

HHP/HPH COVID-19 Community Webinar Series

Monday, December 7, 2020
5:30pm – 6:30pm

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Moderator – 12/07/20

Andy Lee, MD

Medical Director, *Hawai'i Health Partners*
Chief of Staff, *Pali Momi Medical Center*
Hawai'i Pacific Health

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- The following is intended as information resource only for HHP/HPH providers, clinicians, administrative and clinical leaders.
- Specific areas may not pertain directly to your clinical practice area and/or may not be applicable to your practice based on your existing workflows, infrastructure, software (e.g. EHR), and communications processes.

Webinar Information

- You have been automatically muted. You cannot unmute yourself.
- You will be able to submit questions via the Q&A section.
 - Due to time constraints, any unanswered questions will be addressed this week and posted on the HHP website
- A recording of the meeting will be available tomorrow on the HHP website and intranet.

How to Claim CME Credit

1. Step 1: Confirm your attendance

- You should have completed a brief questionnaire before joining today's live webinar.

2. Step 2: HPH CME team will email you instructions

- Complete and submit evaluation survey that will be emailed to you within one week of the offering.
- Your CE certificate will be immediately available to you upon completion of your evaluation.
- Questions? Email hphcontinuingeduc@hawaiipacifichealth.org

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- In support of improving patient care, Hawai'i Pacific Health is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.
- Hawai'i Pacific Health designates this webinar activity for a maximum of 1.0 AMA PRA Category 1 Credit (s) TM for physicians. This activity is assigned 1.0 contact hour for attendance at the entire CE session.



JOINTLY ACCREDITED PROVIDER TM
INTERPROFESSIONAL CONTINUING EDUCATION

Disclosures

- The planners and presenters of this activity report no relationships with companies whose products or services (may) pertain to the subject matter of this meeting



COVID-19 Updates

Gerard Livaudais, MD, MPH

*Executive Vice President, Population
Health and Provider Networks,
Hawai'i Pacific Health*

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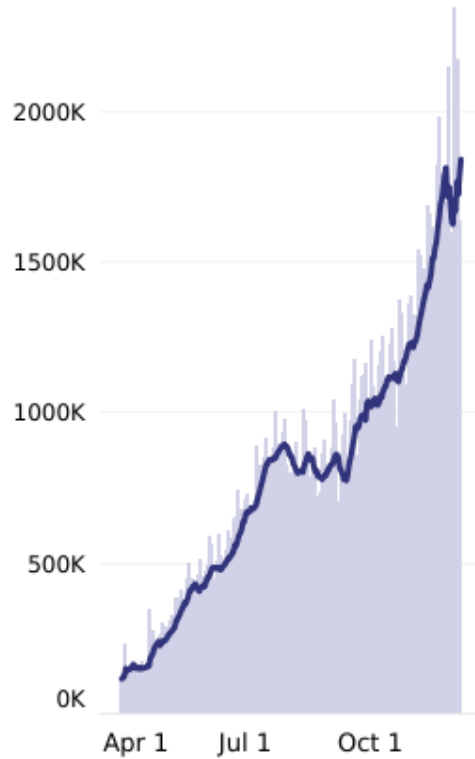
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NATIONWIDE COVID-19 METRICS SINCE APRIL 1. 7-DAY AVERAGE LINES

Choose Census Region
All

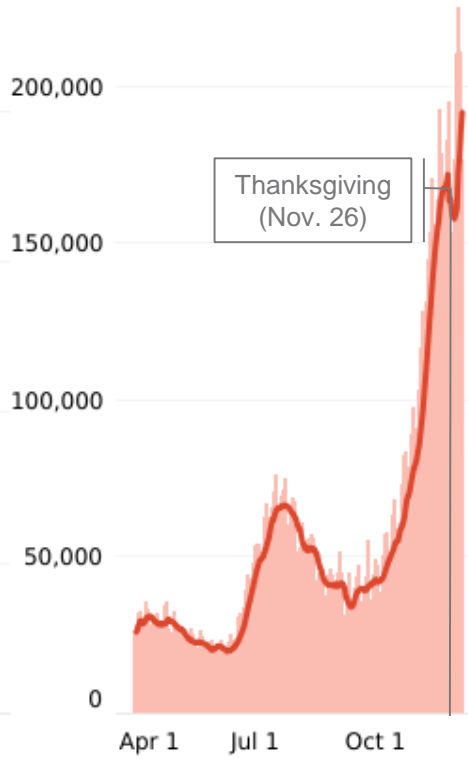
Daily Tests

Dec 6: **1.63M**



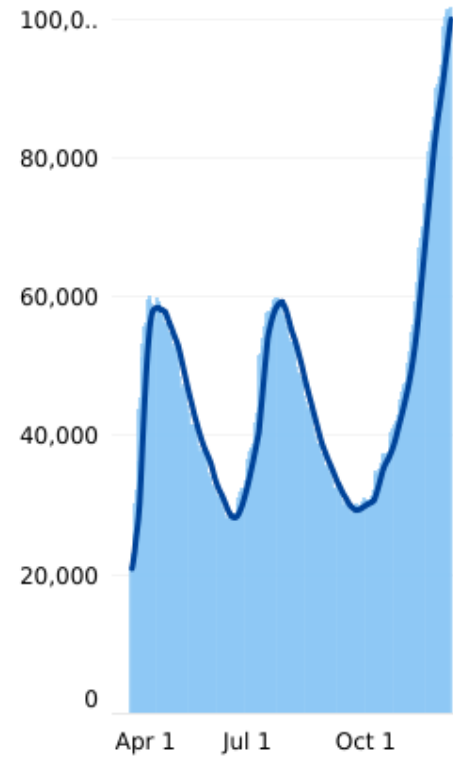
Daily Cases

Dec 6: **176,771**



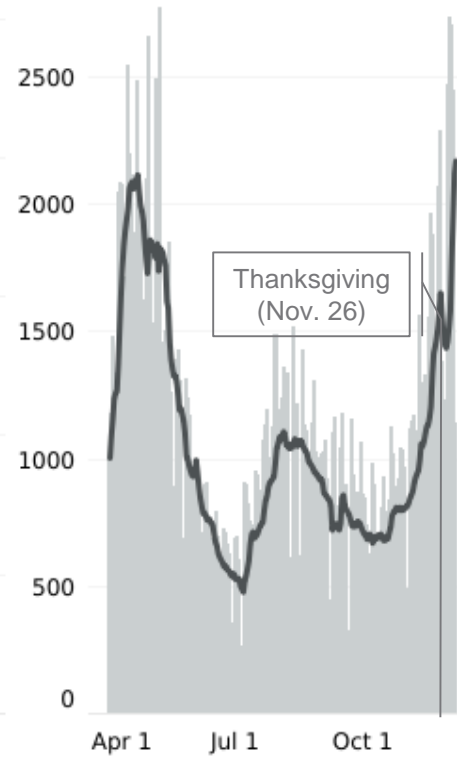
Currently Hospitalized

Dec 6: **101,487**



Daily Deaths

Dec 6: **1,138**



<https://covidtracking.com/data/charts/us-daily-tests> as of 12/07/2020

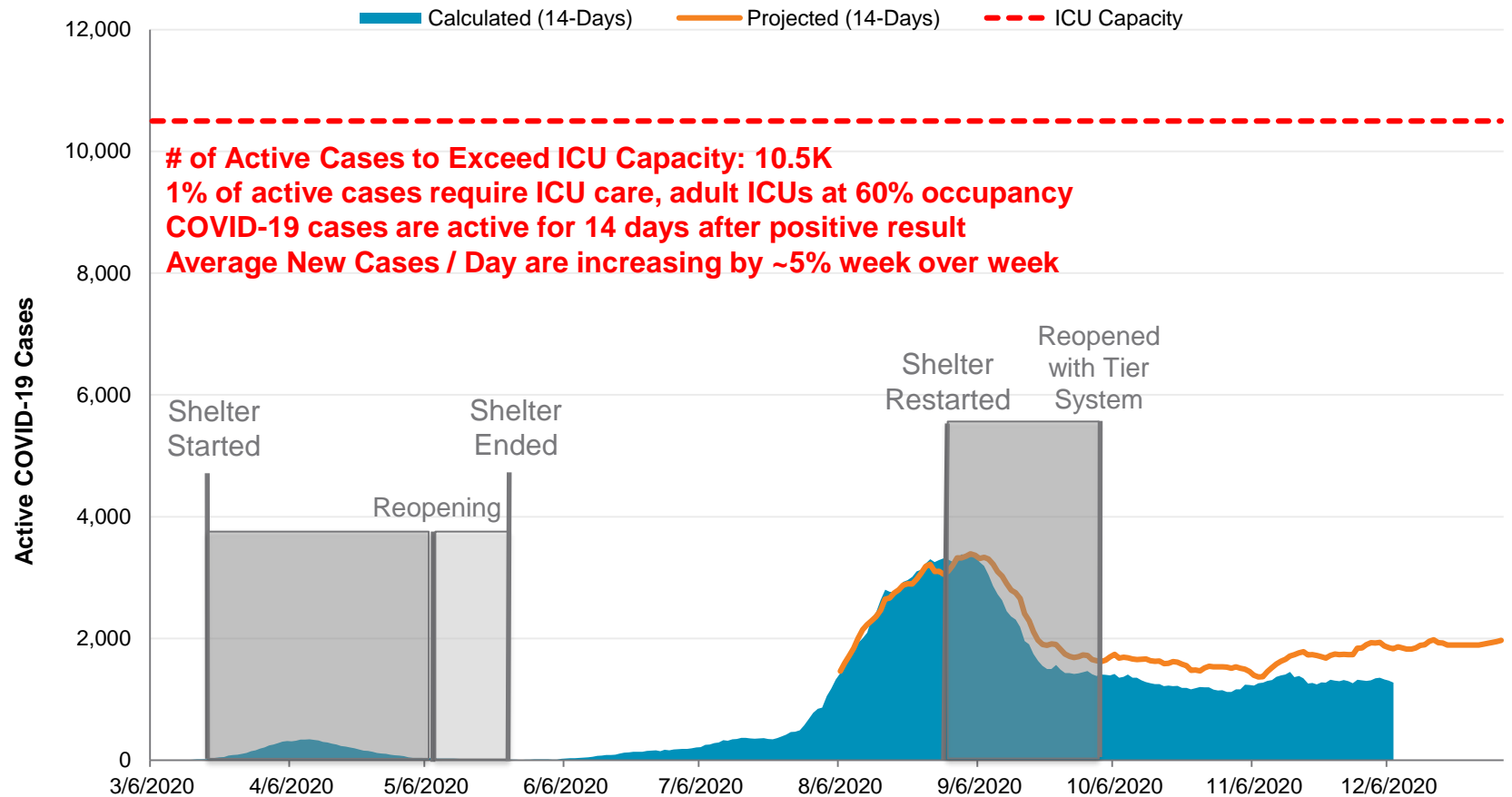
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Projected Active COVID-19 Cases

Hawaii Actual v. Projected Active COVID-19 Cases Updated 12/7/2020





COVID-19 Epi Curve*, Hawaii 2020

Updated Monday, December 7, 2020

Select County

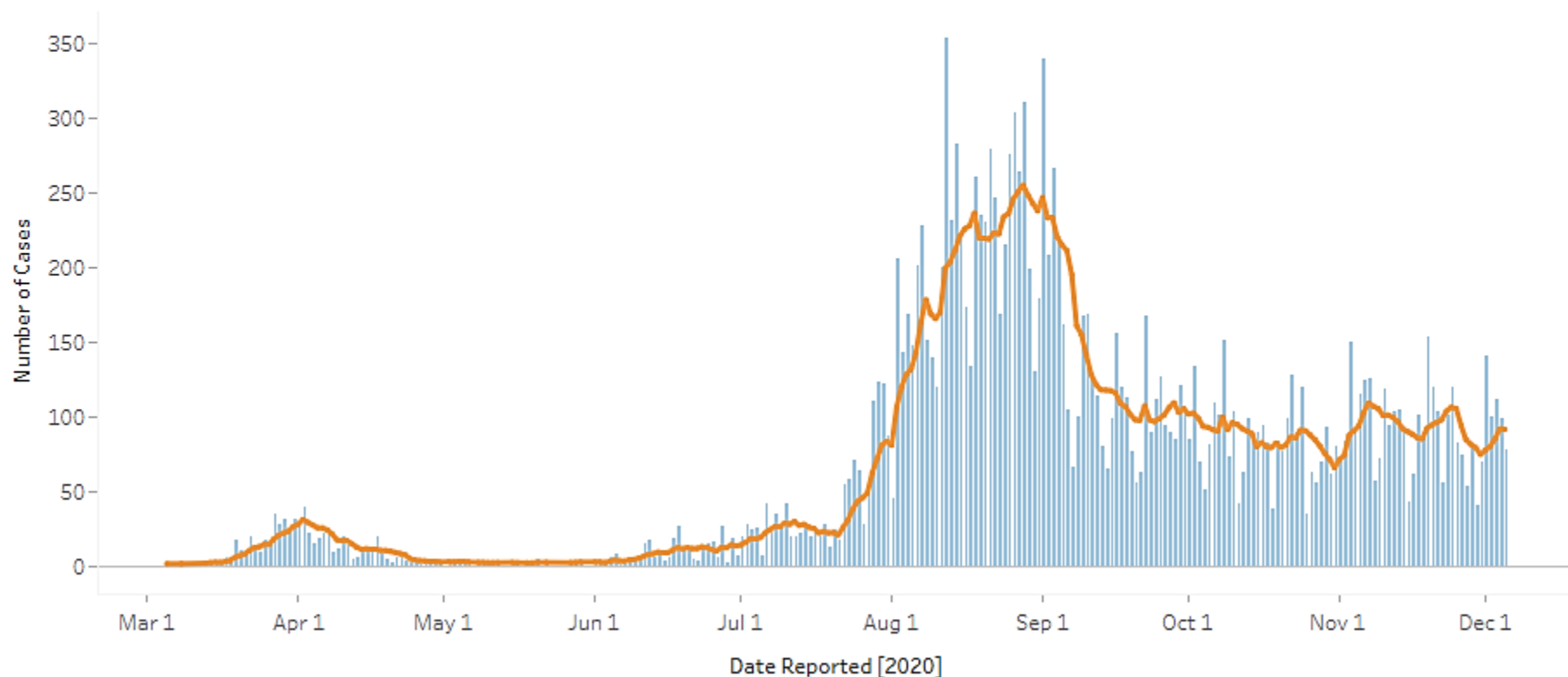
Statewide

91

Average cases/day
(past 7 days)

18,337

Total Cases



*Includes all cases diagnosed in the state (residents, non-residents, and military); Excludes residents diagnosed out-of-state. Data as of 11:59 pm Saturday, December 5, 2020

<https://health.hawaii.gov/coronavirusdisease2019/what-you-should-know/current-situation-in-hawaii/>



COVID-19 Testing*, Hawaii 2020

Updated Monday, December 7, 2020

Filter by County

(All)

Filter by Surge

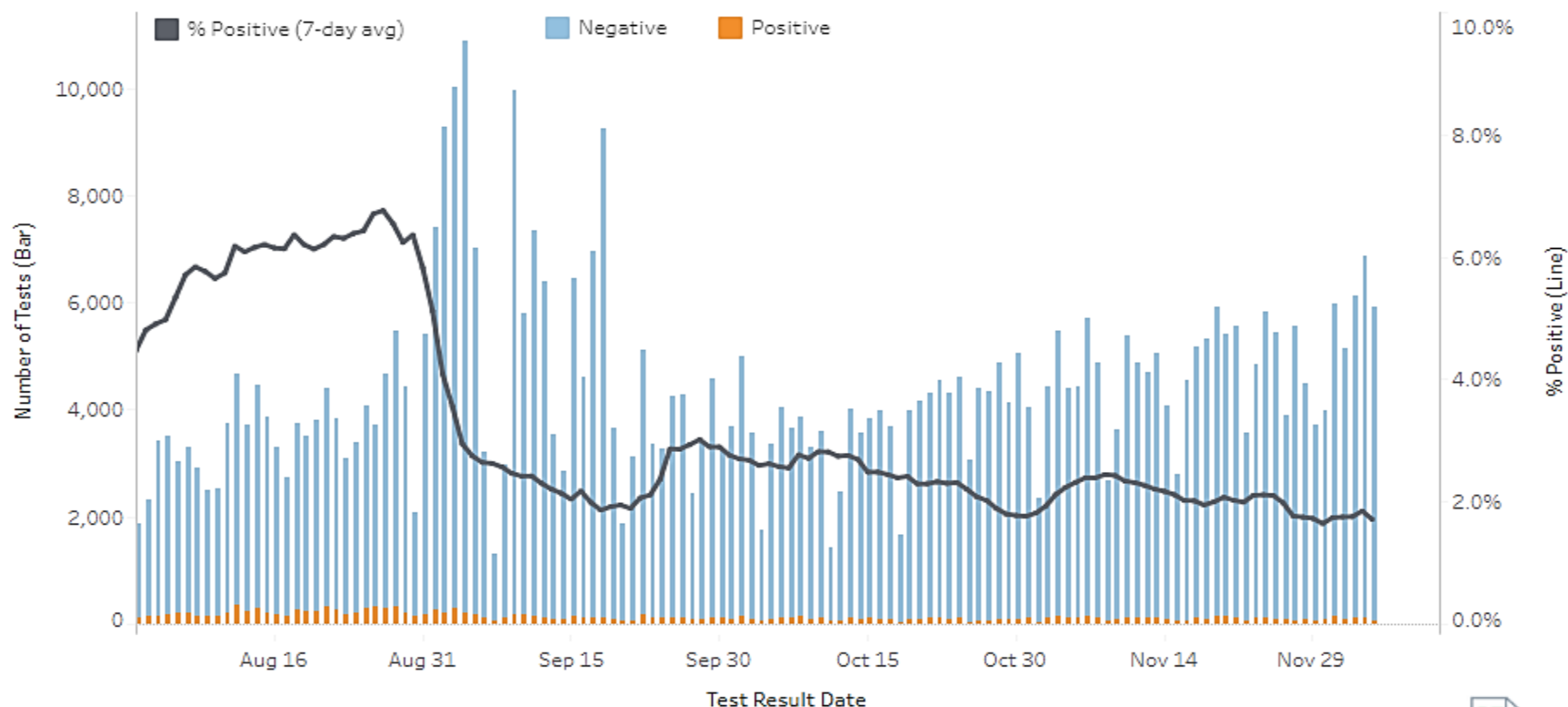
(All)

5,393

Average Daily Tests Performed
(past 7 days)

1.7%

Percent Positive
(past 7 days)



*Data as of 11:59pm December 5, 2020

Turnaround Time



<https://health.hawaii.gov/coronavirusdisease2019/what-you-should-know/current-situation-in-hawaii/>

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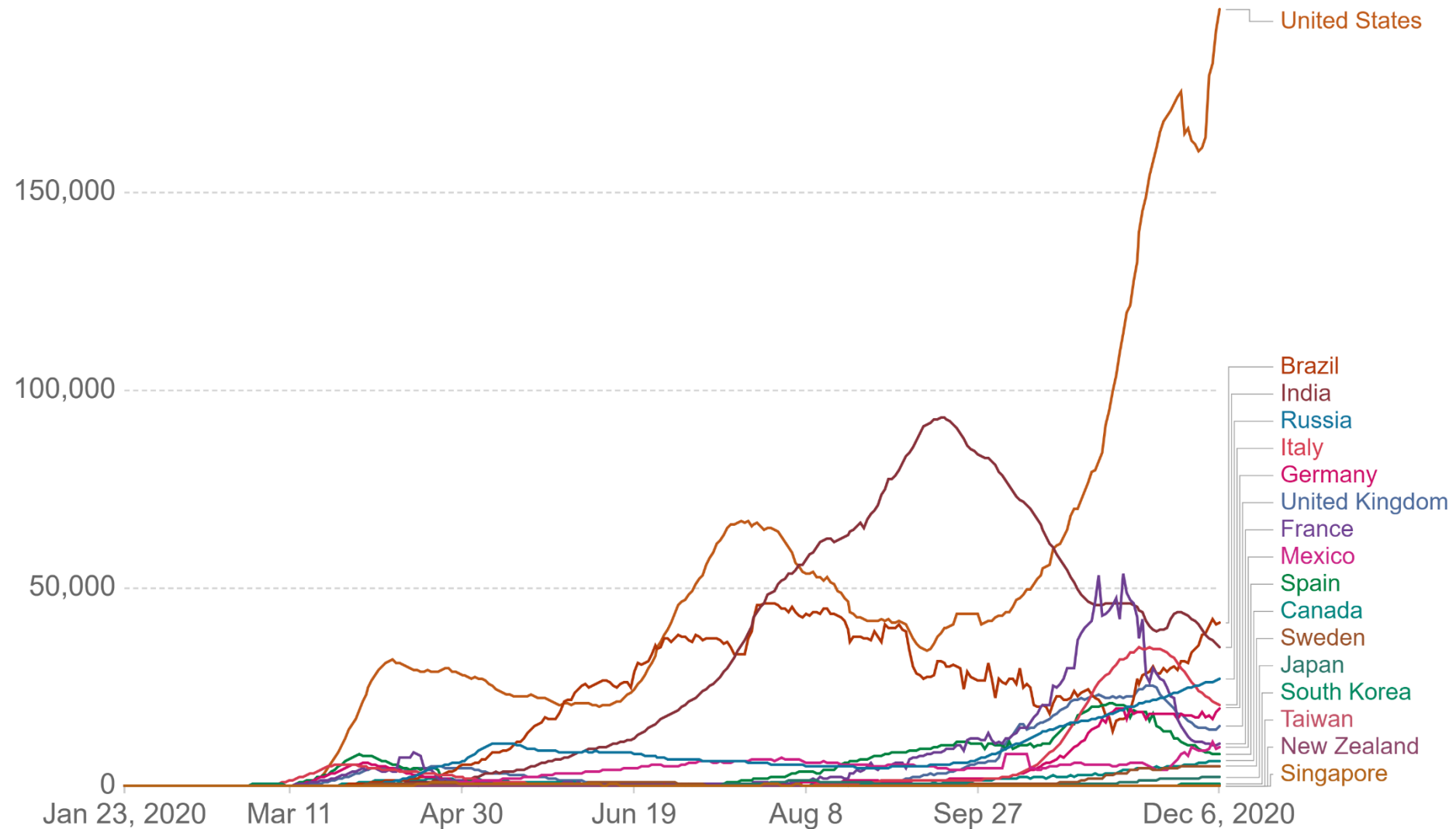
As of 12/07/20	Total Census	ICU beds occupied	# Ventilators in use	# New Admissions w/ positive COVID-19	# Patients currently hospitalized w/ suspect or confirmed COVID-19	# Patients currently on a ventilator w/ confirmed COVID-19	# Patients currently in ICU w/ confirmed COVID-19
KMCWC	124	AICU: 0 NICU: 54 PICU: 7	AICU: 0 NICU: 12 PICU: 4	0	S: 0 C: 0	0	0
PMMC	104	9	7	0	S: 4 C: 3	3	3
SMC	132	15	9	1	S: 2 C: 3	0	1
WMC	50	6	2	0	S: 0 C: 1	1	1

S = Suspected; C= Confirmed

Daily new confirmed COVID-19 cases

Shown is the rolling 7-day average. The number of confirmed cases is lower than the number of actual cases; the main reason for that is limited testing.

Our World
in Data

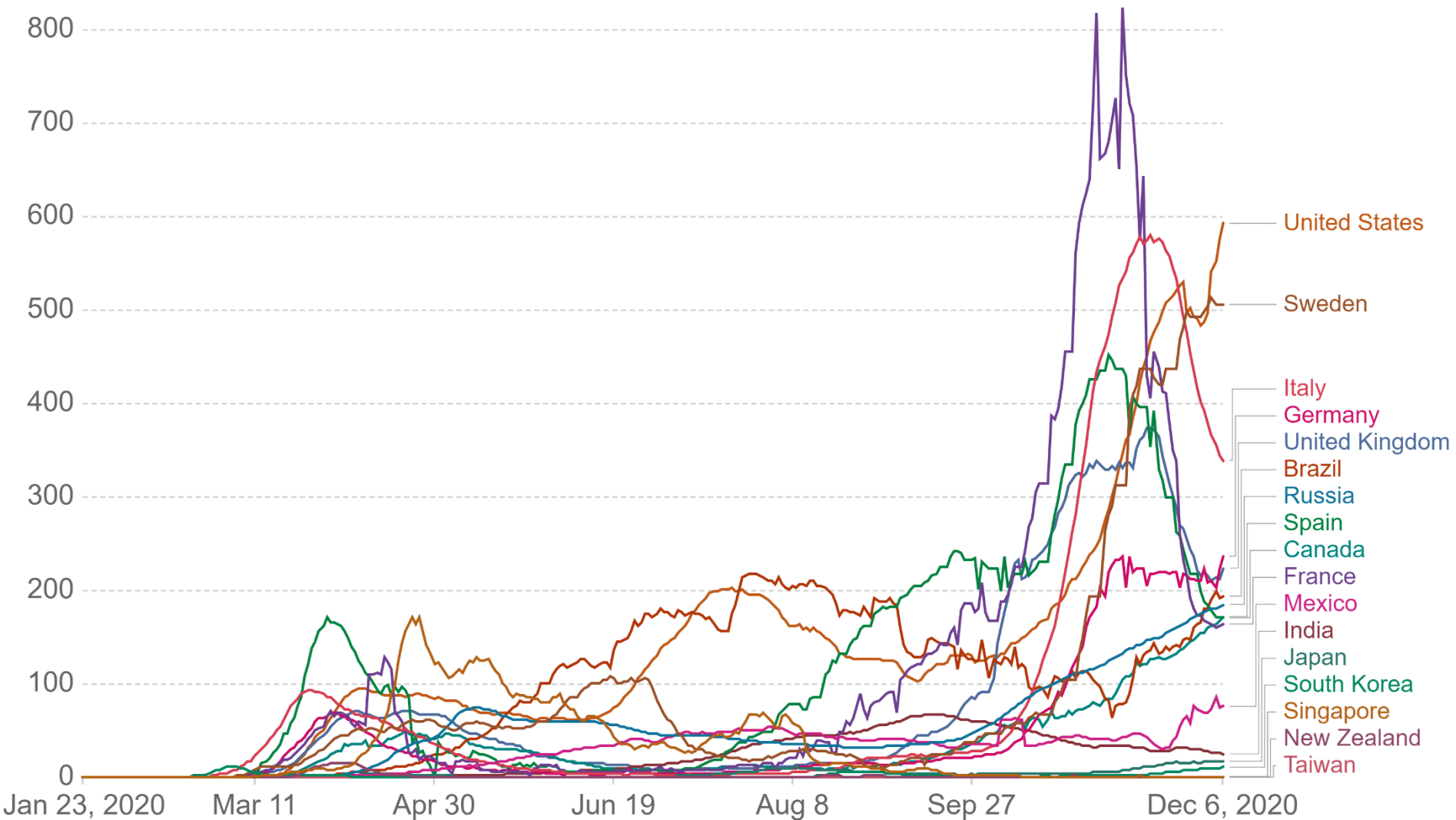


Source: Johns Hopkins University CSSE COVID-19 Data – Last updated 7 December, 06:06 (London time)

CC BY

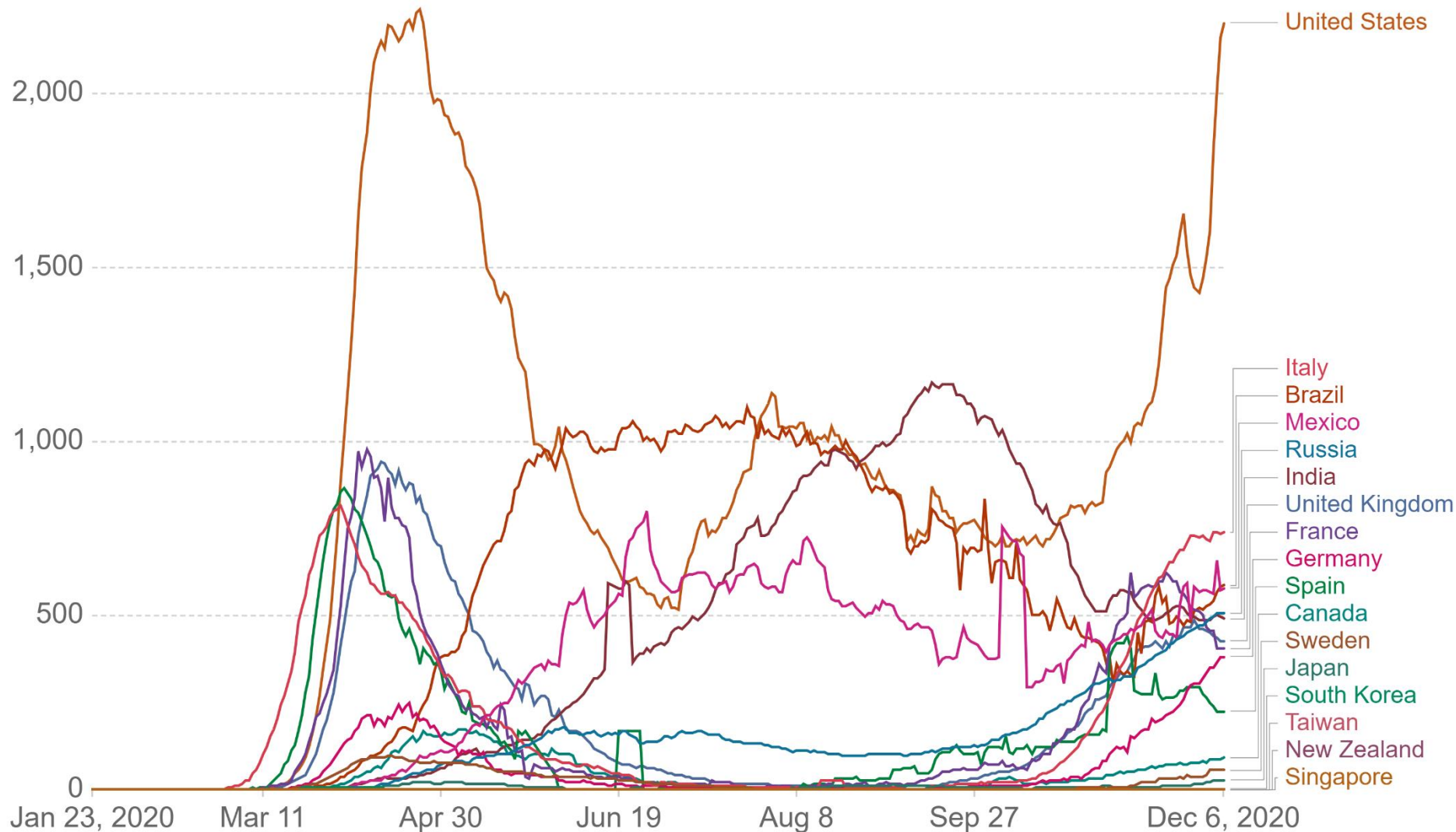
Daily new confirmed COVID-19 cases per million people

Shown is the rolling 7-day average. The number of confirmed cases is lower than the number of actual cases; the main reason for that is limited testing.



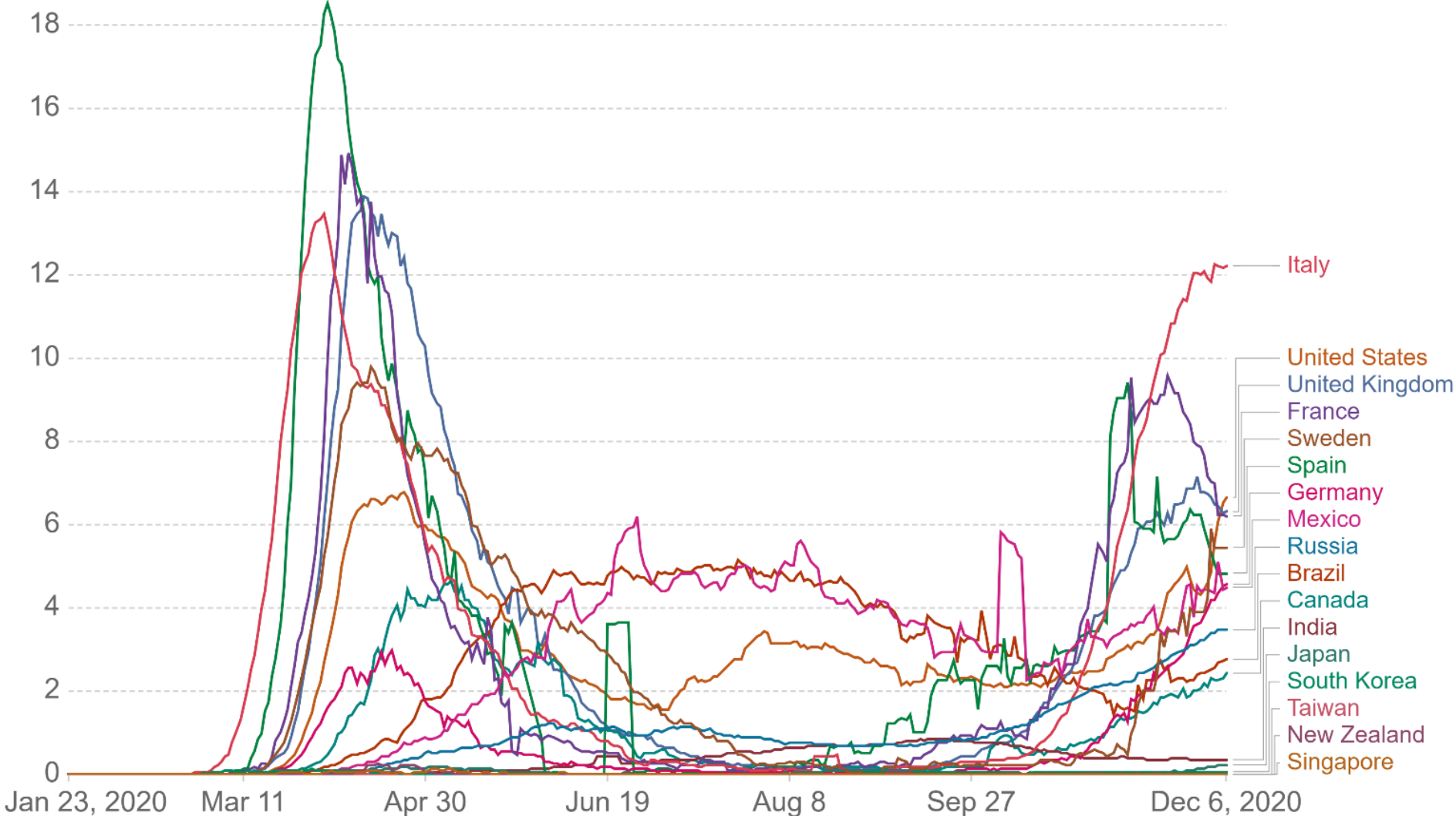
Daily new confirmed COVID-19 deaths

Shown is the rolling 7-day average. Limited testing and challenges in the attribution of the cause of death means that the number of confirmed deaths may not be an accurate count of the true number of deaths from COVID-19.

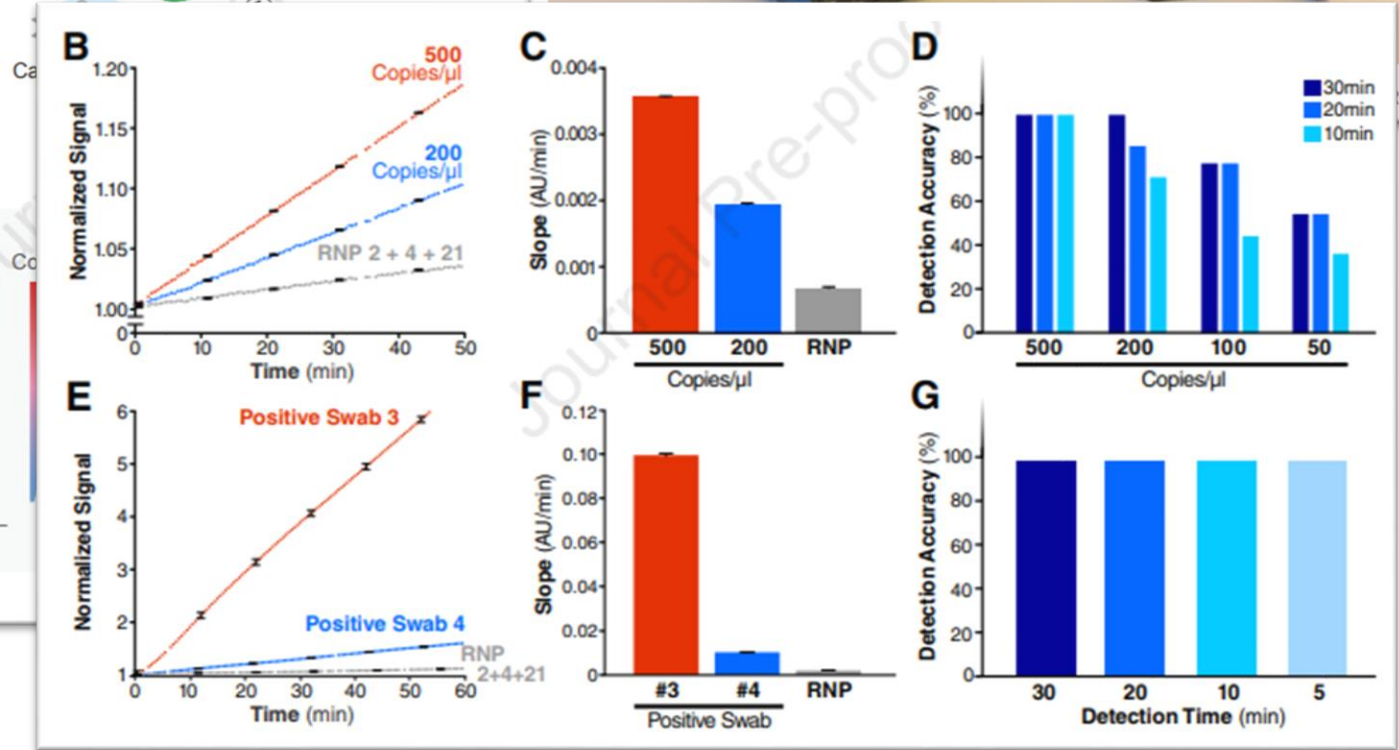
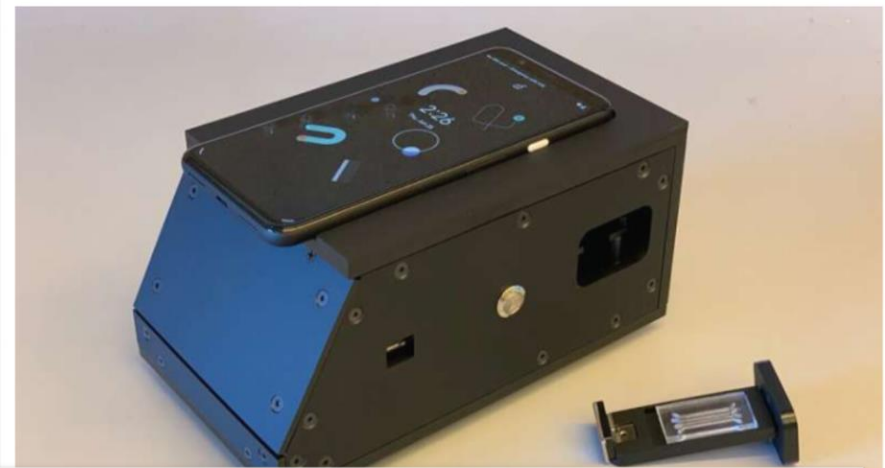
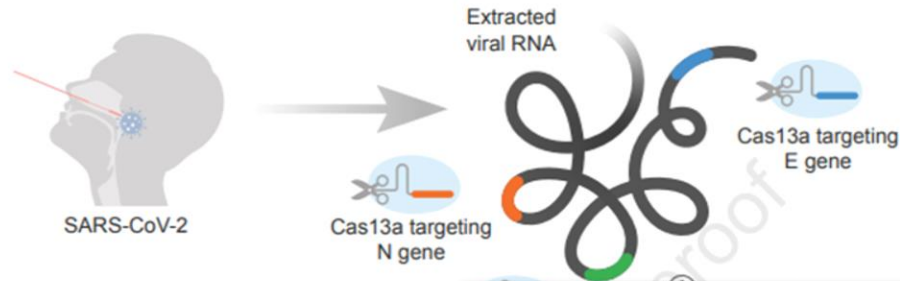


Daily new confirmed COVID-19 deaths per million people

Shown is the rolling 7-day average. Limited testing and challenges in the attribution of the cause of death means that the number of confirmed deaths may not be an accurate count of the true number of deaths from COVID-19.



CRISPR Rapid COVID Testing



Amplification-free detection of SARS-CoV-2 with CRISPR-Cas13a and mobile phone microscopy. Parinaz Fozouni, Sungmin Son, María Díaz de León Derby, Jennifer A. Doudna, Daniel A. Fletcher, Melanie Ott. Published: December 04, 2020 DOI: <https://doi.org/10.1016/j.cell.2020.12.001>

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Hawaii canines being trained to sniff out the scent of coronavirus

Jim Mendoza · 5 days ago



HONOLULU, Hawaii (HawaiiNewsNow) - At Assistance Dogs of Hawaii's Maui campus, four canines are preparing for pandemic work.



© Provided by Honolulu KHNL Assistance Dogs of Hawaii is training four canines to sniff out the scent of COVID-19. The plan is to use the dogs to detect the respiratory illness in places that need an extra layer of Coronavirus screening.

The dogs — Sadie, Sam, Tess and Yuki — will be trained to sniff out the scent of coronavirus.



COVID-19 Therapy with Monoclonal Antibodies – Eligibility Criteria and Administration Process

Sandra Noon, DO

*Chief of Primary Care, Hawai'i Pacific Health Medical Group
Internal Medicine, Straub Medical Center – Mililani Clinic,
Hawai'i Pacific Health Medical Group*

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Monoclonal Antibodies

- Specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells
- Currently available under an EUA:
 - Casirivimab-imdevimab (Regeneron)
 - Bamlanivimab (Eli Lilly)
- Permitted for treatment of **mild-moderate** COVID-19 in adults and pediatric patients who are **≥ 12 years of age** and weighing **≥ 40kg**, and who are at **high risk** for progressing to severe COVID-19 and/or hospitalization

Not Authorized for Use in Patients:

- Who are hospitalized due to COVID-19

OR

- Who require oxygen therapy due to COVID-19

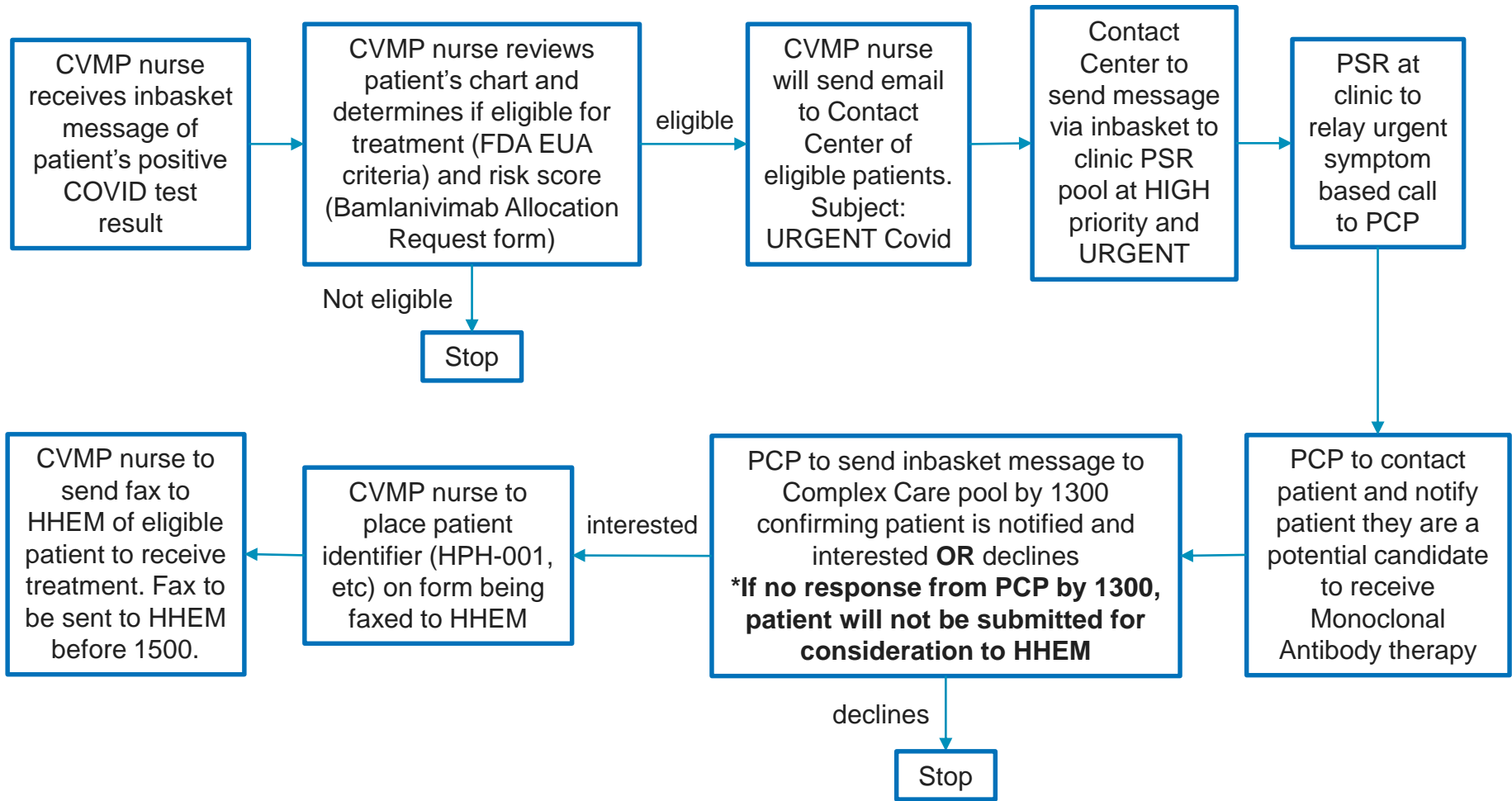
OR

- Who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

Defining Who is High Risk

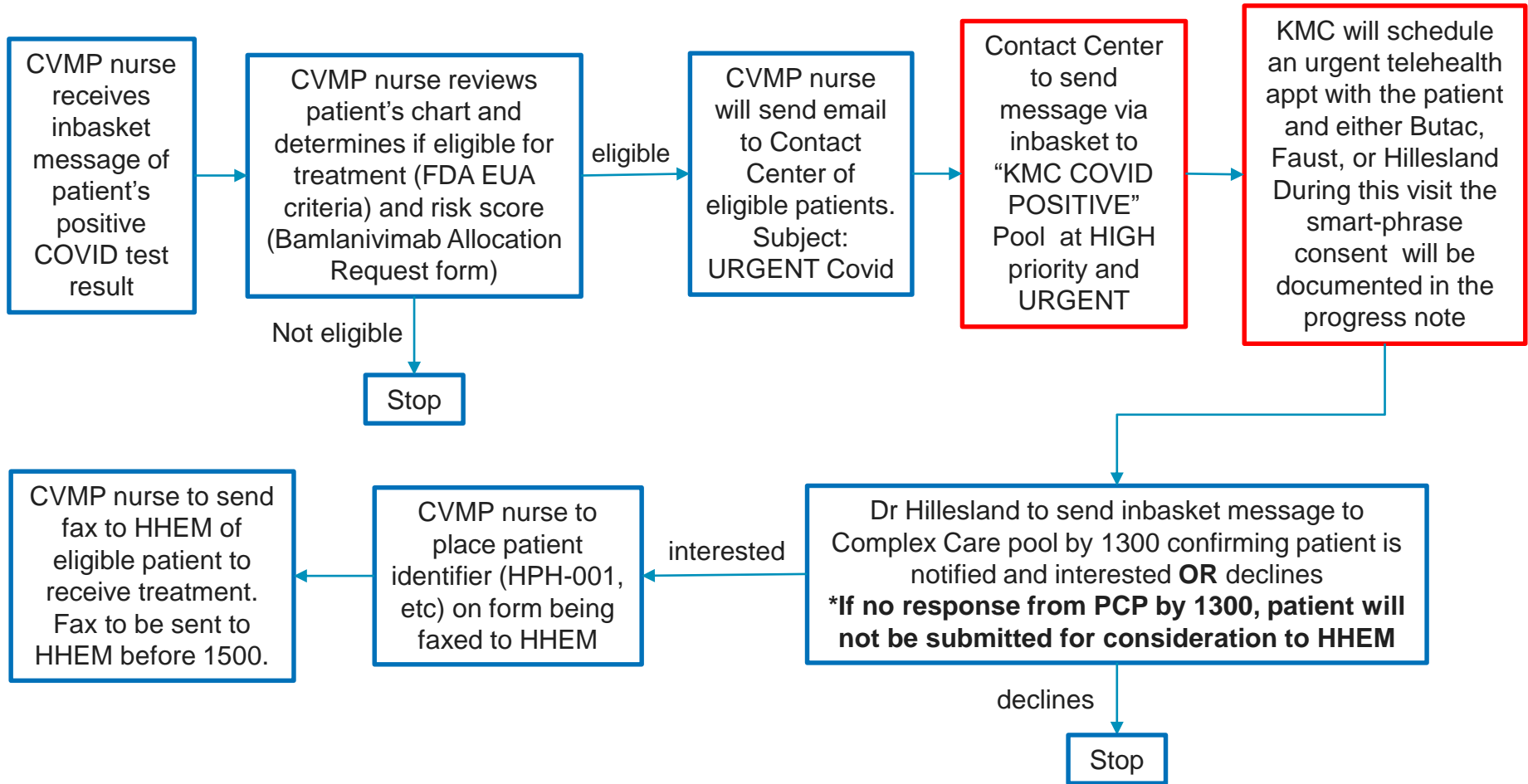
Prioritization Grid: Clinical Considerations for Monoclonal Antibody to reduce progression of disease	Points (select all that apply)
≥ 65 years	2
BMI ≥ 35	2
Chronic kidney disease	1
DM	1
Immunosuppressive disease	1
Immunosuppressant medication	1
≥ 55 years AND Cardiovascular disease	1
≥ 55 years AND hypertension	1
≥ 55 years AND COPD/other respiratory disease	1
12-17 years AND BMI ≥ 85 th percentile for age and gender	1
12-17 years AND sickle cell disease	1
12-17 years AND congenital or acquired heart disease	1
12-17 years AND neurodevelopmental disorder (e.g. cerebral palsy)	1
12-17 years AND medical-related technology dependence	1
12-17 years AND chronic respiratory disease that requires daily medication	1

Flow: Identification of eligible patient to HHEM request submission



Flow: Identification of eligible patient to HHEM request submission

KAUAI



Administration of Bamlanivimab

- Administered **as soon as possible** after positive SARS-CoV-2 viral test and **within 10 days of symptom onset**
- A single intravenous (IV) infusion of 700 mg given over at least 60 minutes
- Patients are clinically monitored during infusion and observed for at least 1 hour after infusion is complete
- Hypersensitivity: including anaphylaxis and infusion-related reactions
- Signs and symptoms of infusion related reactions may include: fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness

Mandatory Requirements for Use of Bamlanivimab Under EUA

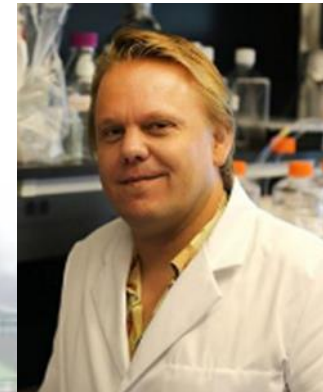
- Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient's medical record that the patient/caregiver has been:
 - Given the “Fact Sheet for Patients, Parents and Caregivers”,
 - Informed of alternatives to receiving authorized bamlanivimab, and
 - Informed that bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization
- Mandatory reporting of all medication errors and serious adverse events potentially related to bamlanivimab treatment within 7 calendar days from the onset of the event



Development of Vaccines targeting COVID-19

Dr. rer. nat. Axel T. Lehrer, Associate Professor

Department of Tropical Medicine, Medical Microbiology and Pharmacology,
John A. Burns School of Medicine
University of Hawai'i at Manoa
Honolulu, Hawaii

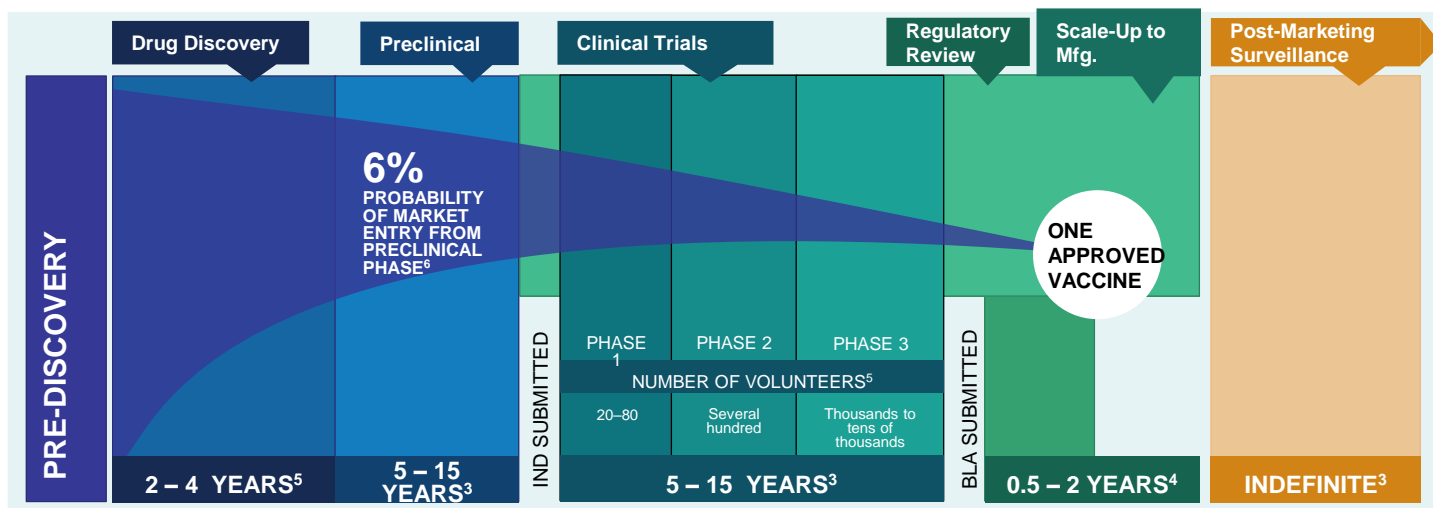




Vaccine Development Path



New vaccine development can take up to **20 years**, and typically costs between **US \$500 million and \$1 billion**, including construction of facilities for manufacture.^{1,2}



Sources: 1. Center for Global Development. Making Markets for Vaccines: Ideas to Action. <https://www.cgdev.org/doc/books/vaccine/MakingMarkets-complete.pdf>. Accessed September 15, 2017 2. Plotkin SA, Mahmoud AAF, Farrar J. Establishing a Global Vaccine-Development Fund. N Engl J Med 373;4: July 23. DOI: 10.1056/NEJMp1506820. Accessed September 15, 2017. 3. Leroux-Roels et al. Chapter 5 in: Garçon et al. Understanding Modern Vaccines, Perspectives in vaccinology, Vol 1, Amsterdam. Elsevier 2011;p115-150. 4. Drug Discovery and Development: Understanding the R&D Process, www.innovation.org. 5. The College of Physicians of Philadelphia. Vaccine Development, Testing, and Regulation. <https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation>. Accessed March 7, 2018. 6. Pronker ES, Weenen TC, Commandeur H, Claassen EHJHM, Osterhaus ADME. Risk in Vaccine Research and Development Quantified. Vasilakis N, ed. PLoS ONE. 2013;8(3):e57755. doi:10.1371/journal.pone.0057755.



A little bit of Luck...



- Outbreak of SARS in 2003 sparked development of Coronavirus vaccines giving basic blueprint of “what works”
- Bird flu in 2005 triggered an effort to prepare for pandemic flu and other viruses with pandemic potential
- MERS cases are first reported in 2012 – triggers accelerated vaccine programs and allow to validate the previously developed technology for Coronavirus vaccines
- West African outbreak of Ebola virus pushes replication incompetent adenovirus-vectored vaccines into late stage development





A little bit of Luck... continues

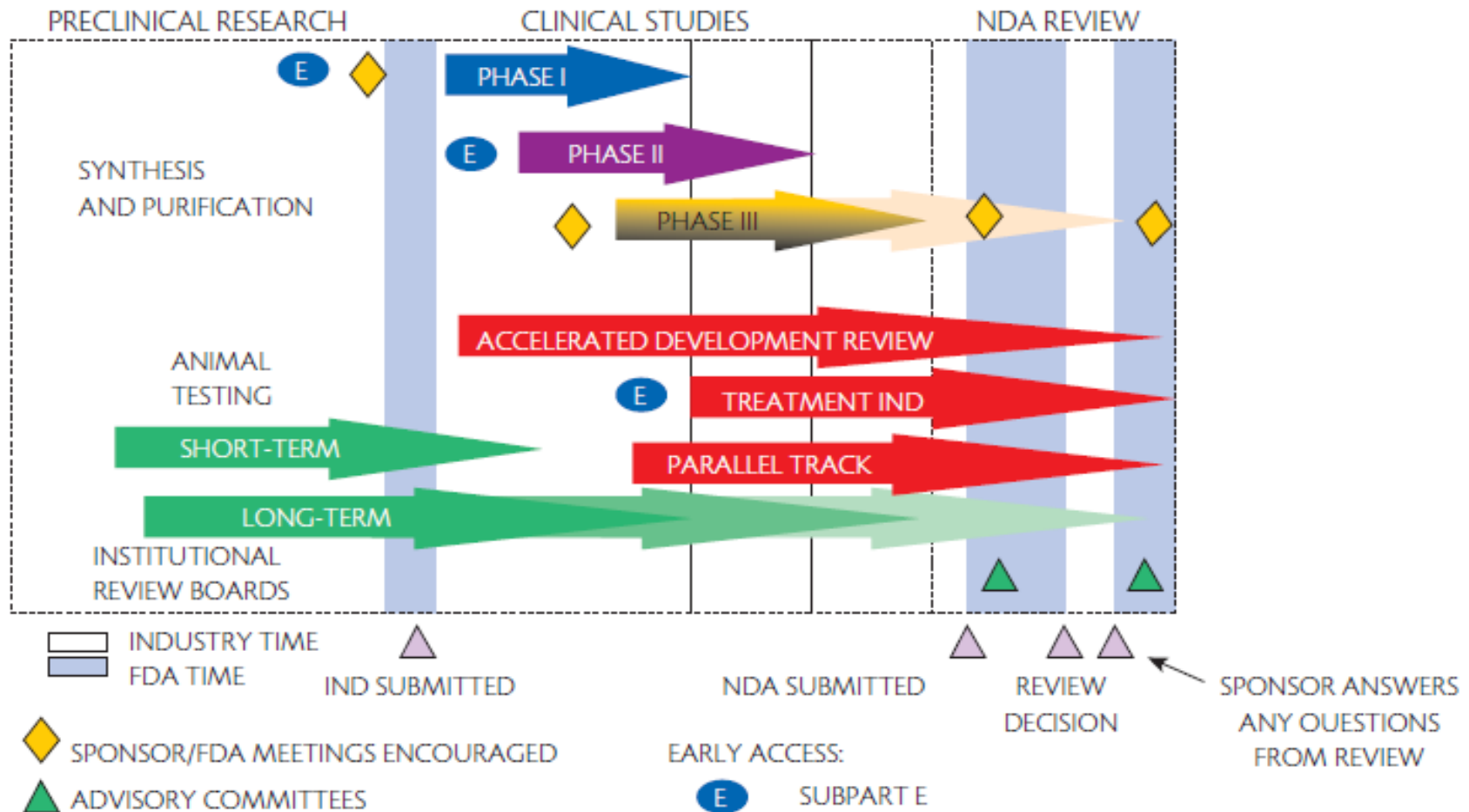


- Continued clinical development of virally vectored Ebola virus vaccines leads to approval of two “first-in-class” vaccines: Ervebo and Ad26/MVA prime boost vaccine by J&J
- Zika virus outbreak in 2015/16 in South America sparked the development of mRNA based vaccines and further honing of production and delivery technologies





FDA - Regulatory Process

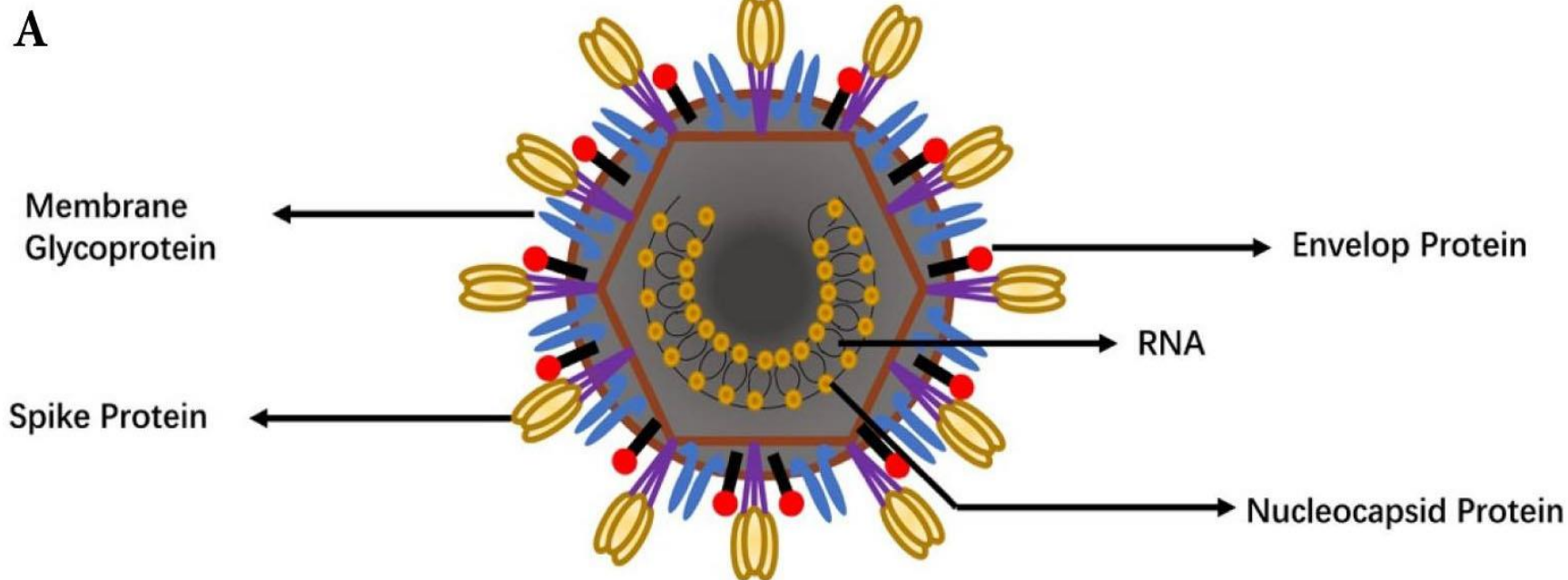


From: Vaccinology – an essential guide (Milligan and Barrett, Wiley, 2015)





Antigen Selection (CoV)



Spike protein function:

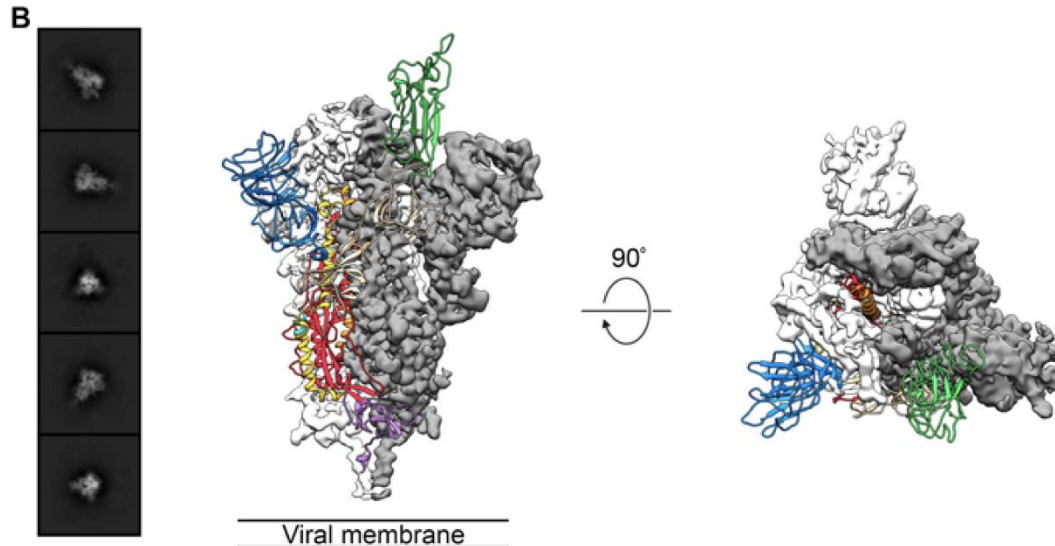
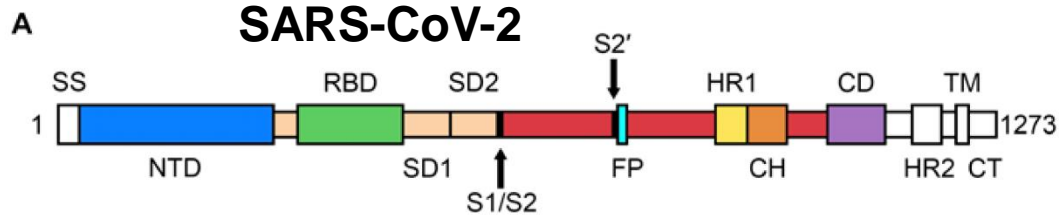
- Receptor binding
- Membrane fusion

Zhou and Zhao, [Int J Biol Sci.](#) 2020; 16(10): 1718–1723.





Spike Protein



Wrapp and Wang et al. Science 2020

Class I fusion glycoprotein on the surface of the virus responsible for to gain entry into host cells.

The S protein is a trimeric protein that exists in a metastable prefusion

~180 kDa if fully glycosylated, 22 glycosylation sites

The monomer consists of S1 and S2 subunit that are associated non-covalently

S1 subunits forming an interwoven cap that rests atop the spring-loaded S2 stem

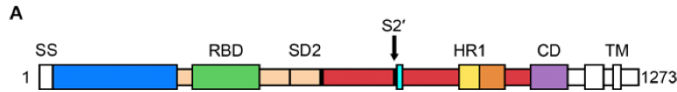
Conformation that undergoes a substantial structural rearrangement to fuse the viral membrane with the host cell membrane

Pallesen et al. PNAS 2017





Spike Protein

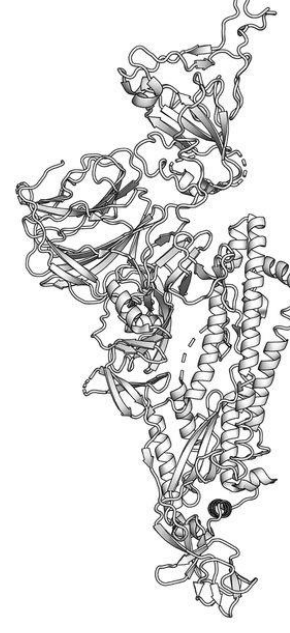
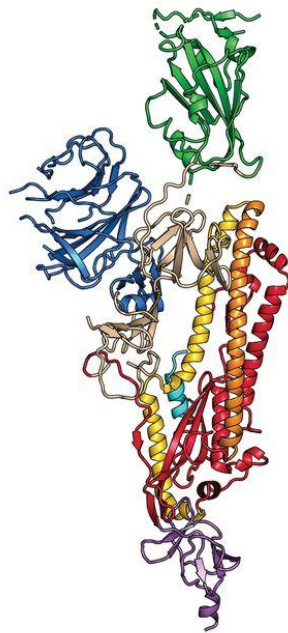
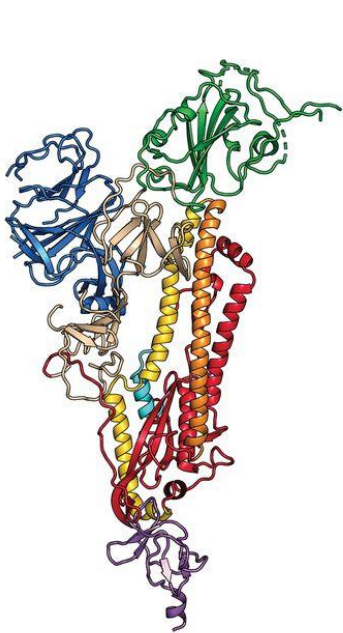


A

2019-nCoV S RBD down protomer

2019-nCoV S RBD up protomer

SARS-CoV S RBD up protomer



Wrapp and Wang et al. Science 2020

S1 subunit contains the RBD and responsible for receptor recognition

S2 subunit responsible for membrane fusion

The SARS-CoV 2 S shares 76% aa homology with SARS-CoV

Ou et al. Nat Comm 2020

**S1 homology is about 64%
RBD homology is about 74%**

Ou et al. Nat Comm 2020

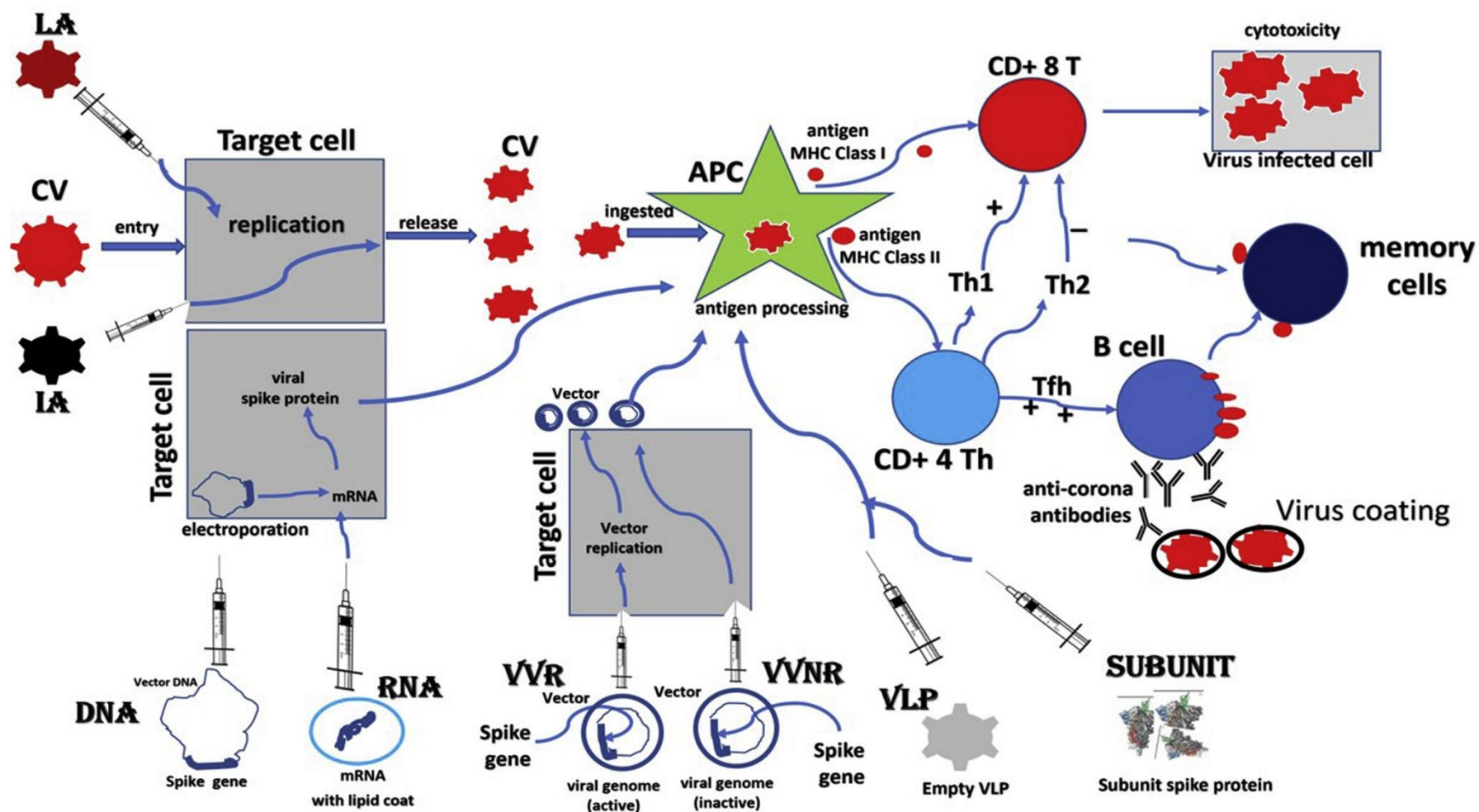
RBD domain exhibits hinge like motion switches between several open and one closed formation

Receptor (Ab) binding is only possible when RBD is in open position





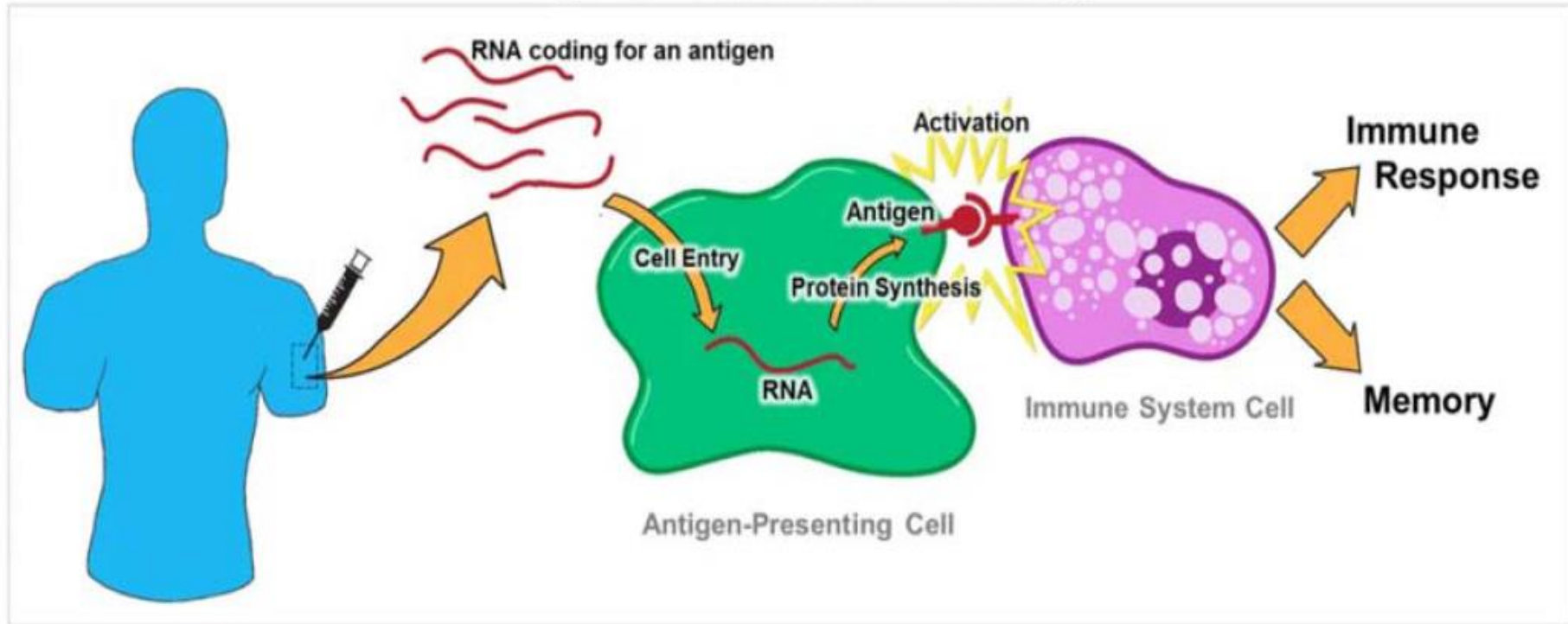
Raising Immunity to SARS-CoV-2



*Journal of Clinical and Experimental
Hepatology* DOI: (10.1016/j.jceh.2020.06.003)



How does an mRNA vaccine work?



Source: Science in the News (Blog)
<http://sitn.hms.harvard.edu/flash/2015/rna-vaccines-a-novel-technology-to-prevent-and-treat-disease/>



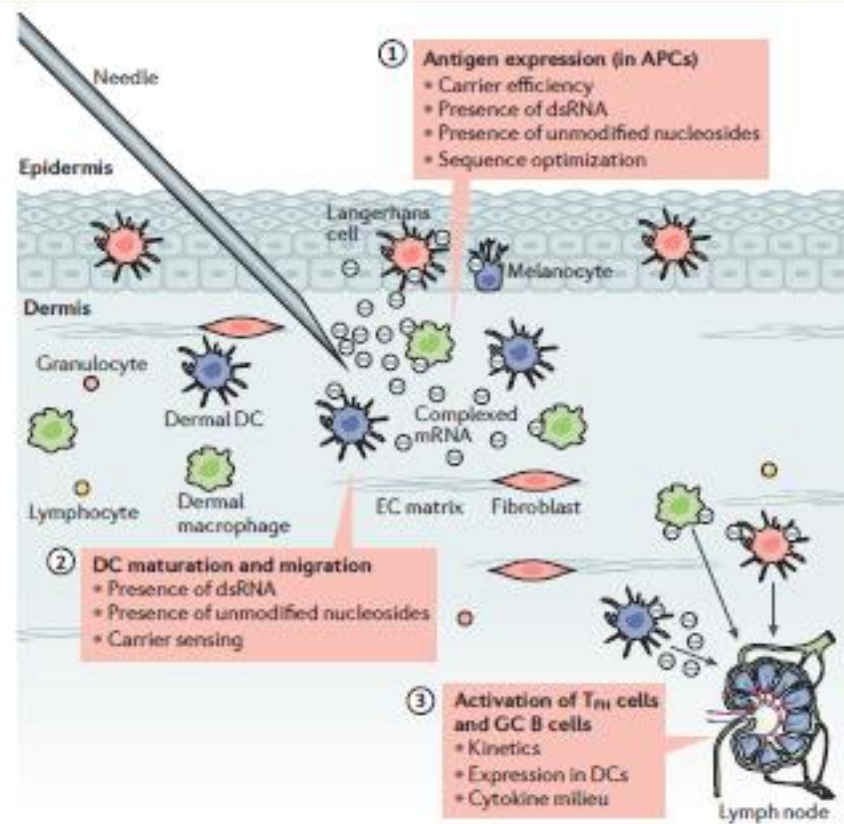


How does an mRNA vaccine work?



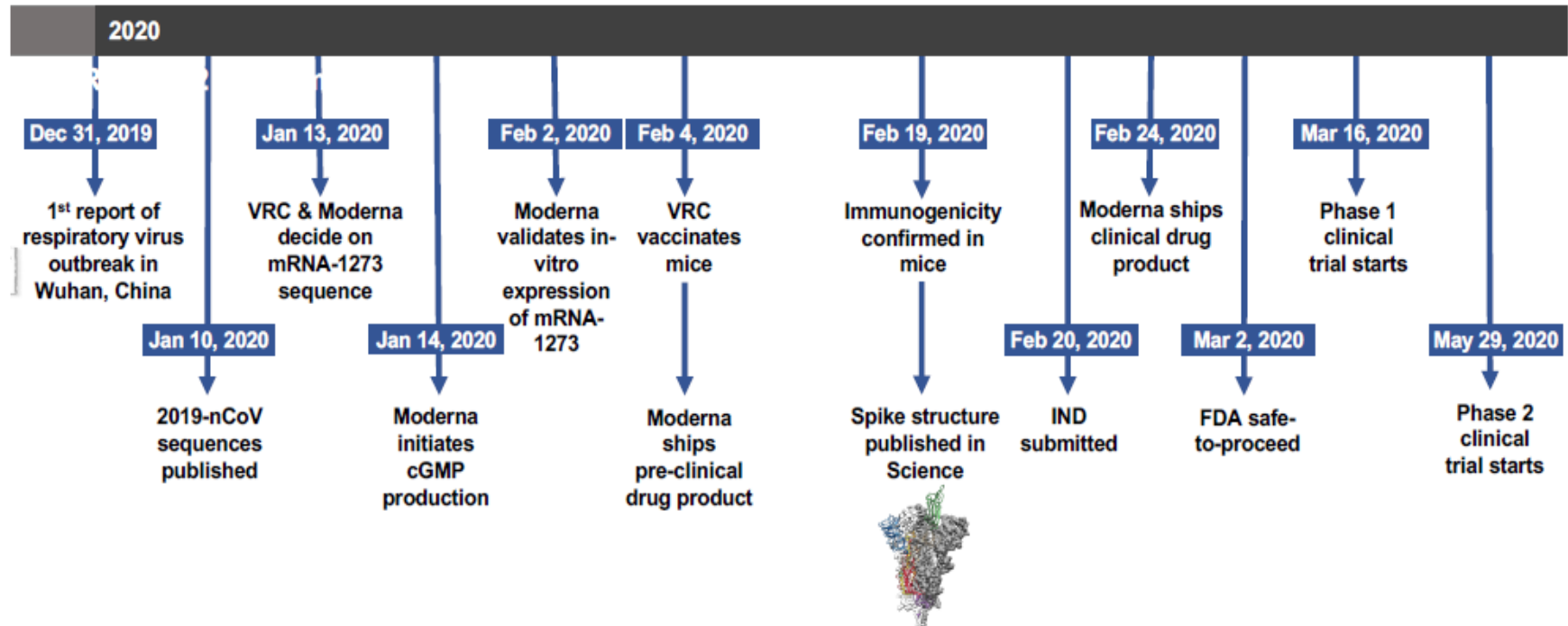
Different delivery techniques are used to apply modified RNA's that are optimized to reduce potential pathologic effects (dsRNA acts as a potent danger signal indicating presence of virus)

Source: Pardi et al, Nature Reviews Drug Discovery (2018)





Moderna: – mRNA (full length Spike)

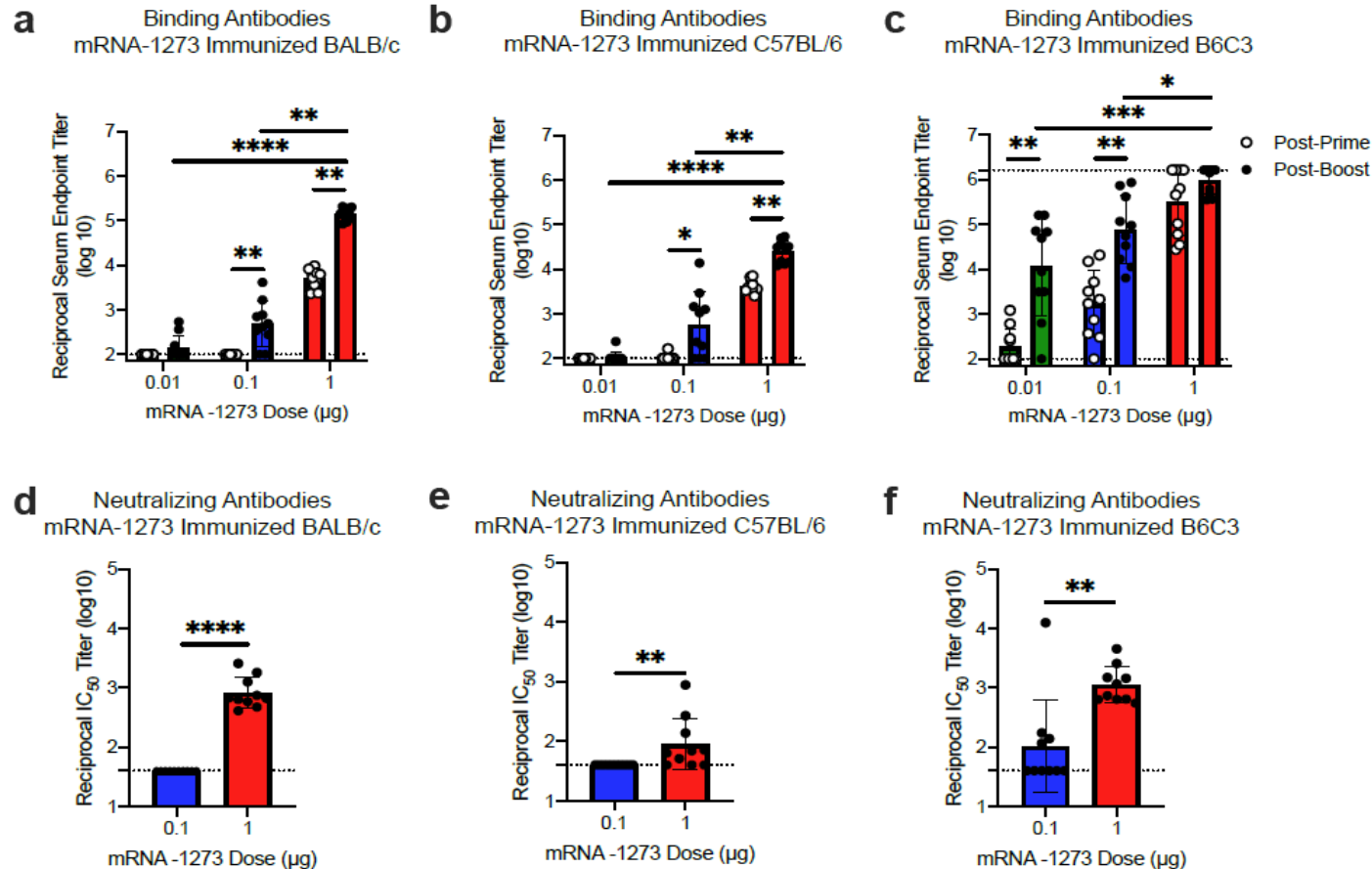


Corbett et al. 2020, bioRxiv preprint doi:
<https://doi.org/10.1101/2020.06.11.145920>.





RNA: Mouse Immunogenicity



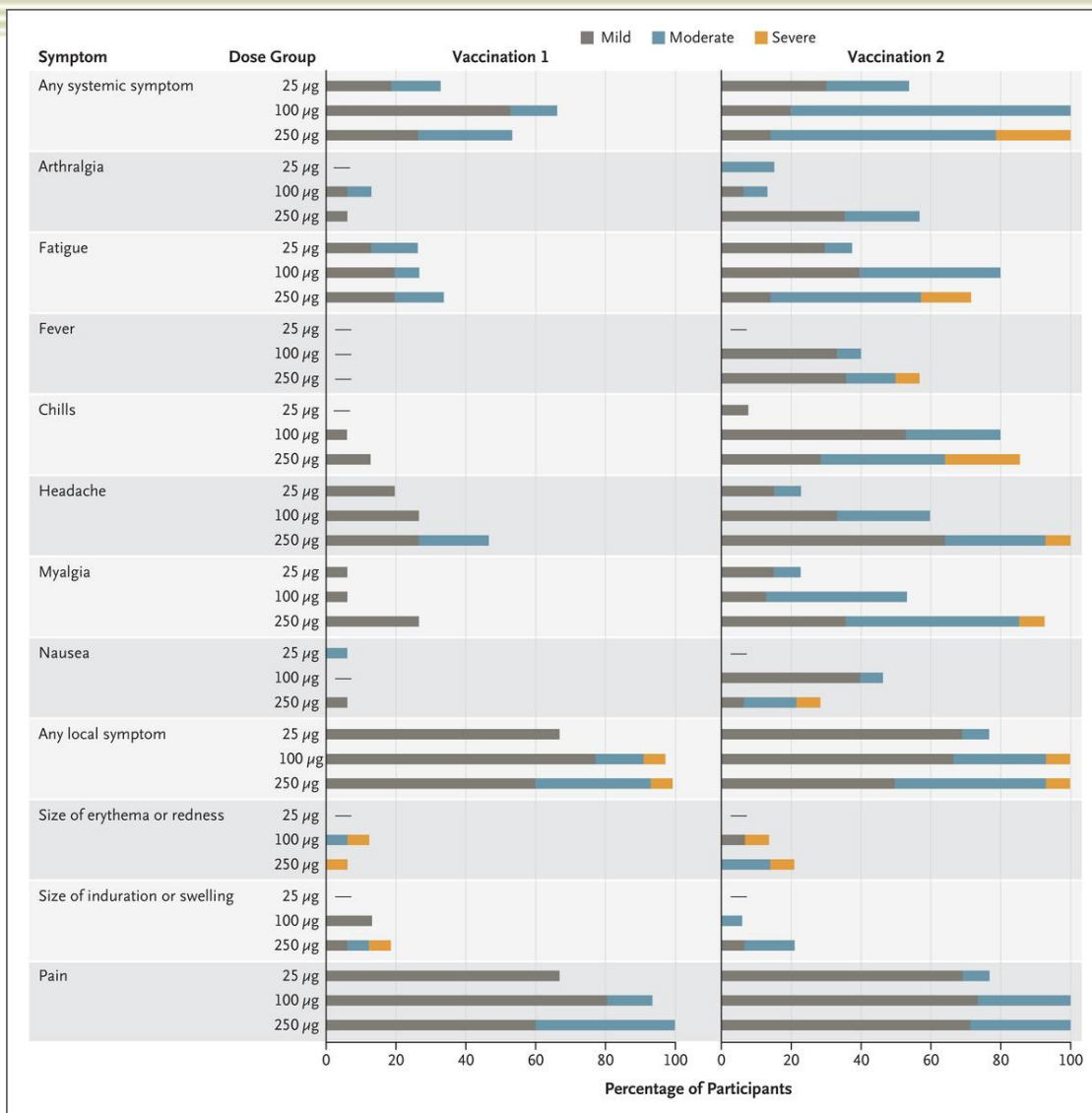
Corbett et al. 2020, bioRxiv preprint doi:
<https://doi.org/10.1101/2020.06.11.145920>.





Moderna RNA – Phase I: Systemic and Local AE's

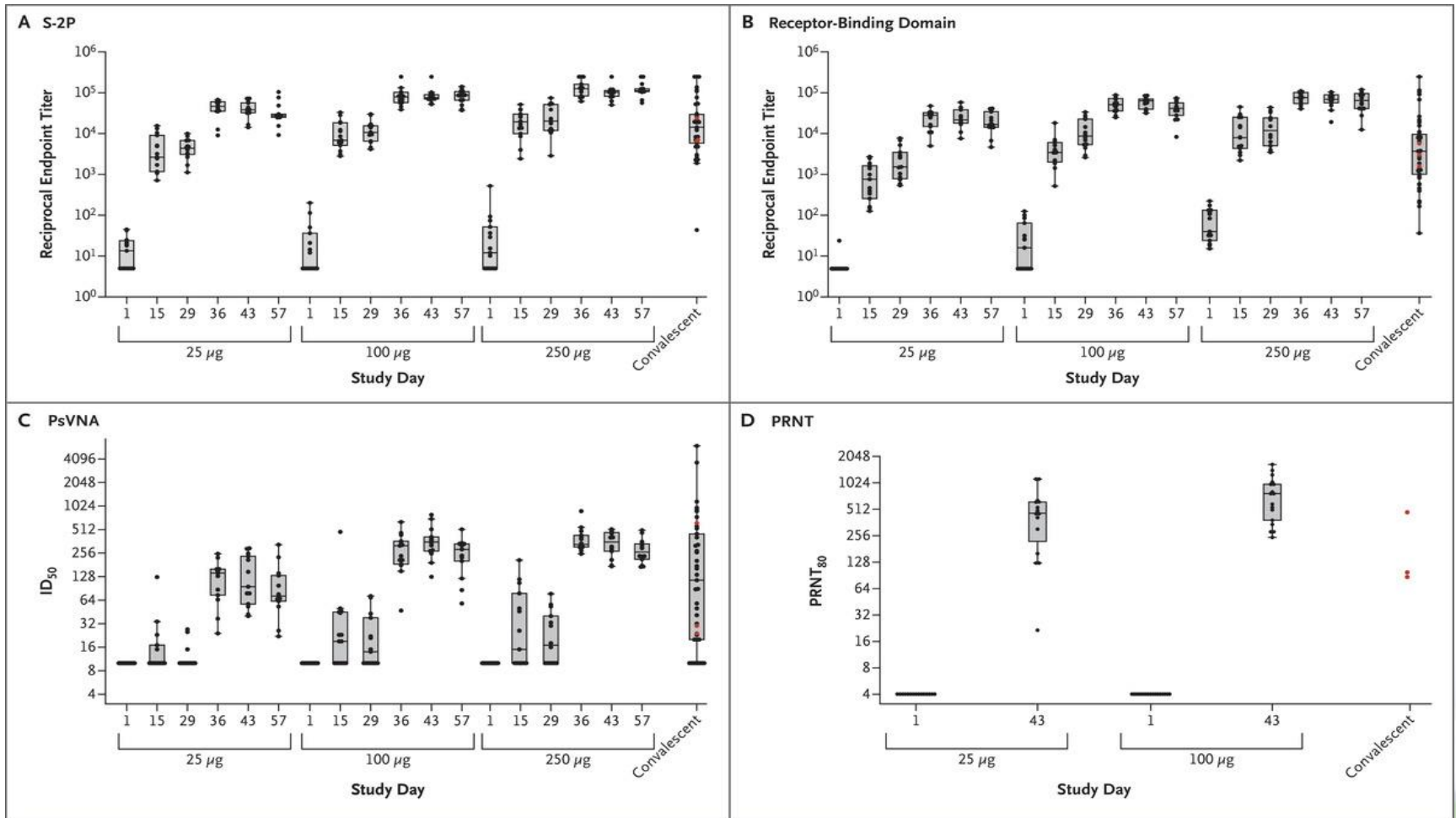
➤ Continued with 100µg dose level



LA Jackson et al. N Engl J Med 2020. DOI: 10.1056/NEJMoa2022483



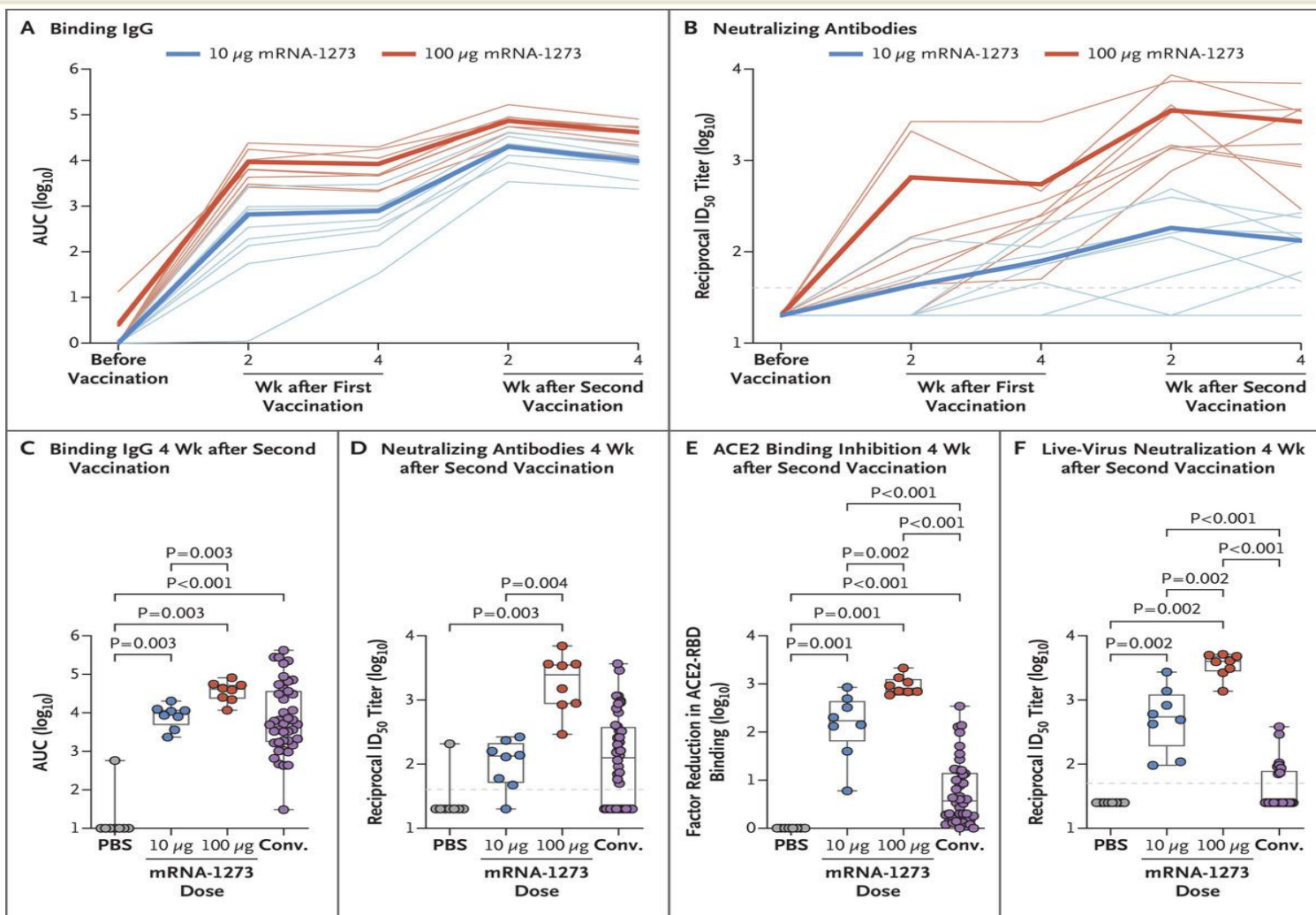
mRNA: Antibody and Neutralization Responses



LA Jackson et al. N Engl J Med 2020.
DOI: 10.1056/NEJMoa2022483



Antibody Responses in Rhesus Macaques (mRNA)

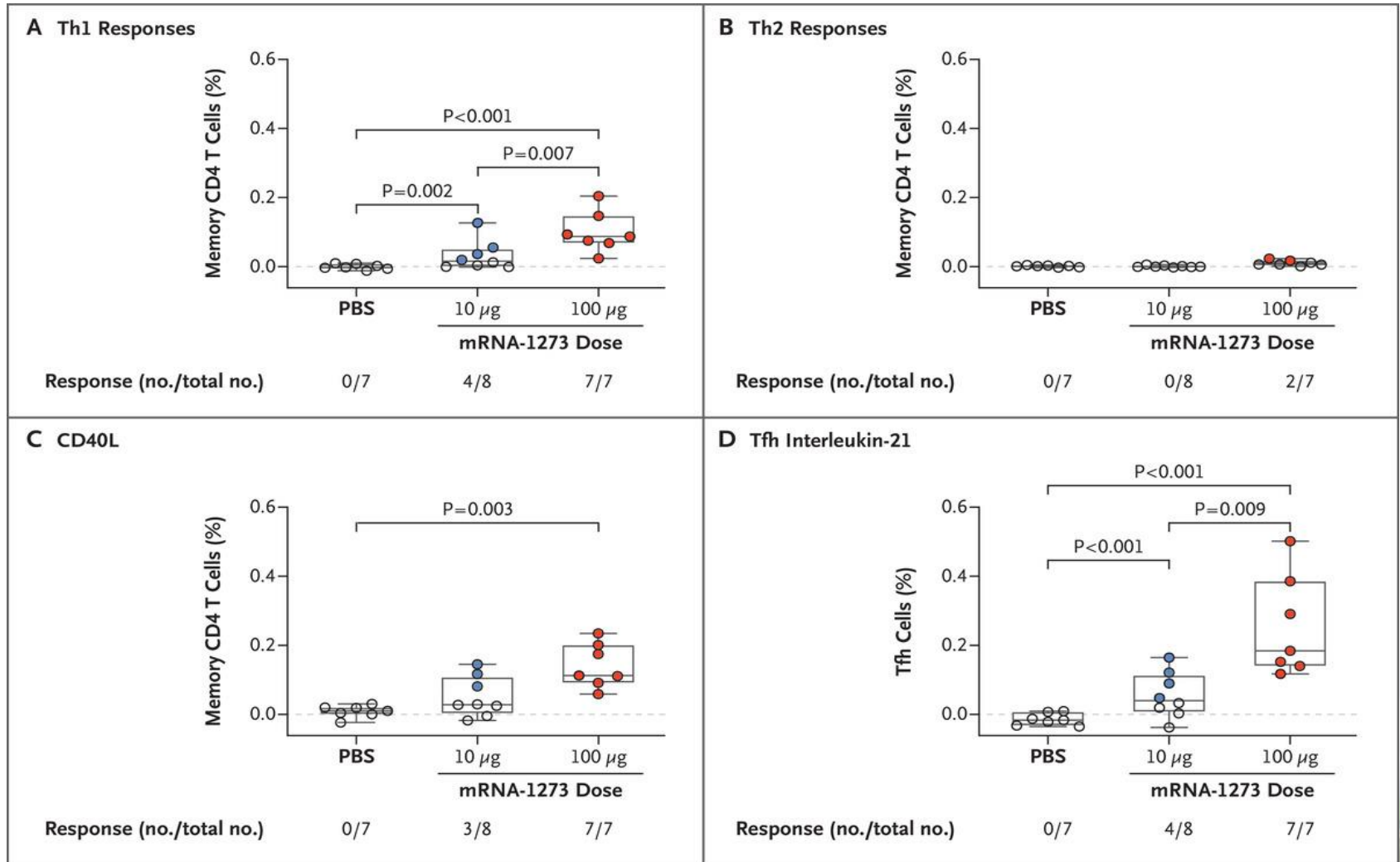


KS Corbett et al. N Engl J Med 2020.

DOI: 10.1056/NEJMoa2024671



T-Cell Responses after mRNA-1273 Vaccination



KS Corbett et al. N Engl J Med 2020.
DOI: 10.1056/NEJMoa2024671





Summary: mRNA vaccines



Moderna (full length Spike) and Pfizer/BioNTech (trimeric RBD)

- Good immunogenicity after two doses in mice, NHP's and humans
- Balanced responses show that delivery seems efficient for this candidate
- Potent virus neutralization shown
- Reduction in viral loads in Rhesus model – lower and upper respiratory tract (Moderna vaccine)
- Initial efficacy (>1 week after 2nd dose): 94.5% (Pfizer) and 95% (Moderna)

Key questions remaining:

- Can delivery of frozen products be achieved?
- Durability of immunity?
- Efficacy after only one dose and kinetics of immune response?

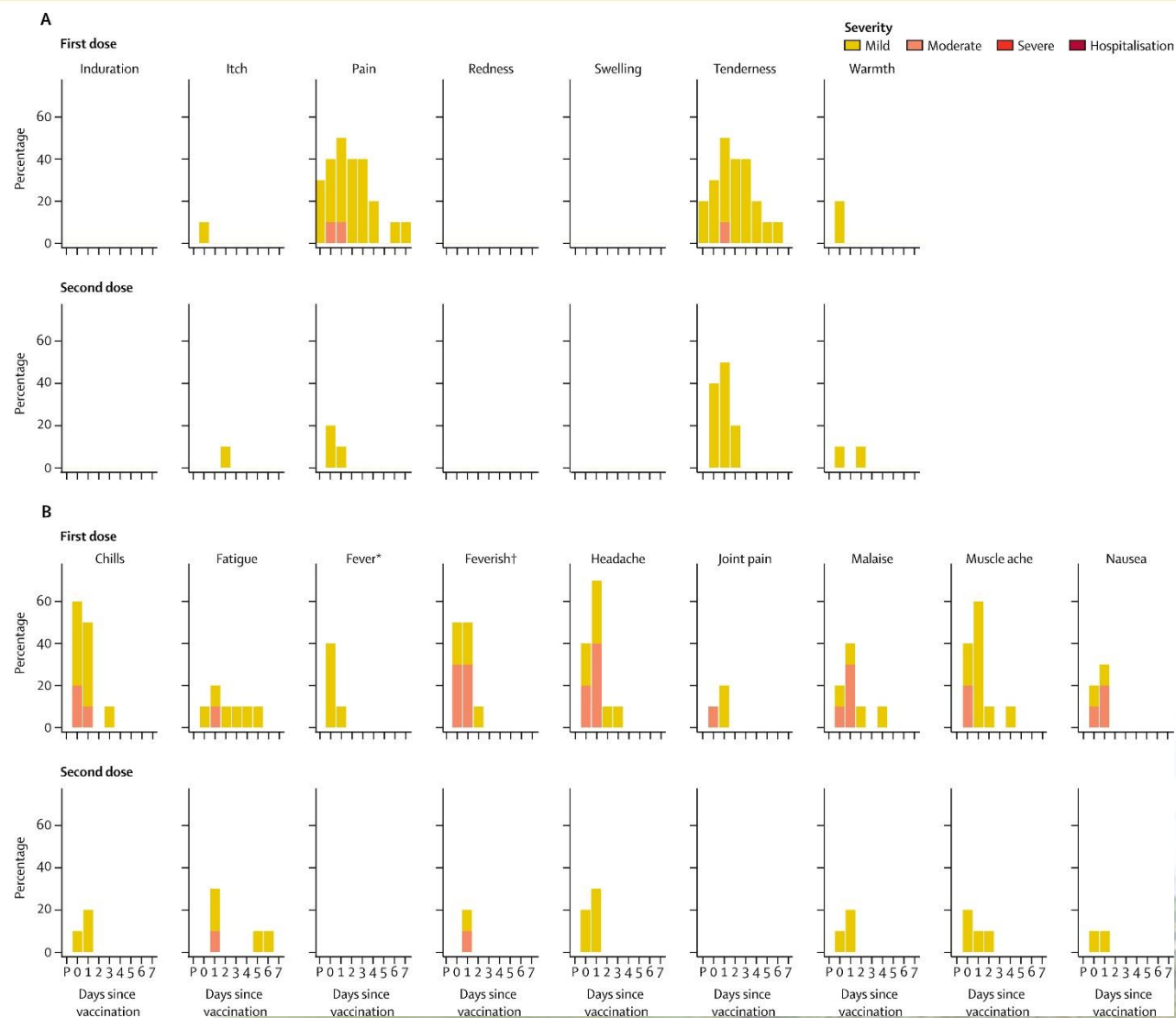




ChAdOx Platform – Human clinical testing



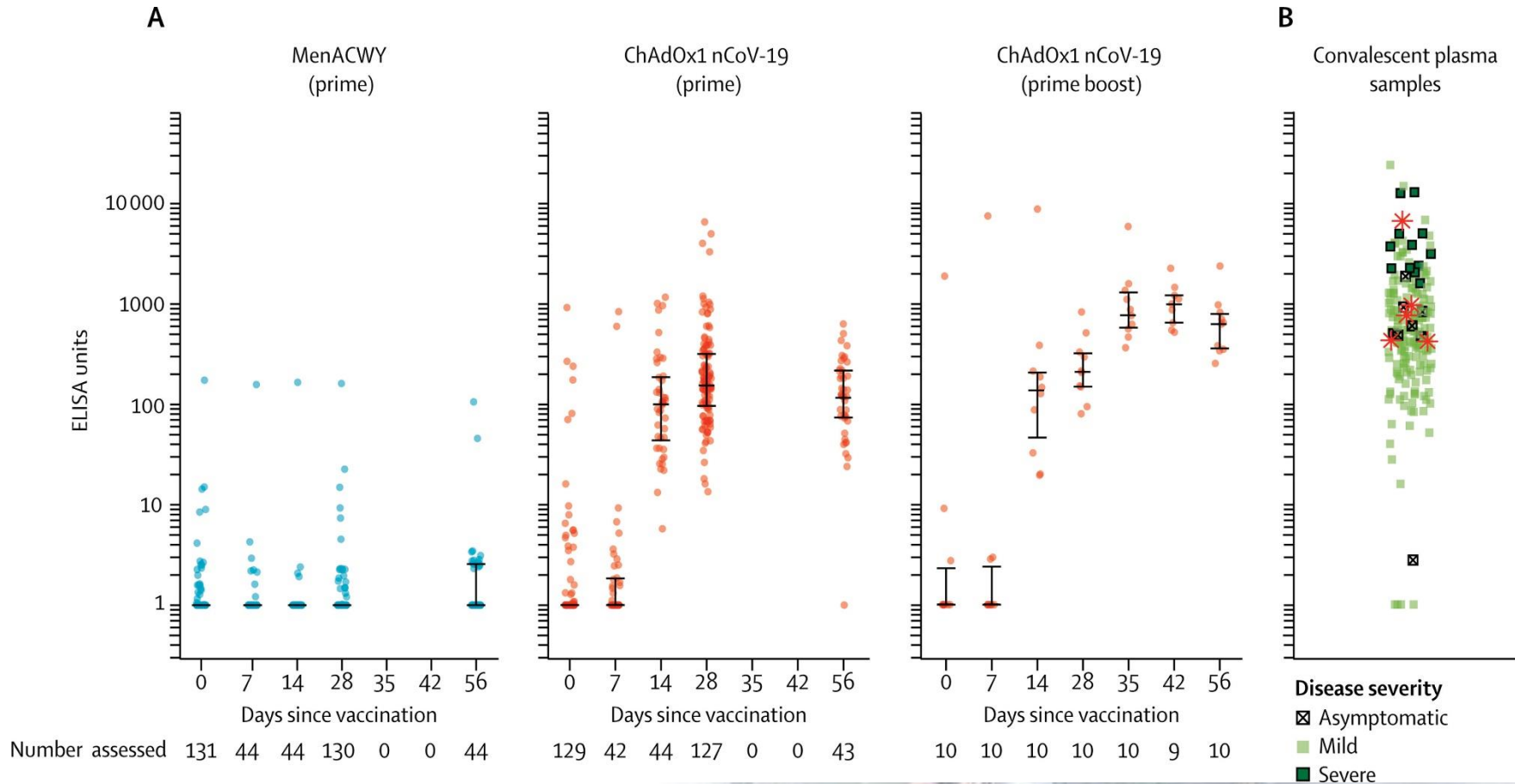
Commercial Developer:
AstraZeneca



Folegatti et al. 2020.
The Lancet DOI: (10.1016/S0140-6736(20)31604-4)



ChAdOx Platform – Human clinical testing

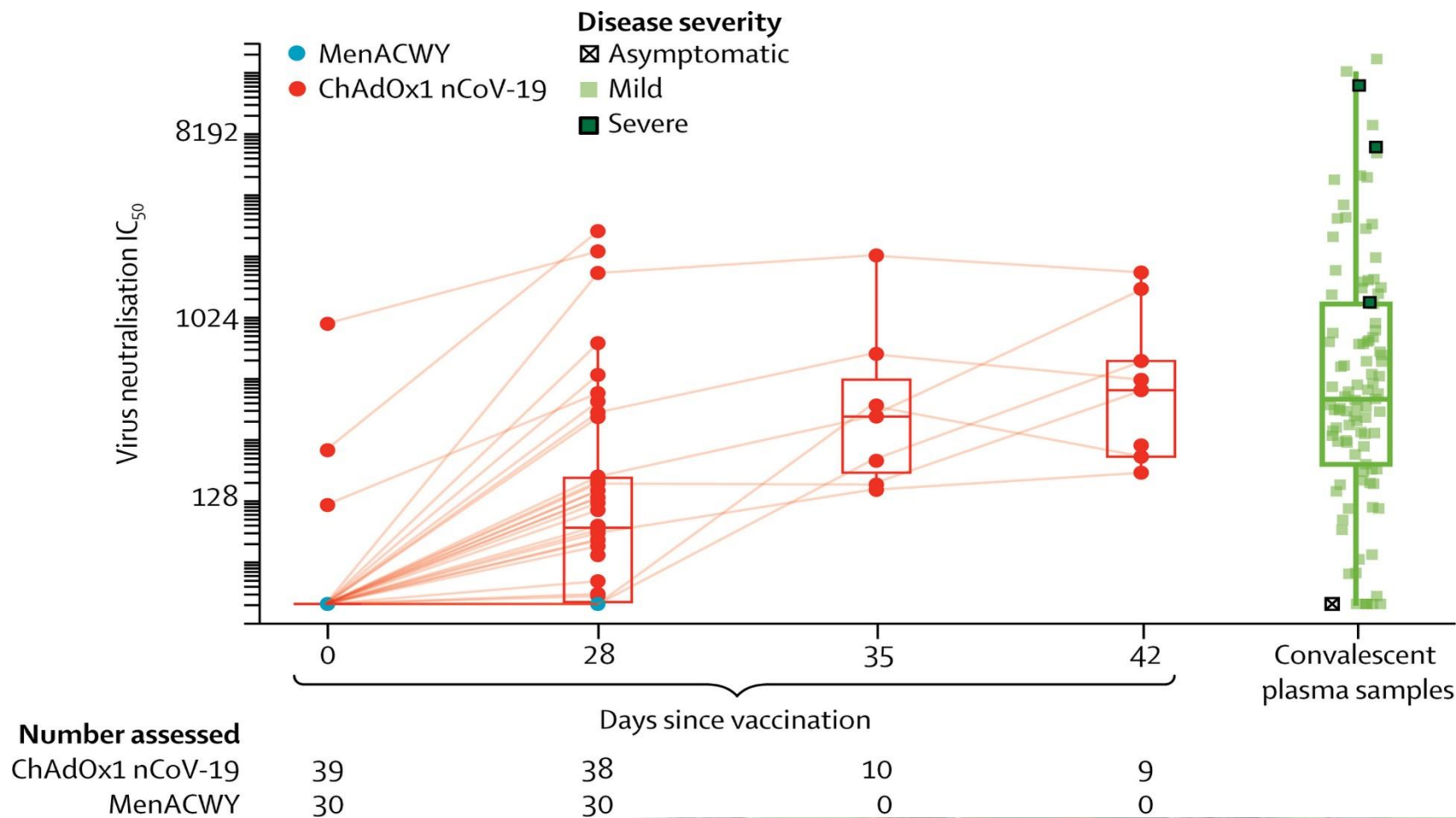


Folegatti et al. 2020
The Lancet DOI: (10.1016/S0140-6736(20)31604-4)





ChAdOx Platform – Human clinical testing

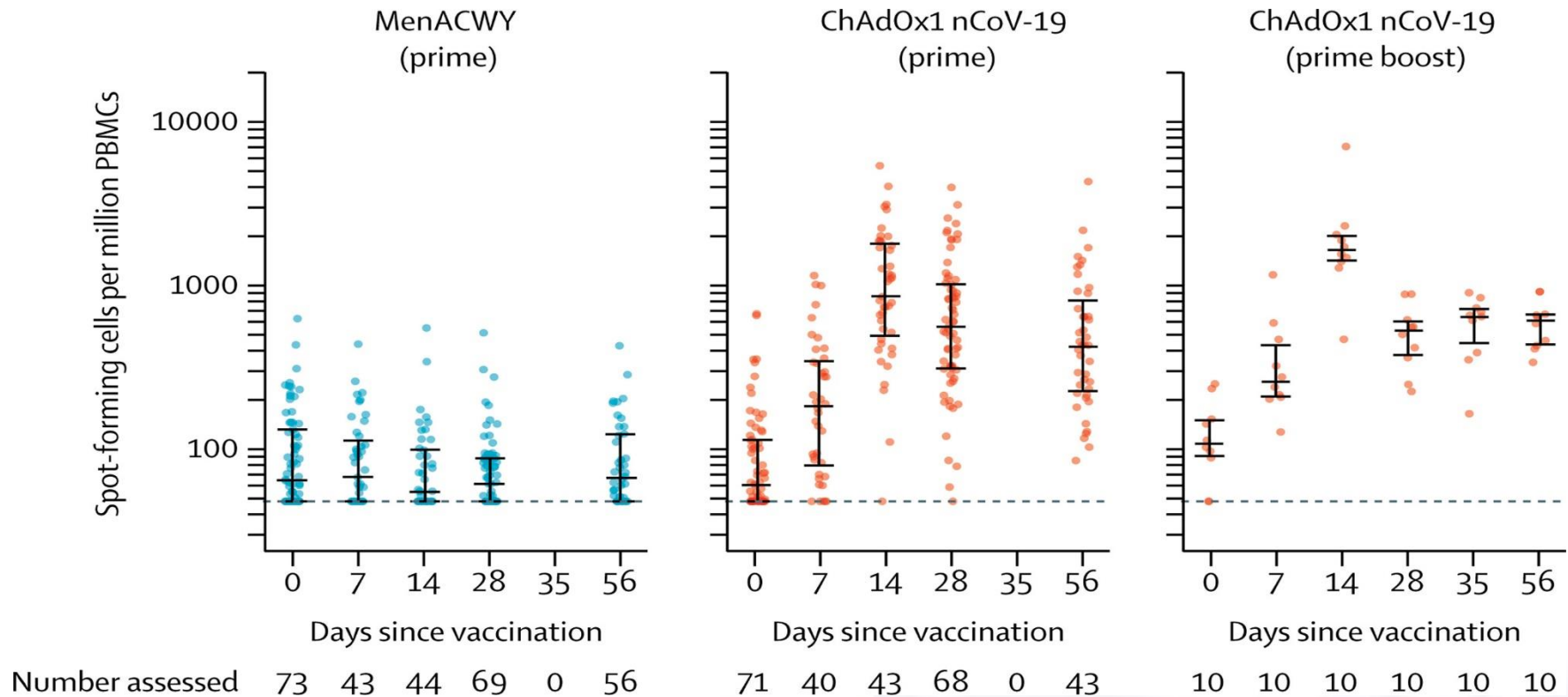


Folegatti et al. 2020

The Lancet DOI: (10.1016/S0140-6736(20)31604-4)



ChAdOx Platform – Human clinical testing



Folegatti et al. 2020
The Lancet DOI: (10.1016/S0140-6736(20)31604-4)





Summary: AstraZeneca vaccine



- ChAdOx1 seems to require two doses
- Balanced immune responses shown
- Potent virus neutralization shown
- Animal efficacy data not conclusive – mostly just reduction in viral load shown
- Efficacy rates of 60 and 90% were reported for different dosing regimens in phase 3 trials

Key Questions remaining:

- Cause of Adverse Reaction that resulted in pause in phase 3 trial of ChAdOx1?
- Do trials have to be extended as wrong dose was given?
- Durability of immunity?
- Adverse reactions and exclusion criteria?





COVID-19 Vaccine: From Approval to Vaccination

Melinda Ashton, MD

Executive Vice President and Chief Quality Officer
Hawai'i Pacific Health

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- **Vaccination**: the act of introducing a vaccine into the body to produce immunity to a specific disease
- **Immunization**: a process by which a person becomes protected against a disease through vaccination

Often used interchangeably

Which Vaccine?

- No input to vaccine supplied
- Either Pfizer or Moderna will require 2 doses
(no less than 21 or 28 days apart)
 - Must be same vaccine
 - Doses registered in Hawaii Immunization Registry
 - Second dose supply will be provided, in addition to subsequent initial doses for next group of recipients

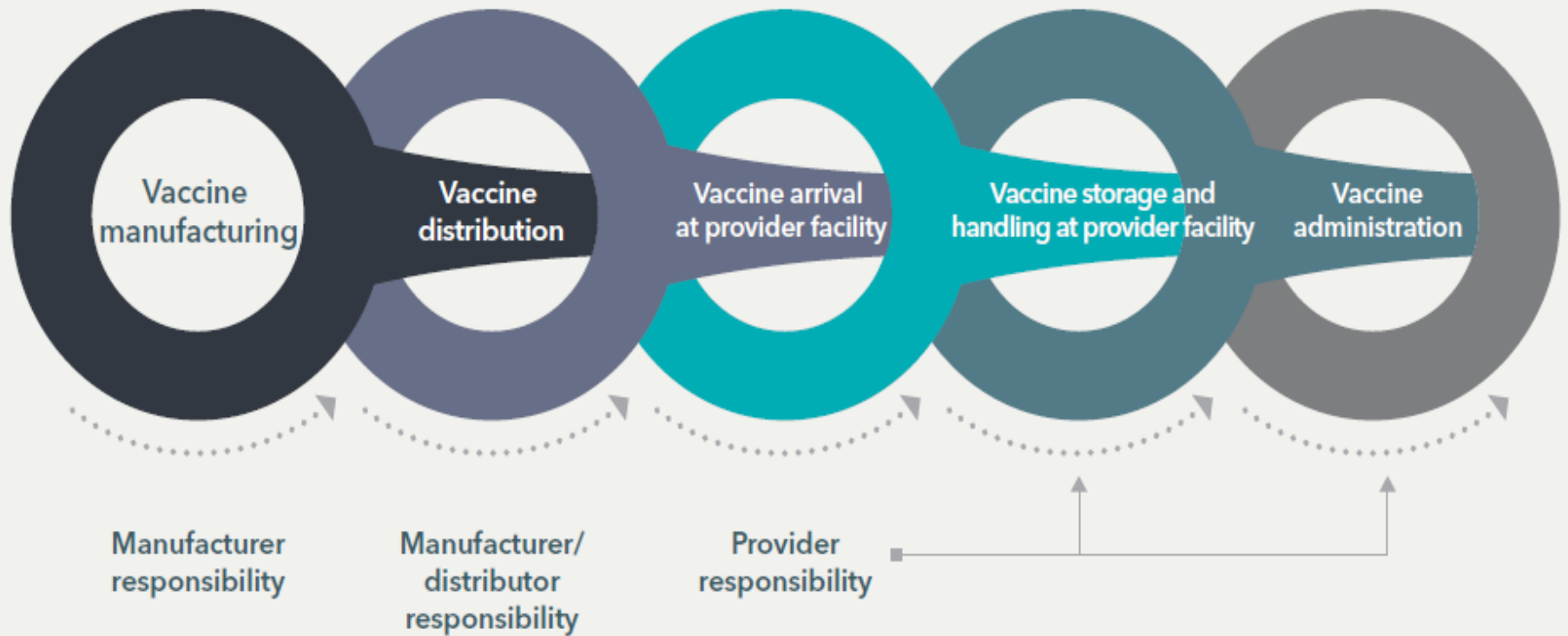
Once the EUA is Issued

- Expectation that vaccine will be shipped within 24 – 48 hours
- Pfizer: expecting initial 6.4 million doses
 - Allocated to states based on proportion of U.S. population
- Managed by State entities
 - If a state is not ready to receive vaccine, their share will be held until ready

From Manufacturer to Point of Use (POU)

- Vaccine will be directly shipped to hospitals and to CVS and Walgreens pharmacies
 - Prepositioning already occurring
- Pfizer vaccine: minimum order 975 doses

Cold Chain Flowchart



Pfizer Vaccine

- **GPS-enabled thermal sensors** track the location and temperature of each vaccine shipment 24/7
- Once a POU receives a thermal shipper with vaccine, there are three options for storage:
 - Ultra-low-temperature freezers extend shelf life for **up to six months**
 - The Pfizer thermal shippers serve as temporary storage units by refilling with dry ice every five days for **up to 30 days of storage**
 - The vaccine can be stored for **five days** at refrigerated **2-8°C conditions**
 - After storage for up to 30 days in the Pfizer thermal shipper, vaccination centers can transfer the vials to 2-8°C storage conditions for an additional five days, for a total of up to 35 days. Once thawed and stored under 2-8°C conditions, the vials cannot be re-frozen or stored under frozen conditions

Moderna Vaccine

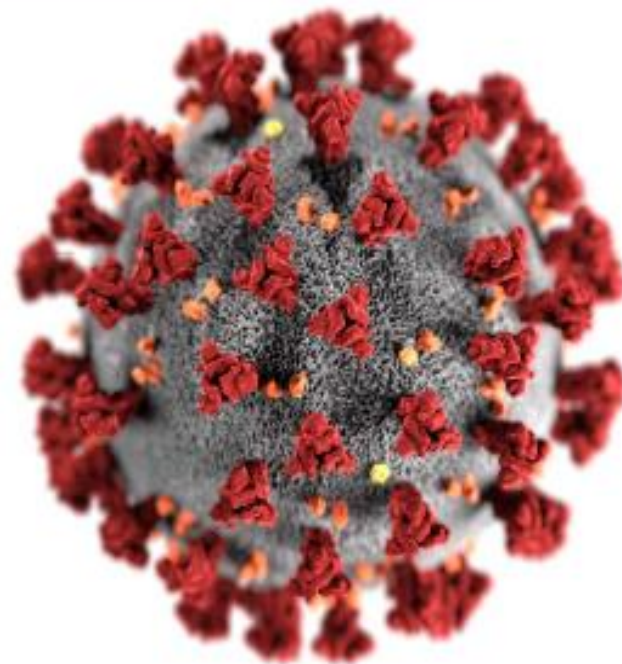
- Anticipated to be much less complicated to receive, store and provide vaccinations

Demand will be more than supply

Table ES-1: Population Groups

Allocation Stage	Population Group
Stage 1a	High-risk health workers (e.g., in hospitals or nursing homes, or providing home care)—these health professionals are involved in direct patient care. Also included are workers who provide transportation, environmental services, and other health care facility services and who risk exposure to bodily fluids or aerosols.
	First responders whose jobs put them at high risk of exposure to COVID-19
Stage 1b	People of all ages with comorbid and underlying conditions that put them at significantly higher risk
	Adults aged 65 and older living in congregate or overcrowded settings
Stage 2	K-12 teachers and school staff
	Critical risk workers in high-risk settings - workers who are both in industries essential to the functioning of society and at substantially high risk of exposure
	People of all ages with comorbid and underlying conditions that put them at moderately higher risk
	People in homeless shelters or group homes for individuals with physical or mental disabilities or in recovery and staff who work in those facilities
	People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings
	Adults aged 65 and older not included in Allocation Stage 1
Stage 3	Young Adults (18-22)
	Children (0-17)
	Workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Allocation Stages 1 or 2
Stage 4	Everyone residing in Hawaii who did not have access to the vaccine in previous allocation stages

Clinical Considerations for Populations Included in Phase 1a



Sara Oliver MD, MSPH
ACIP Meeting
December 1, 2020

Clinical Considerations

- **Health Care Personnel**
 - Sub-prioritization
 - Reactogenicity
 - Considerations for implementation

- **Long-Term Care Facility Residents**
 - Sub-prioritization
 - Reactogenicity
 - Considerations for implementation

Need for Sub-prioritization

- One or more COVID-19 vaccines may be authorized by FDA for use in December
- Initial doses of any COVID-19 vaccine will be limited. We expect a constrained supply environment for some months and need to make the best use of available vaccine.
- By the end of December, the number of doses available will be about **40 million**, enough to vaccinate **20 million** people
 - Anticipate **5-10** million doses per week post-authorization

Clinical Considerations: Health Care Personnel



Health Care Personnel: Sub-prioritization Considerations

- Where sub-prioritization of health care personnel is needed, consider:
 - Individuals with **direct patient contact**¹ and unable to telework:
 - Personnel who provide services to patients or patients' family members
 - Personnel who handle infectious materials
 - Can include inpatient or outpatient settings
 - Personnel working in residential care or long-term care facilities
 - Personnel without known infection in prior **90 days**
 - Reinfection appears uncommon during the initial 90 days after symptom onset of preceding infection²
 - Serologic testing **not recommended** prior to vaccination

¹Within 6 feet

²[Duration of Isolation and Precautions for Adults with COVID-19 | CDC](#)

Health Care Personnel:

Clinical Considerations: Pregnancy or Breastfeeding

- **75%** of health care workforce are women
 - Approximately **330,000** health care personnel could be pregnant or recently postpartum at the time of vaccine implementation
- Data demonstrate potentially increased risks of severe maternal illness and preterm birth due to COVID-19 disease
- **No data** on use of mRNA vaccines in pregnant/breastfeeding women
- Await Phase III data, FDA assessment, EUA Conditions of Use
 - Once reviewed, anticipate further guidance around use of COVID-19 vaccines in pregnant/breastfeeding Phase 1a populations

Reactogenicity

Data from published Phase I/II trials

Moderna¹

Adults 18–55 years of age

100µg	Post-dose 1			Post-dose 2		
N=15	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	—	—	—	5 (33%)	1 (7%)	—
Headache	4 (27%)	—	—	5 (33%)	4 (27%)	—
Myalgia	1 (7%)	—	—	2 (13%)	6 (40%)	—

Pfizer²

30µg	Post-dose 1			Post-dose 2		
N=12	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	1 (8%)	1 (8%)	—	—	2 (17%)	—
Headache	3 (25%)	1 (8%)	2 (17%)	6 (50%)	2 (17%)	—
Myalgia	1 (8%)	1 (8%)	1 (8%)	4 (33%)	3 (25%)	—

Systemic symptoms more common after **second** dose

¹Jackson et al. An mRNA Vaccine against SARS-CoV-2- Preliminary report. NEJM 2020;20:1920-1931.

²Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14.

Health Care Personnel: Considerations for Implementation

- Health care systems and public health should work together to ensure vaccine **access** to health care personnel who are not affiliated with hospitals
- Consider **staggering** vaccination of personnel from similar units or positions
- Planning for personnel to have **time away** from clinical care if HCP experience systemic symptoms post-vaccination
- Additional CDC guidance forthcoming:
 - Approach to systemic symptoms in HCP after COVID-19 vaccination

Clinical Considerations: Long-Term Care Facility Residents



Long-Term Care Facility Residents: Sub-prioritization Considerations

- Where sub-prioritization of long-term care facilities needed, consider:
 - **Skilled nursing facilities** care for most medically vulnerable residents
 - After skilled nursing facilities, consider **broadening** to other facilities, including:
 - Assisted living facilities
 - Residential care communities
 - Intermediate care facilities for individuals with developmental disabilities
 - State Veterans Homes

Reactogenicity

Data from published Phase I/II trials

Moderna¹ ≥71 years of age Community-dwelling older adults

100µg	Post-dose 1			Post-dose 2		
N=10	Mild	Moderate	Severe	Mild	Moderate	Severe
Any systemic symptom	3 (30%)	—	—	3 (30%)	3 (30%)	1 (10%)*

*Grade 3 fatigue

Pfizer² 65-85 years of age

30µg	Post-dose 1			Post-dose 2		
N=12	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	—	—	—	1 (8%)	—	—
Headache	—	—	—	2 (17%)	1 (8%)	—
Myalgia	—	—	—	2 (17%)	1 (8%)	—

¹Anderson et al. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. NEJM 2020; online publication Sept 29

²Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14

Long-Term Care Facility Residents: Considerations for Implementation

- Federal pharmacy partners supporting the LTCF program will be required to adhere to all EUA Conditions of Use
 - Must provide **fact sheets** to recipients in accordance with the conditions of use
 - EUA fact sheets will be provided directly to staff and residents getting vaccinated, as well as families/medical proxies as applicable
 - Language clarifying available data in adults ≥ 65 years of age, and lack of data specific to individuals in LTCF will be included in information on CDC's website

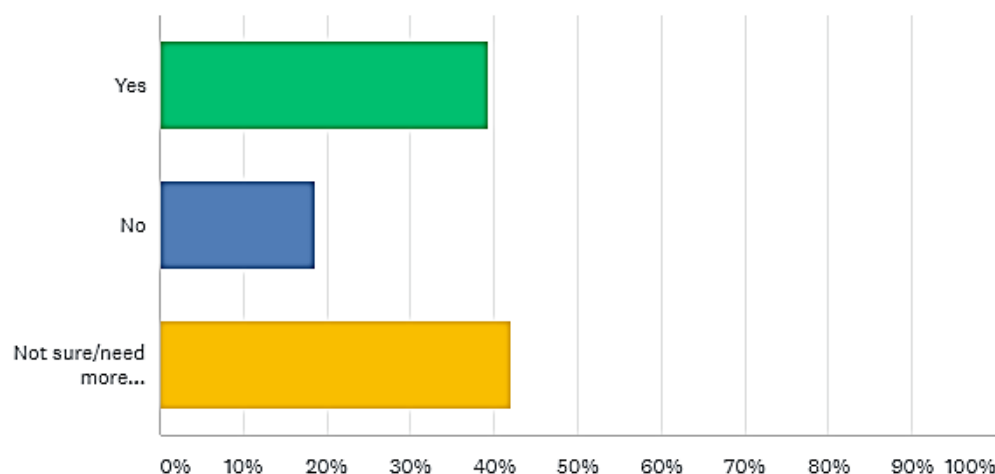
Consent/assent will be obtained from residents or families/medical proxies and documented in the patients' charts as is standard practice for other vaccines

HPH Vaccine Planning

- Expect to receive vaccine at each hospital
- Plan to provide vaccination by appointment
 - Sign up for first and second dose dates
 - Information regarding vaccine will be provided as registration for appointments is done
 - Expect to also survey risk factors for severe COVID-19 illness to assist in sub-prioritization
 - Sign consent at time of vaccination

It is possible that an FDA-approved COVID-19 vaccine will be available in the next few weeks. Healthcare workers will be prioritized as early recipients. If an FDA-approved vaccine to prevent COVID-19 was available right now at no cost, would you agree to be vaccinated?

Answered: 863 Skipped: 21



As of 12/5/20

ANSWER CHOICES	RESPONSES	
Yes	39.40%	340
No	18.54%	160
Not sure/need more information	42.06%	363
TOTAL		863

HPH Vaccine Planning

- Emphasize highest risk of COVID-19 exposure
 - e.g. all staff who work in: ICU, ED, drive-up specimen collection staff, labor and delivery, infectious disease and REC, hospitalist and general med staff nurses
- Sub-prioritization as needed
- Then continue to work through all who want vaccine as supplies allow

HPH Vaccine Planning

- We will provide vaccine to contracted employees (as their priority occurs)
- Also, residents and medical staff who are affiliated with our hospitals (HHP also)
- We may also provide vaccination for first responders

HPH Vaccine Planning

- Vaccine for our patients
 - Will be arranged as we move beyond first tiers (if not in first tier categories)
 - Prioritization schemes taking into account risk of severe disease and risk of exposure will be needed
 - We recommend you do not create vaccine waiting lists
 - Unknown at this time: mass vaccination public clinics?
Role of pharmacies

Thoughts About How to Promote Vaccination

- Address concerns about safety regarding speed of development
 - Scientific safety has not been compromised
- Reiterate COVID-19 is serious
- Anticipate that vaccine may cause side effects
 - Some concern that second dose may be skipped
 - Side effects can be welcomed as sign that immune system is actually working

Q&A

Save the Date:

The 3rd Annual HHP Webinar

Thursday, January 14, 2021

12:00pm – 1:00 pm

More information to come via Info@hawaiihealthpartners.org

Thank you!

- A recording of the meeting will be available afterwards.
- Unanswered question?
 - Contact us at Covid19Bulletin@hawaiipacifichealth.org