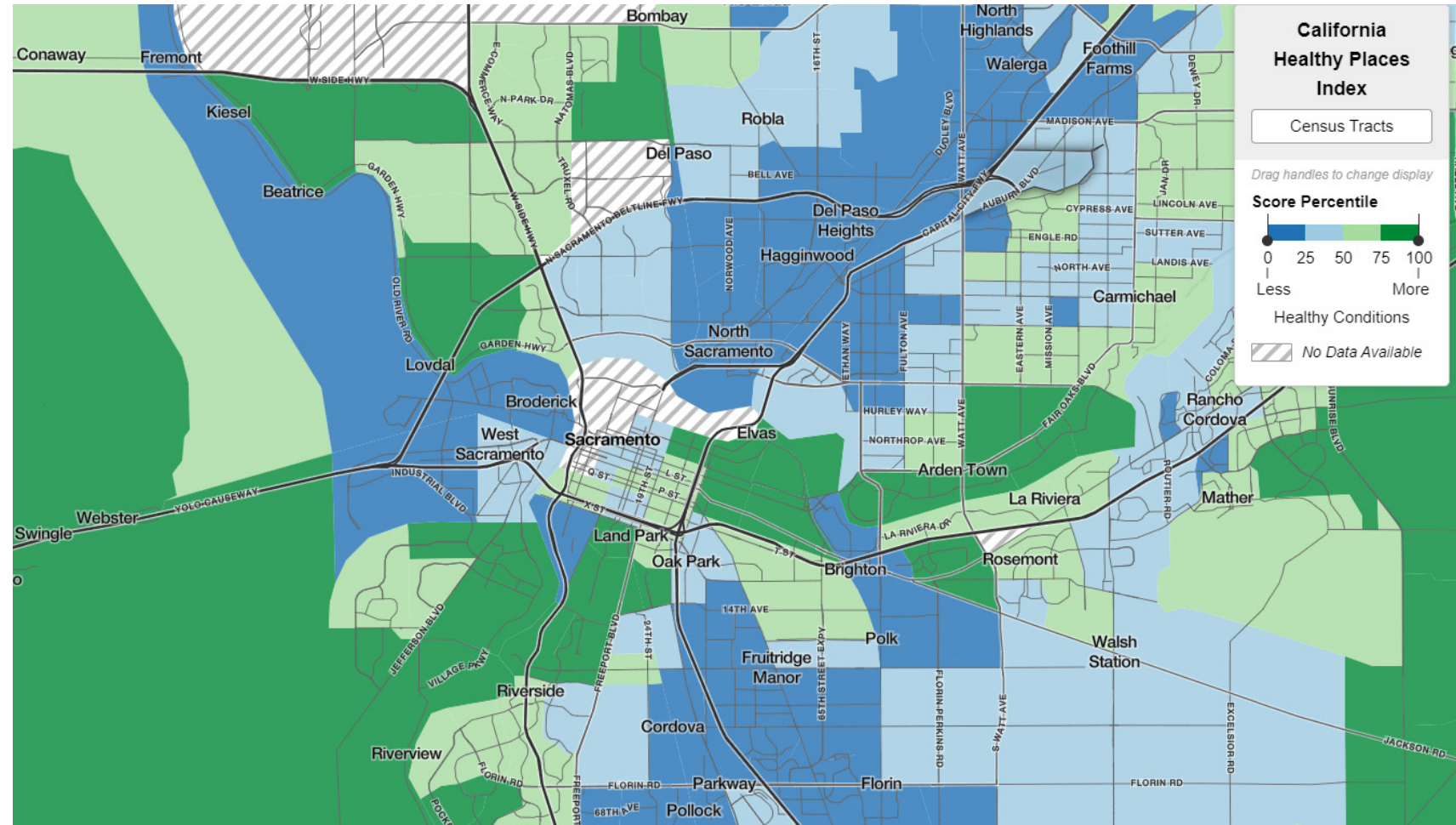
Community Vulnerability Index

- California Healthy Places Index (HPI)
- HPI - PH Alliance of So. CA
 - 25 variables, 8 themes:
 - Economic, Education
 - Housing, Health care access
 - Neighborhood, Clean environment
 - Transportation, Social factors
- Currently used in *Blueprint for a Safer Economy* and COVID-19 health equity playbook



Our Most Vulnerable Communities

- Healthy Places Index Map
- Most Vulnerable Communities are in Blue



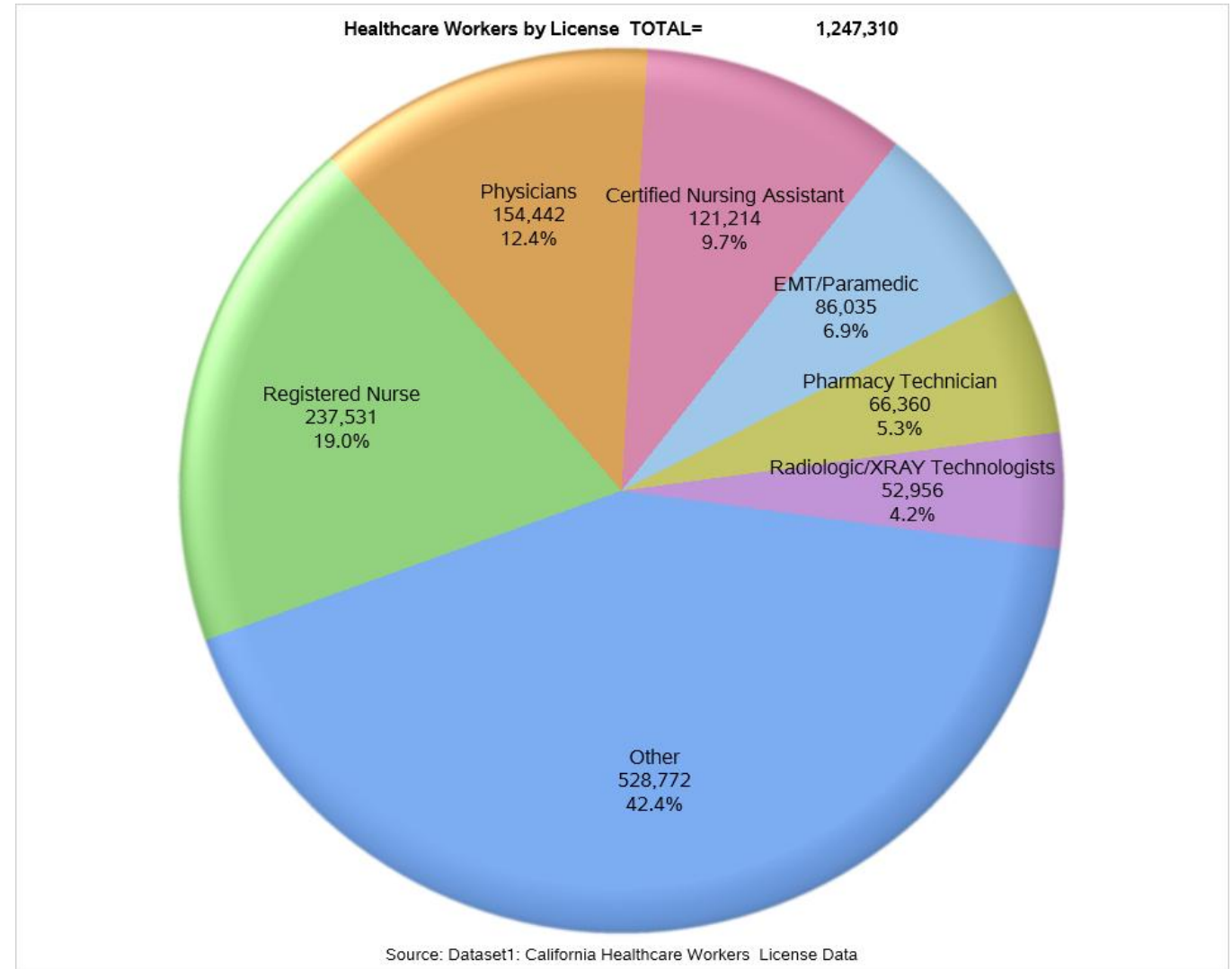
Attributes of Individual Healthcare Workers

- What personal characteristics of a healthcare worker might make them more of a priority for vaccination when vaccine is limited? Occupation, Age, Sex, Race/Ethnicity, Co-morbid conditions
- What information will vaccinator have access to?
 - Committee reviewing approaches, including encouragement and supporting immunization of workers who are at highest risk based upon their individual attributes.



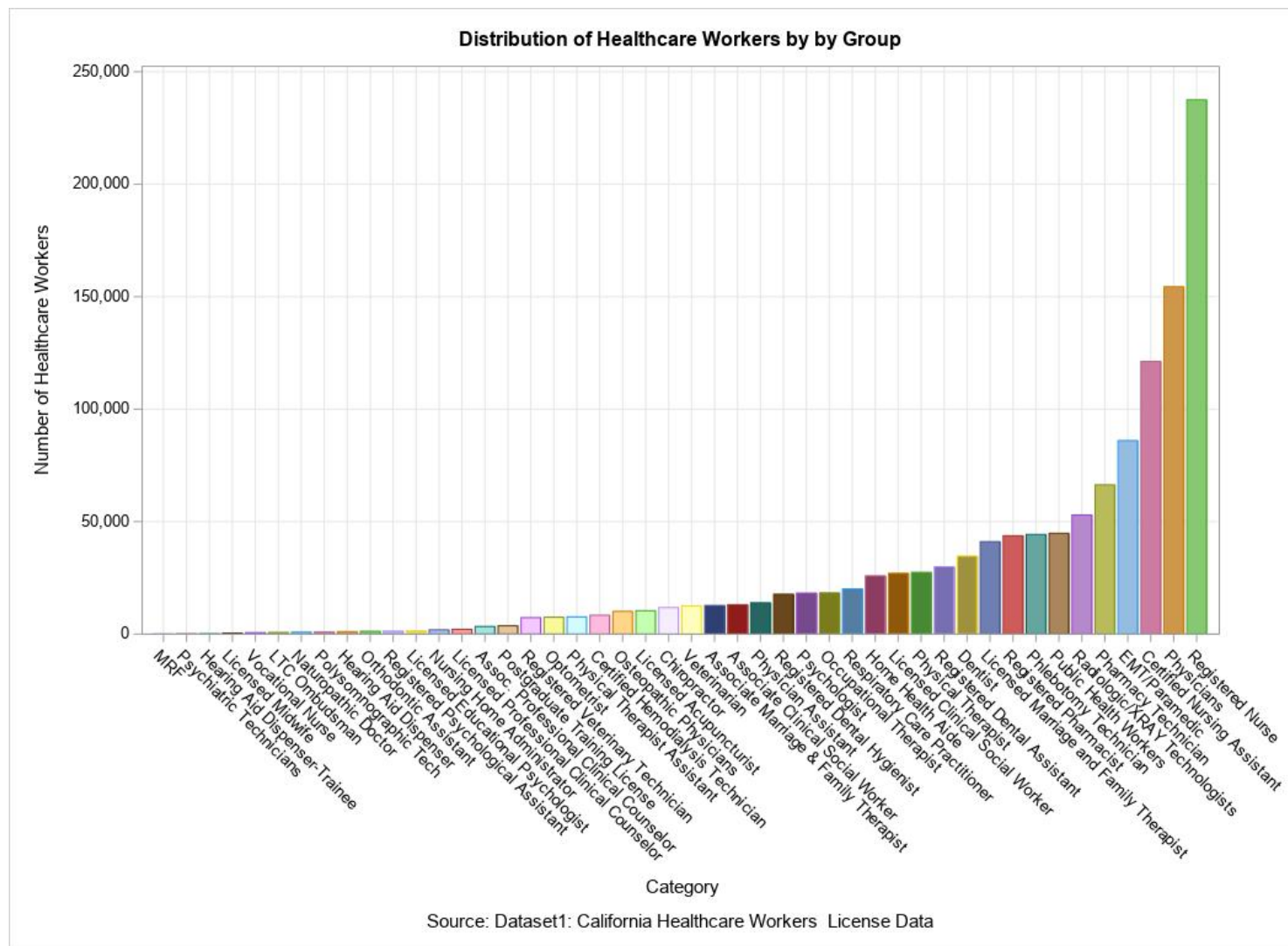
Dataset 1

Healthcare Workers by License



Dataset 1

Healthcare Workers by License



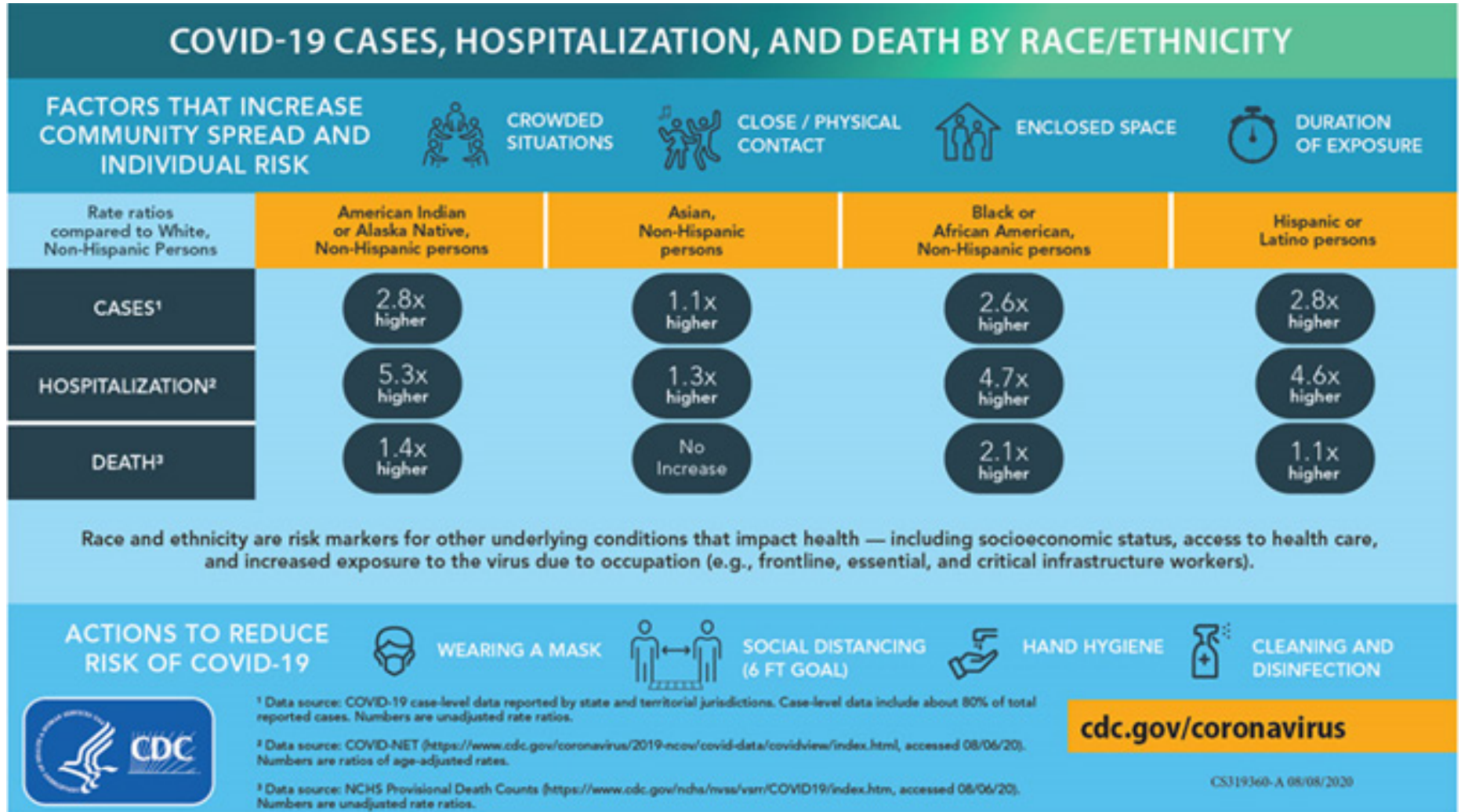
Underlying Conditions

Strongest and most consistent evidence

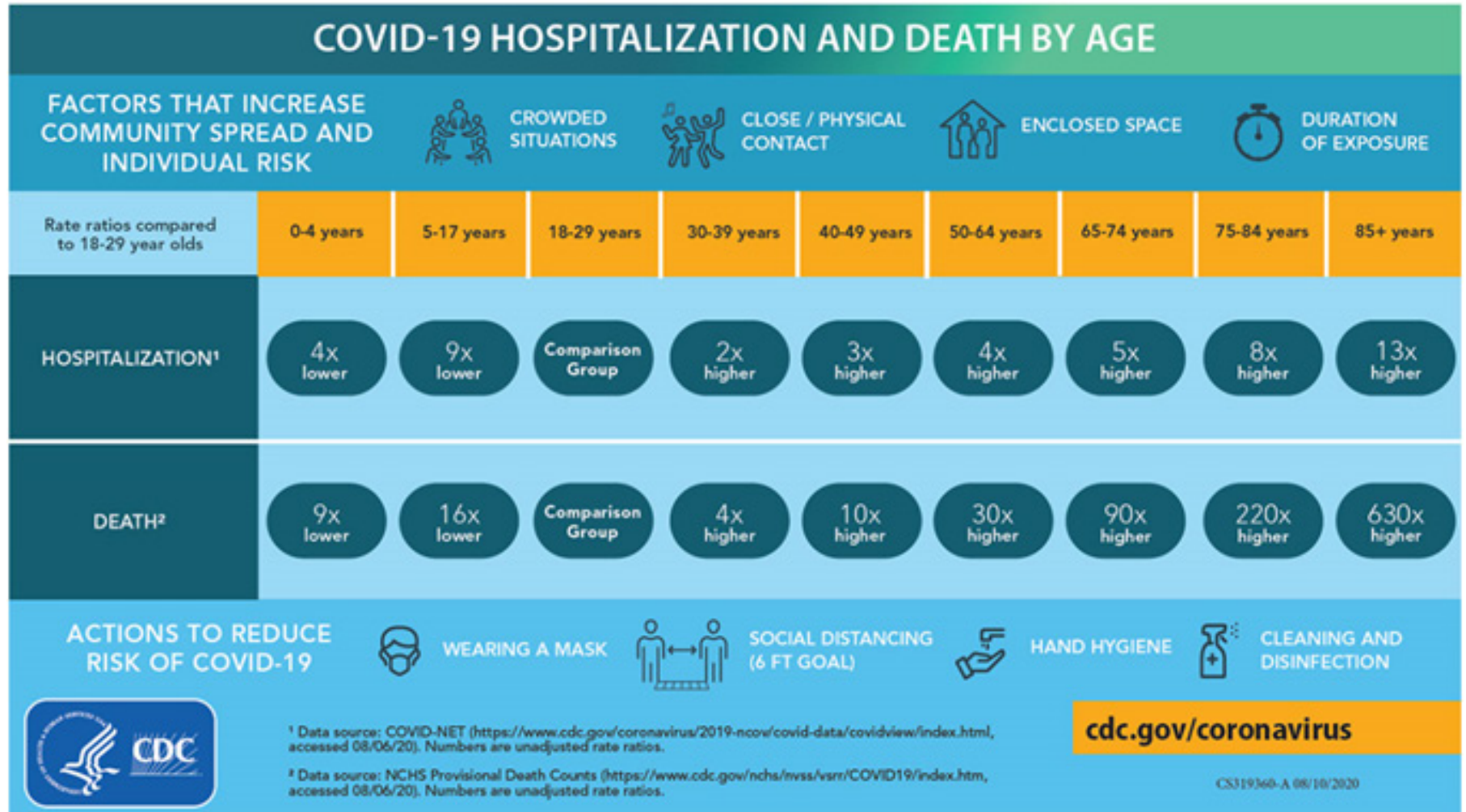
- Cancer
- Chronic kidney disease
- COPD
- Heart Disease
- Obesity & Severe Obesity
- Pregnancy
- Sickle cell disease
- Smoking
- Solid organ transplantation
- Type 2 DM



COVID-19 by Race/Ethnicity



COVID-19 by Age



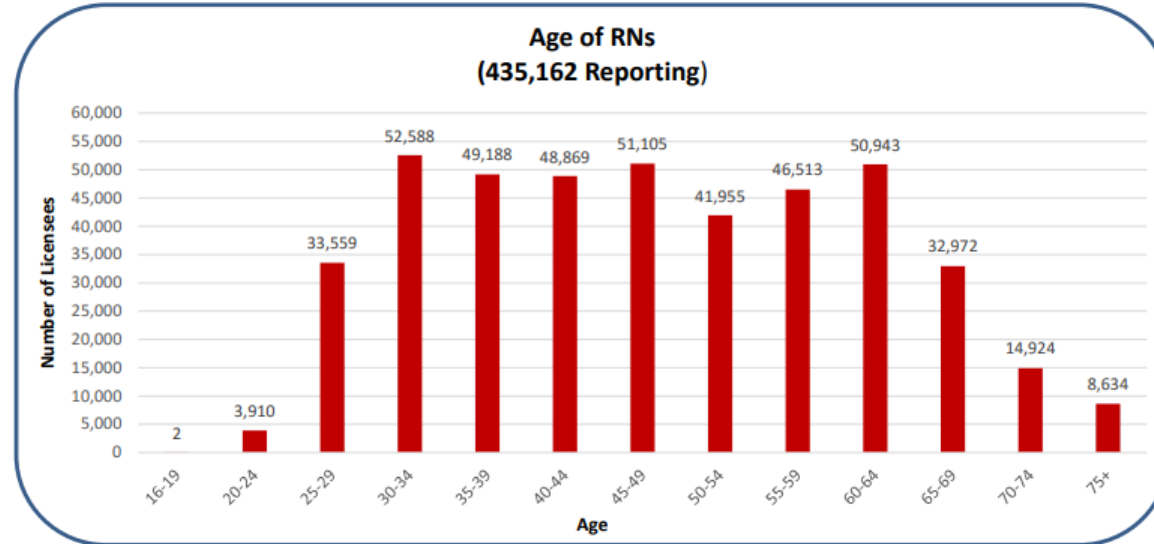
Registered Nurses



REGISTERED NURSES

As of August 2017, the California Board of Registered Nurses reported 435,162 active Registered Nurses (RN). The average age of RNs was 48 years old.

FACT SHEET



Source: California Department of Consumer Affairs (DCA), Board of Registered Nurses Master File, September 2017. For the purposes of this Fact Sheet, currently licensed Registered Nurses are defined as 'renewed and current.'



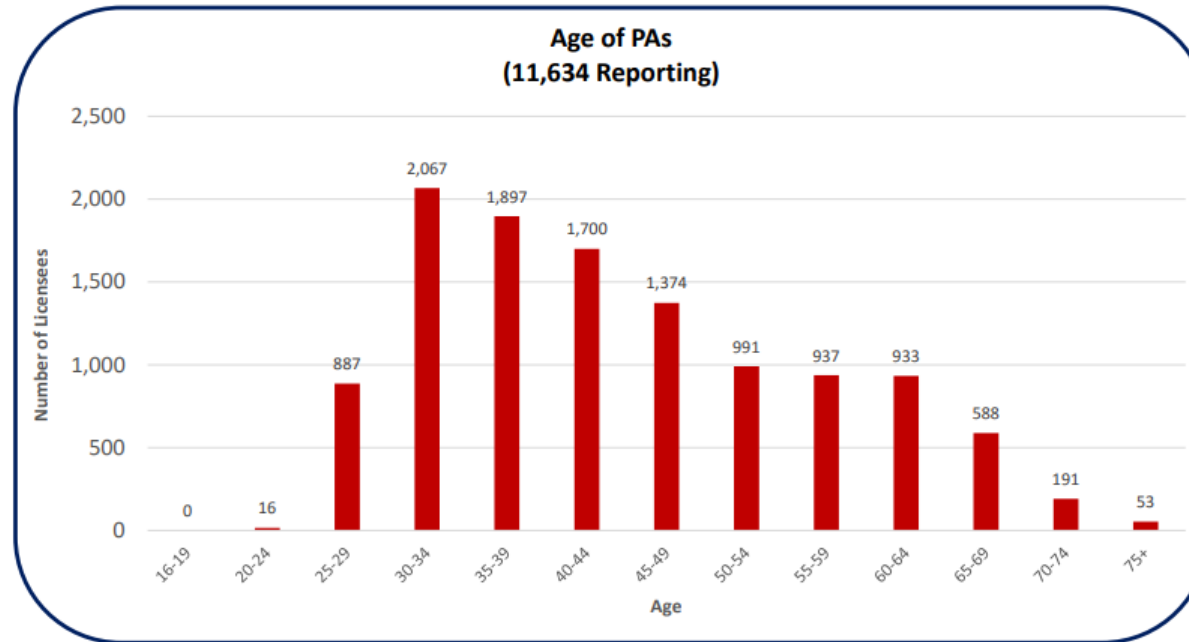
Physician Assistants



PHYSICIAN ASSISTANTS (PA)

As of August 2017, California's Physician Assistant Board reported 11,634 Physician Assistants (PA). The average age of PAs was 44 years old.

FACT SHEET



Source: California Department of Consumer Affairs, Physician Assistant Committee of California Public Master File, September 2017. For the purposes of this Fact Sheet, currently licensed PAs are defined as 'renewed and current.'



To Be Continued Monday, November 30

- What will make this a fair process for you and the people of California?
- Your feedback will go back to the Drafting Guidelines Workgroup on this Friday November 27, 2020.
- How your feedback influenced the workgroup will be shared on Nov 30.





Closing Comments and Q&A

- Next Meetings
 - November 30, 2020 from 3:00 – 6:00pm
 - December 9, 2020 from 3:00 – 6:00pm
 - December 16, 2020 from 3:00 – 6:00pm
 - December 21, 2020 from 3:00 – 6:00pm
- Agenda for Next Meeting
- How to Make Public Comment

Thank you

