

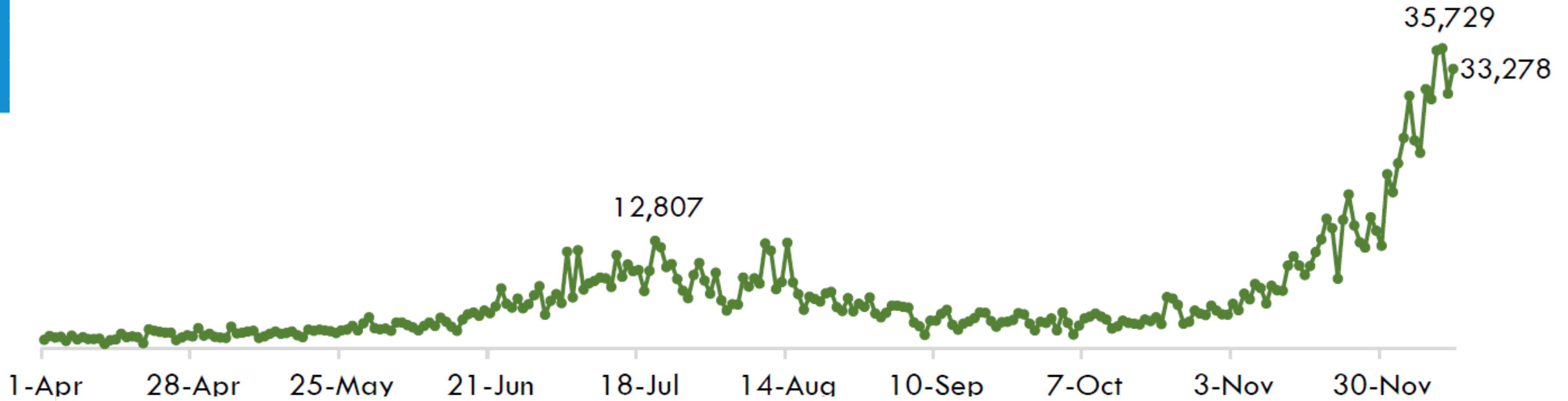


CRIHB COVID-19 Updates December 15, 2020

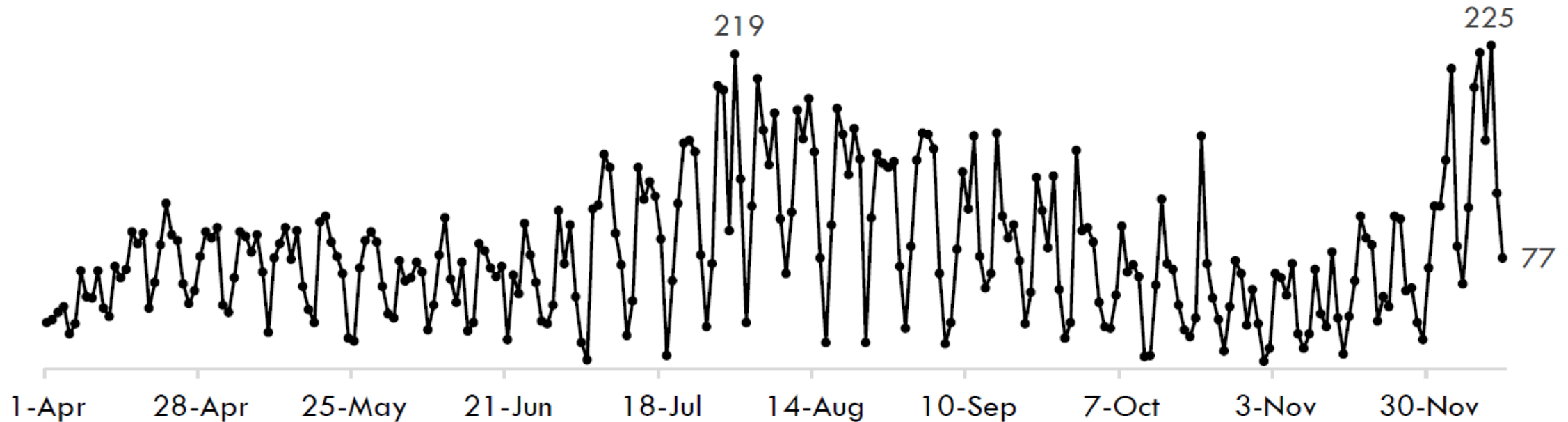
*Please sign-in in the Group
Chat with your name and
Tribe or Indian Health
Program name*



New Confirmed Cases in California by Date



New Confirmed Deaths in California by Date





California COVID-19 threat level: **Severe outbreak**

DAILY NEW CASES

 **80.2** PER 100K

VERY DANGEROUS
NUMBER OF NEW CASES

INFECTION RATE

 **1.24**

ACTIVE CASES ARE
RAPIDLY INCREASING

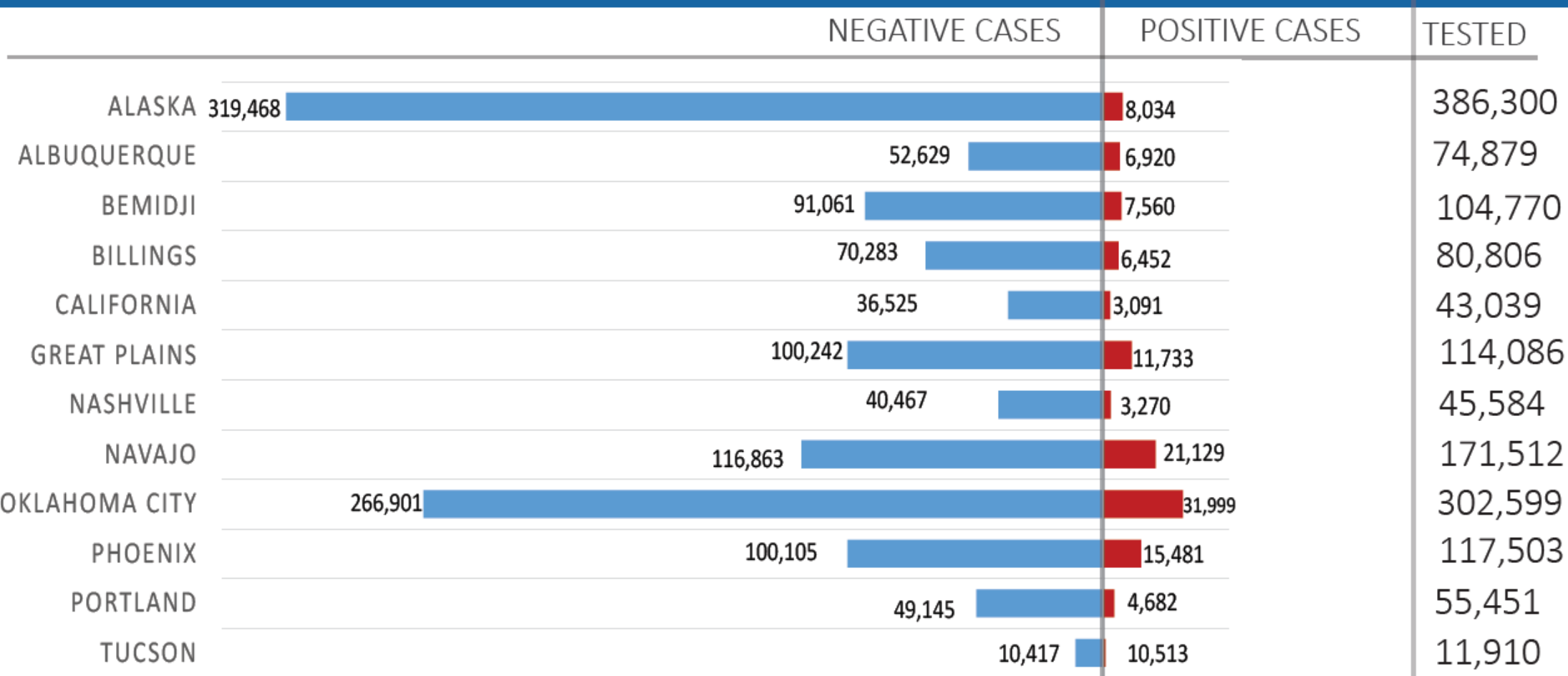
POSITIVE TEST RATE

 **9.8 %**

INDICATES ADEQUATE
TESTING

As of 12/15/2020. Source: COVID Act Now

COVID-19 CASES BY IHS AREA

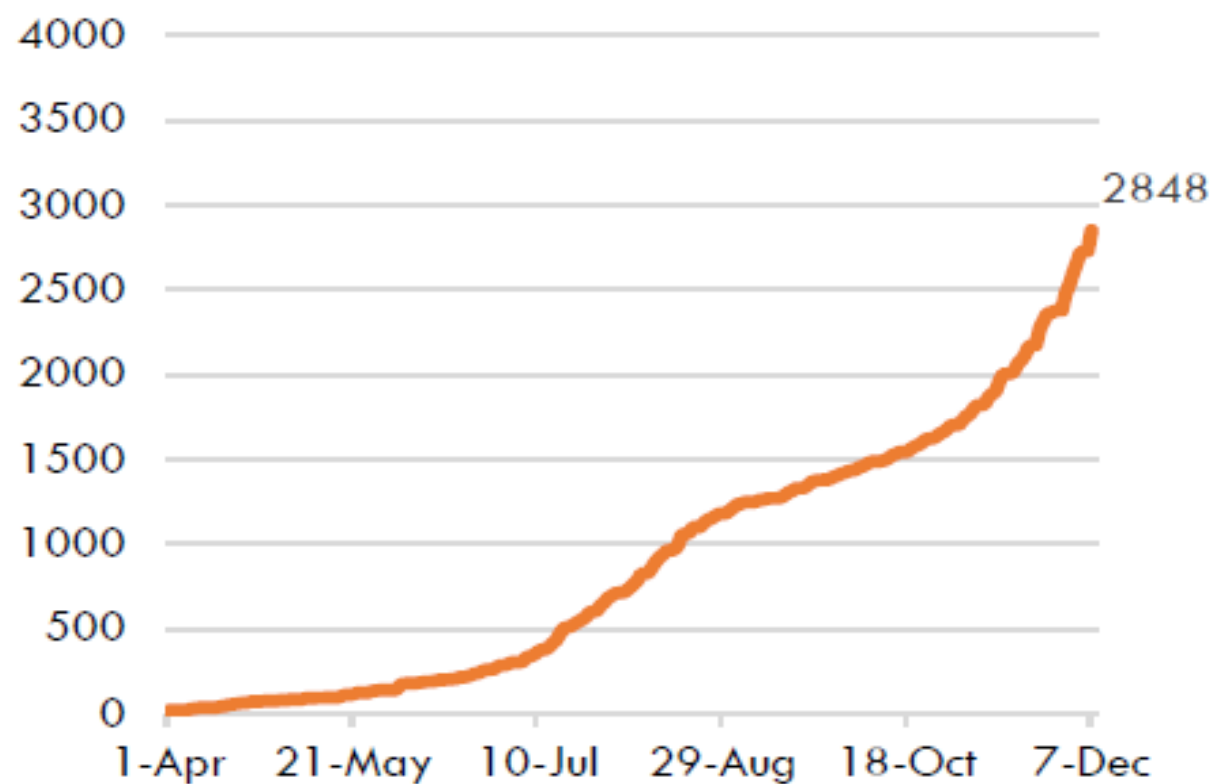


*as of 11:59PM EST December 12, 2020

Based on self-reported data to IHS

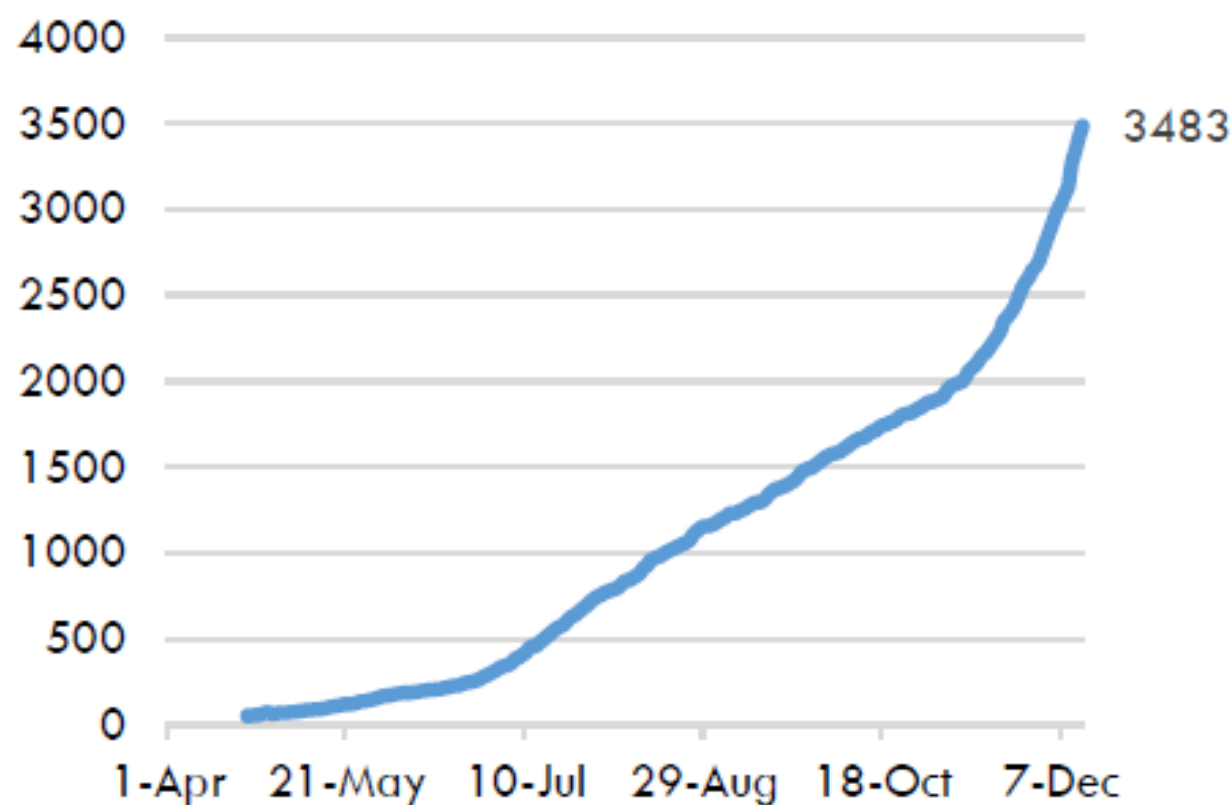


Data from the **Indian Health Service (IHS)** include positive cases reported by Tribal and Urban Indian Health Programs.



As of 12/1/2020. Source: IHS

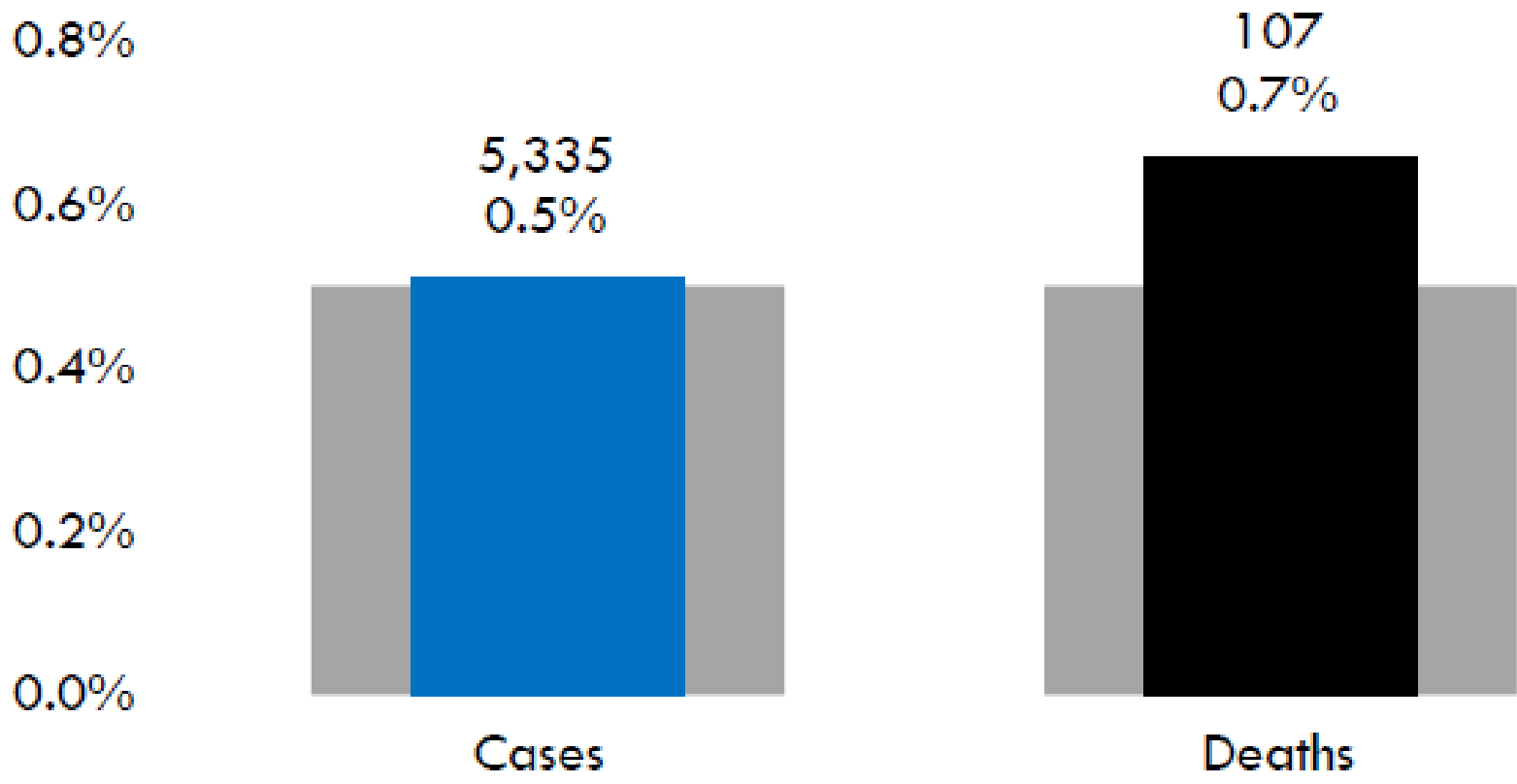
Data from **California Department of Public Health (CDPH)** include all positive cases of AIAN diagnosed in California.



As of 12/14/2020. Source: CDPH



CDC data show that AIAN in California are testing positive for COVID-19 at rates that are proportionate to their population in California but dying at rates that are higher. This includes a total of **5,335 cases** and **107 deaths**.



As of 12/7/2020. Source: CDC

○ Number of positive cases identified by region



COVID-19 Research & Vaccines
for AI/AN Communities

December 15 • 2 p.m. ET / 11 a.m. PT

featuring

Dr. Anthony Fauci

&

NIH Tribal Health Research Office

Director Dr. David Wilson



LIVE on NIH's Facebook & Twitter



**A Q&A on COVID-19 Research & Vaccines for
American Indian & Alaska Native Communities**

Link: <https://www.facebook.com/nih.gov/videos/187155926446875>



CDC Foundation COVID-19 Corps Staff

- The CDC Foundation has hired following positions to serve California Tribal communities. These are 100% remote and will work directly with California Tribes and Tribal/Urban Indian Health Programs.
- Tribal Nation Epidemiologist (1)
 - Inger Appanaitis, iappanaitis@cdcfoundation.org
- Tribal Nation Emergency Preparedness Planner (2)
 - Isabella Kaser, ikaser@cdcfoundation.org
 - Mitchell Saraceno, msaraceno@cdcfoundation.org
- Tribal Nation Public Health Disease Investigator (2)
 - Annie Rivera, arivera@cdcfoundation.org
 - Mwhiki Gaciri, mgaciri@cdcfoundation.org



Indian Health Service

COVID-19 Vaccine Distribution List by IHS Area

The Indian Health Service COVID-19 Vaccine Distribution List includes the 337 IHS direct, tribal health programs, and urban Indian organizations that chose to receive a COVID-19 vaccine from the IHS when it becomes available. The information is current as of November 25, 2020. IHS will continue to update the list as needed based on final decisions of tribal health programs and urban Indian organizations.

IHS COVID-19 Vaccine Distribution List – IHS, Tribal Health Programs, and Urban Indian Organizations	
Alaska Area	2
Albuquerque Area	27
Bemidji Area	35
Billings Area	13
California Area	61
Great Plains Area	28
Nashville Area	26
Navajo Area	27
Oklahoma City Area	62
Phoenix Area	33
Portland Area	21
Tucson Area	2
Grand Total	337

Indian Health Service COVID-19 Vaccine Allocation by IHS Area

The Indian Health Service is coordinating closely with Operation Warp Speed in preparation for the availability of a COVID-19 vaccine. The IHS anticipates that vaccines will be shipped to IHS within 24 hours of a vaccine receiving emergency use authorization from the FDA.

To enable equitable and expedient distribution of COVID vaccine, the IHS has worked with tribal communities to design distribution plans based on each local community and the unique populations and geographical characteristics of the community. This includes preparing for appropriate storage and handling of vaccines, once authorized or approved.

The Indian Health Service is expecting to receive an initial allocation of approximately 22,400 doses of the Pfizer vaccine and 46,000 doses of the Moderna vaccine. IHS supports CDC and the Advisory Committee on Immunization Practices recommendations for vaccine release, including prioritization of health care workers and residents of long-term-care facilities.

The expected doses in this initial allocation will allow IHS to provide the first vaccine dose to 100% of its health care work force and residents of long-term-care facilities not accounted for by the Centers for Medicare and Medicaid Services. Health facilities will receive the remainder of the Pfizer and Moderna doses to vaccinate the next priority populations based on ACIP guidelines.

Operation Warp Speed is reserving an equal number of doses in this initial allocation that will be delivered to IHS to provide the second dose for the individuals vaccinated with the first allocation. At this time, IHS does not have information on further allocations.

Area	Anticipated Pfizer Doses	Anticipated Moderna Doses
Albuquerque	975	2600
Bemidji	1950	2900
Billings	975	1700
California	975	5100
Great Plains	1950	3000
Nashville	975	3400
Navajo	3900	7900
Oklahoma City	5850	8900
Phoenix	3900	7300
Portland	975	2300
Tucson	0	900
Totals	22425	46000

CDPH Community Vaccine Advisory Committee

Link:

<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Community-Vaccine-Advisory-Committee.aspx>

Upcoming Meetings


Date: Wednesday, December 16, 2020

Time: 3:00 p.m. - 6:00 p.m.

Access Information:

- English Toll free: 844-721-7237
- English Access Code: 2243784
- Spanish Toll-Free: 844-721-7237
- Spanish Access Code: 8752493
- Live stream via [YouTube](#)



California Department of Public Health 

December 11 at 9:58 AM · 



Get exposure notifications and help stop the spread. Sign up for [#COVID19](#) exposure notifications on your phone with CA Notify. The privacy-protected tool lets you know if you were exposed to someone who tested positive for COVID-19.

Sign Up. Save Lives.

[#CANotify](#)

[CANotify.ca.gov](https://canotify.ca.gov)



Add Your Phone. Stop the Spread.


Help protect your community
while maintaining your privacy.



CA NOTIFY

canotify.ca.gov





Submit CTEC TA online request:
<https://crihb.org/technical-assistance-request-form/>

How to reach us for questions:

Clinical-related assistance:

Thomas Kim, MD, MPH
Medical Director/Epidemiologist
tkim@crihb.org

PPE-related questions:

Rosario Arreola Pro, MPH
Director, Health Systems Development
rarreolapro@crihb.org

Community or grant-related assistance:

Vanesscia Cresci, MSW, MPA
Director, Research and Public Health
vcresci@crihb.org

Epidemiologic or data-related assistance:

Aurimar Ayala, MPH
Epidemiology Manager
aayala@crihb.org



Public Service Announcements

- Southern California: American Indian Media Concepts
- Eastern California: Tazbah Chavez
- Far Northern California: Wingspan Media
- Central California (southern): Tazbah Chavez
- Central California (northern): Happy Valley Film Company (*In process*)
- Sonoma/Mendocino Area: California Indian Museum and Cultural Center (*In process*)

CRIHB YouTube channel:

<https://www.youtube.com/channel/UCI4YV6tGvzZupdqzHSx6WnA/>

BNT162b2 (Pfizer/BioNTech) Covid-19 Vaccine Safety & Efficacy

KEY POINTS

December 15, 2020

CRIHB Tribal/THP Covid-19 Call

Pfizer-BioNTech Vaccine

- A vaccine is needed to control the pandemic
- “Pfizer” Vaccine
 - Start of vaccine development – January 10
 - FDA Emergency Use Authorization – December 11
 - Recommended by the CDC Advisory Committee on Immunization Practices – December 12
 - Shipments to California – December 14
- New type of vaccine: mRNA in a lipid nanoparticle
 - mRNA encodes a modified S Protein (spike) of SARS CoV-2
 - Ultra-cold storage (-80C to -60C)
 - IM injection
 - Dilution with NaCl injection diluent

Safety & Efficacy Phase 2/3 Trial

- Multinational
- Stacked phases
- Placebo-controlled
- Observer-blinded
- Randomized
- 2 months follow up

Participants

- 12 years and older (primarily 16 and older)
- Healthy or stable chronic medical conditions
- Randomized 1:1
 - Receive 2 doses of test vaccine = 18,556
 - Receive 2 doses of placebo (saline solution) = 18,530
 - Doses given 21 days apart

Demographic Characteristics of the Participants in the Main Safety Population.*

Table 1. Demographic Characteristics of the Participants in the Main Safety Population.*

Characteristic	BNT162b2 (N=18,860)	Placebo (N=18,846)	Total (N=37,706)
Sex — no. (%)			
Male	9,639 (51.1)	9,436 (50.1)	19,075 (50.6)
Female	9,221 (48.9)	9,410 (49.9)	18,631 (49.4)
Race or ethnic group — no. (%)†			
White	15,636 (82.9)	15,630 (82.9)	31,266 (82.9)
Black or African American	1,729 (9.2)	1,763 (9.4)	3,492 (9.3)
Asian	801 (4.2)	807 (4.3)	1,608 (4.3)
Native American or Alaska Native	102 (0.5)	99 (0.5)	201 (0.5)
Native Hawaiian or other Pacific Islander	50 (0.3)	26 (0.1)	76 (0.2)
Multiracial	449 (2.4)	406 (2.2)	855 (2.3)
Not reported	93 (0.5)	115 (0.6)	208 (0.6)
Hispanic or Latinx	5,266 (27.9)	5,277 (28.0)	10,543 (28.0)
Country — no. (%)			
Argentina	2,883 (15.3)	2,881 (15.3)	5,764 (15.3)
Brazil	1,145 (6.1)	1,139 (6.0)	2,284 (6.1)
South Africa	372 (2.0)	372 (2.0)	744 (2.0)
United States	14,460 (76.7)	14,454 (76.7)	28,914 (76.7)
Age group — no. (%)			
16–55 yr	10,889 (57.7)	10,896 (57.8)	21,785 (57.8)
>55 yr	7,971 (42.3)	7,950 (42.2)	15,921 (42.2)
Age at vaccination — yr			
Median	52.0	52.0	52.0
Range	16–89	16–91	16–91
Body-mass index‡			
≥30.0: obese	6,556 (34.8)	6,662 (35.3)	13,218 (35.1)

* Percentages may not total 100 because of rounding.

† Race or ethnic group was reported by the participants.

‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.

Efficacy

- Defining endpoints
 - PCR confirmed Covid-19 infection with symptoms
 - 7 days after the second dose
 - In participants with no evidence of prior infection
 - Total = 36,523 participants
- Results
 - 50-60% efficacy goal
 - 8 cases in vaccine group
 - 162 cases in placebo group
 - Corresponds to “vaccine efficacy” of 95% (90.3-97.6%)
 - Early divergence in case separation by day 10-12

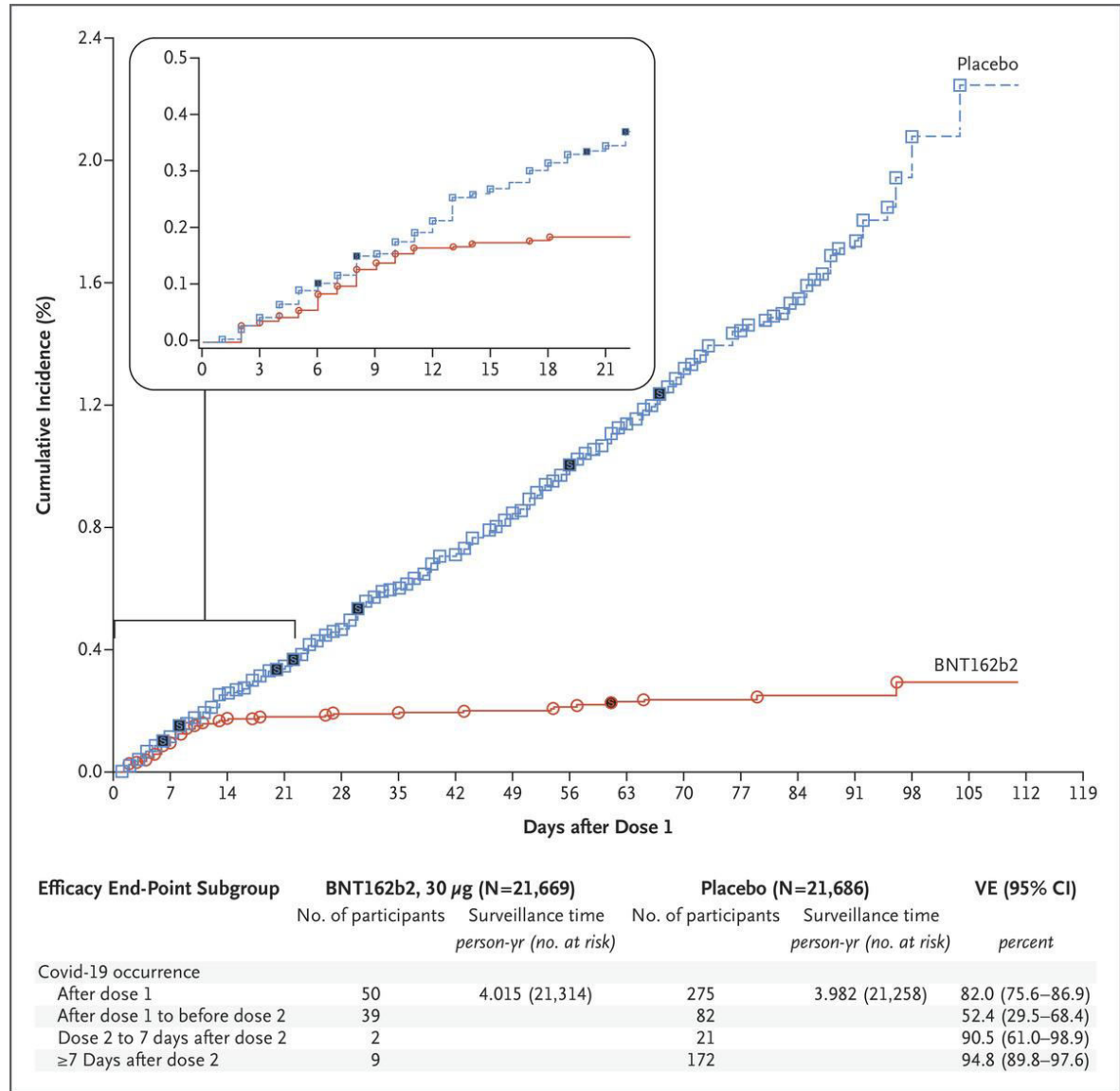


Table 3. Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection before 7 Days after Dose 2.

Efficacy End-Point Subgroup	BNT162b2 (N=18,198)		Placebo (N=18,325)		Vaccine Efficacy, % (95% CI) [†]
	No. of Cases	Surveillance Time (No. at Risk)*	No. of Cases	Surveillance Time (No. at Risk)*	
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0–97.9)
Age group					
16 to 55 yr	5	1.234 (9,897)	114	1.239 (9,955)	95.6 (89.4–98.6)
>55 yr	3	0.980 (7,500)	48	0.983 (7,543)	93.7 (80.6–98.8)
≥65 yr	1	0.508 (3,848)	19	0.511 (3,880)	94.7 (66.7–99.9)
≥75 yr	0	0.102 (774)	5	0.106 (785)	100.0 (–13.1–100.0)
Sex					
Male	3	1.124 (8,875)	81	1.108 (8762)	96.4 (88.9–99.3)
Female	5	1.090 (8,536)	81	1.114 (8,749)	93.7 (84.7–98.0)
Race or ethnic group [‡]					
White	7	1.889 (14,504)	146	1.903 (14,670)	95.2 (89.8–98.1)
Black or African American	0	0.165 (1,502)	7	0.164 (1,486)	100.0 (31.2–100.0)
All others	1	0.160 (1,405)	9	0.155 (1,355)	89.3 (22.6–99.8)
Hispanic or Latinx	3	0.605 (4,764)	53	0.600 (4,746)	94.4 (82.7–98.9)
Non-Hispanic, non-Latinx	5	1.596 (12,548)	109	1.608 (12,661)	95.4 (88.9–98.5)
Country					
Argentina	1	0.351 (2,545)	35	0.346 (2,521)	97.2 (83.3–99.9)
Brazil	1	0.119 (1,129)	8	0.117 (1,121)	87.7 (8.1–99.7)
United States	6	1.732 (13,359)	119	1.747 (13,506)	94.9 (88.6–98.2)

* Surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from 7 days after the second dose to the end of the surveillance period.

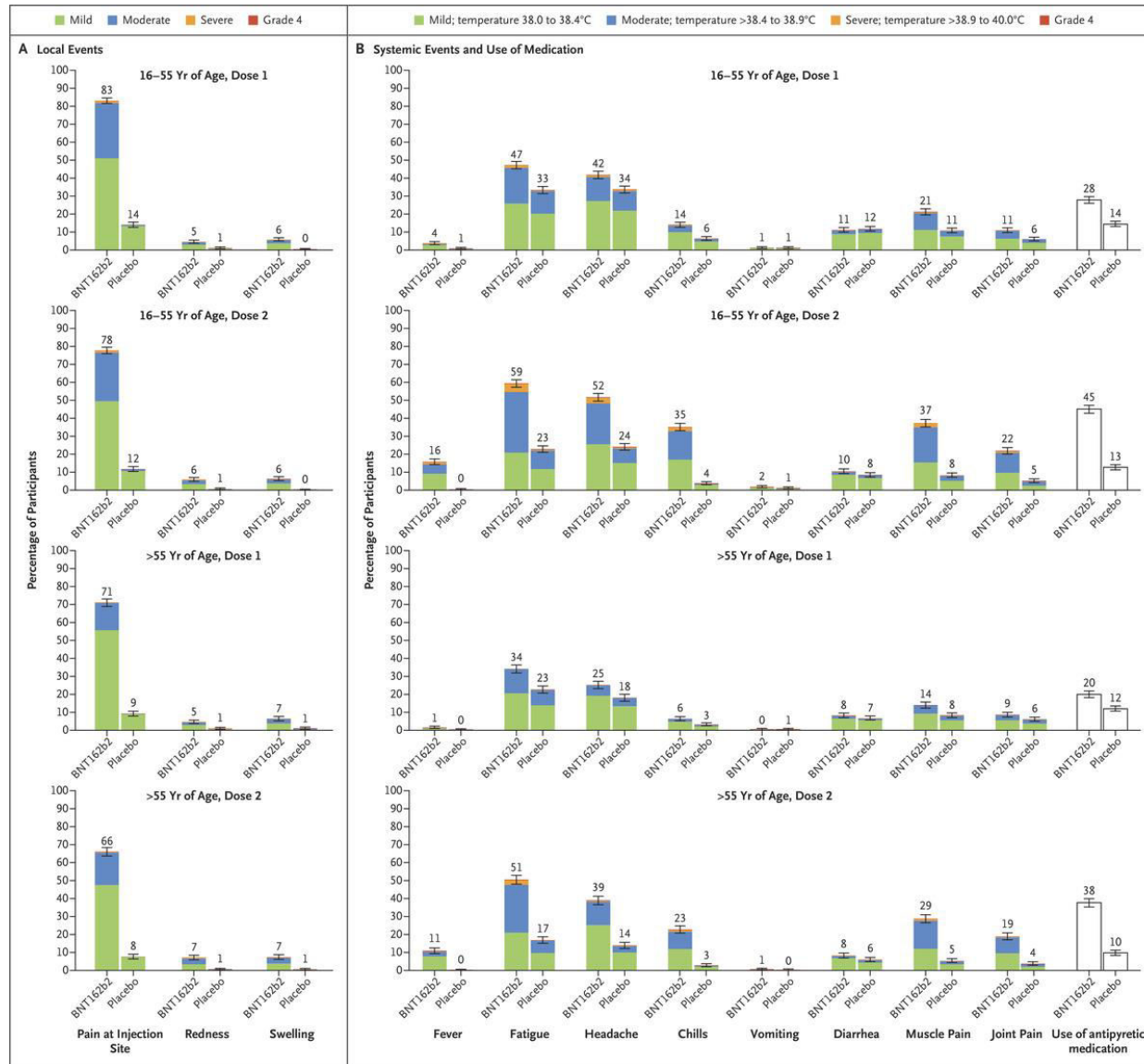
[†] The confidence interval (CI) for vaccine efficacy is derived according to the Clopper–Pearson method, adjusted for surveillance time.

[‡] Race or ethnic group was reported by the participants. “All others” included the following categories: American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported.

Safety (vaccine vs. placebo)

- Safety endpoints
 - Local reactions or “reactogenicity”
 - Systemic reactions
 - Use of antipyretics or pain medication within 7 days of injection
- Findings in Age 15-55 after First Dose
 - Pain at injection site 83% vs 14%
 - Fatigue 47% vs 33%
 - Headache 42% vs 34%
- Findings in Age >55 after First Dose
 - Pain at injection site 71% vs 9%
 - Fatigue 34% vs 23%
 - Headache 25% vs 18%
- Overall, side effects were less common in older vaccine recipients
- Most side effects were mild to moderate in severity; worse after 2nd dose for systemic reactogenicity
- Serious side effects 0.6% vs 0.5%

Local and Systemic Reactions Reported within 7 Days after Injection of BNT162b2 or Placebo, According to Age Group.



Adverse Events Surveillance

- Vaccine Adverse Event Reporting System (VAERS)
- V-Safe active surveillance
- Mandatory reporting
 - Vaccine administration errors
 - Serious adverse events (irrespective to vaccine attribution)
 - Serious = life-threatening, hospitalization, death, incapacity, affect normal life function, or birth defect
 - Multi-system Inflammatory Syndrome
 - Cases of Covid-19 that result in hospitalization or death
- Continuing post-observational observational studies by Pfizer especially looking at subgroups: pregnant women, immunocompromised individuals, healthcare workers, etc.

Manufacturer COVID-19 Vaccine Training & Education Series, Week of December 15

This week, Pfizer will be hosting a series of training sessions to review information and answer questions about their COVID-19 vaccine. Please share these training opportunities with clinicians and COVID-19 vaccine providers. Please click on the link below to join the sessions at the designated times.

Date & Time

[December 15, 2020 4:30 PM ET](#) Password cXQqYzTM352
[December 16, 2020 9:30 AM ET](#) Password yDxuqt6Pg52
[December 16, 2020 4:30 PM ET](#) Password auKMUdmJ687
[December 17, 2020 9:30 AM ET](#) Password TMr7GvMc2P2
[December 17, 2020 4:30 PM ET](#) Password PPxyyuGP249
[December 18, 2020 9:30 AM ET](#) Password GawpMXB2X95
[December 18, 2020 4:30 PM ET](#) Password w3kBrP9ReU3

Summary

- Vaccine Efficacy calculated to be 95%
- Safety profile consists of mostly mild to moderate pain at the injection site, fatigue and headache with an adverse event rate similar to other vaccines
- Reports do not address children, adolescents, pregnant women due to insufficient statistical power
- Ongoing monitoring and surveillance for adverse events
- Critical for the global control of pandemic
- Challenges in communicating and informing our Tribal Communities

CRIHB COVID-19 Meeting Notes

TRIBE, THP, and UIHP

ATTENDEES:

1. Tuolumne Band of Me-Wuk
2. Graton Rancheria
3. Jed Rudd, UIHS
4. Darla Clark, Chapa-De Indian Health
5. Frank Kearns, Pit River Health
6. Rachel Harvey, CAIHS
7. Carolyn Pumares, CA Area Office
8. Inger Appanaitis, CDC Foundation
9. Ethan Dexter
10. Laura Caswell
11. Clara Stairs
12. Loren Ellery
13. Shirley Laos
14. Kerry Patterson
15. Ernesto Padilla
16. Frank Isele
17. Willie Carrillo
18. Will Micklin
19. Michael Garcia

CRIHB STAFF

ATTENDEES:

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

DATE: Tuesday December 15, 2020 (3:30PM-4:30PM, PST)

HOST: CRIHB

Meeting Recording: <https://youtu.be/G2K-Xfnkj98>

COVID-19 Update

- 33,278 new confirmed cases in California as of 12/14/20, this is double the amount seen in July
- 3,091 cases self-reported to IHS as of 12/12/20
- Recording of COVID-19 Research & Vaccines for AI/AN Communities with Dr. Fauci and NIH Tribal Health Research Office Director:
<https://www.facebook.com/nih.gov/videos/187155926446875>
- IHS COVID-19 vaccine allocation
 - California anticipated to receive 975 Pfizer doses and 5100 Moderna doses

CDPH Community Vaccine Advisory Committee

- Link for committee information:
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Community-Vaccine-Advisory-Committee.aspx>
 - Upcoming meeting: Wednesday, December 16, 2020 3 pm – 6 pm
 - Dr. Thomas Kim represents CRIHB, meetings are public
- CDPH announced CA Notify. Sign up to get exposure notifications on your phone, canotify.ca.gov/

CRIHB Response

- Public Service Announcements available on CRIHB's YouTube channel:
<https://www.youtube.com/channel/UCI4YV6tGvzZupdqzHSx6WnA/>

Pfizer/BioNTech COVID-19 Vaccine Safety & Efficacy

- Vaccines are necessary to control the pandemic
- Vaccine evaluated in large multinational trials. 201 AIANs were included in the Pfizer vaccine study. 102 (.5 % of study participants) given the vaccine and 99 given the placebo
- In over 36,000 participants, 8 cases of Covid-19 developed in the vaccine group and 162 cases in the placebo group. Corresponding to a "vaccine efficacy" of 95%. The influenza (flu) vaccine has a typical vaccine efficacy of 40-60% depending on year
- Most side effects were mild to moderate in severity. Rate of serious side effects no different to other vaccines in use
- December 15–18, 2020 Pfizer is hosting COVID-19 Vaccine Training & Education series for clinicians and vaccine providers

CA IHS Area Office Update Vaccine Distribution

- Pfizer vaccine arrived at Pit River and will be distributed to 7 spoke sites within the week
- Both vaccines require 2 doses and Operation Warp Speed is holding back doses so people can complete the series
- All CA tribal and urban health programs that chose to receive vaccine through IHS have orders placed to receive Moderna vaccine once approved
- CA area vaccine office hours are weekly Mondays at 11 am, contact Rachel Harvey for call information

Questions

Q: When will phase 2 of Pfizer or Moderna vaccine be shipped?

A: Second dose of vaccine is coming. No word of second phase yet

Q: If this first shipment is 100 doses, is that for 50 people?

A: No, the first shipment of 100 doses is for 100 patients and the second dose for those patients will arrive within the 21-day window