12-10-2020

Covid-19 Clinical Update 12/10/2020

George Washington University

COVID-19 UPDATE

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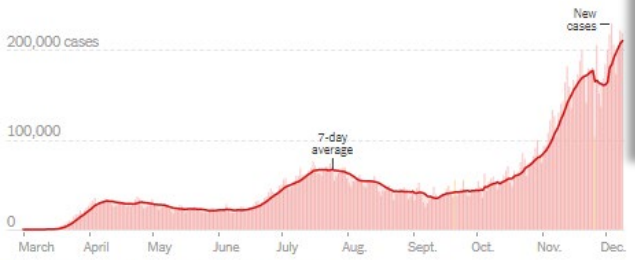
GW DIVISION OF INFECTIOUS DISEASES

12/10/2020

1. EPIDEMIOLOGY
2. VACCINE NEWS
3. GW UPDATES

DISCLOSURES: NO FINANCIAL COI. INVESTIGATOR ON MODERNA VACCINE TRIAL. PRE-PRINT FINDINGS AND INVESTIGATIONAL USE MAY BE DISCUSSED.

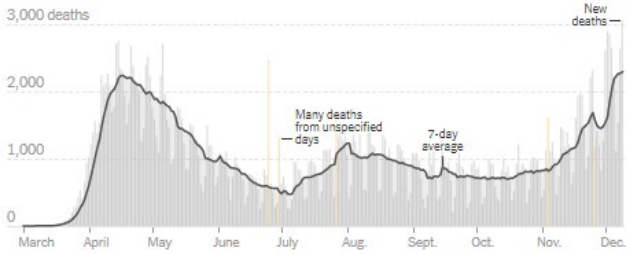
New reported cases by day



These are days with a reporting anomaly. Read more here.

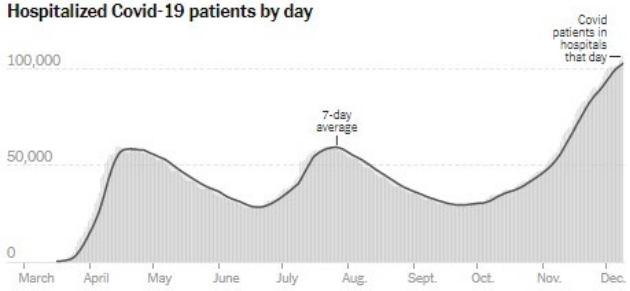
Note: The seven-day average is the average of a day and the previous six days of data.

New reported deaths by day



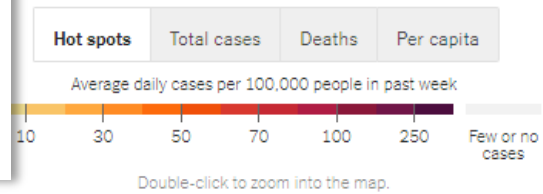
These are days with a reporting anomaly. Read more here.

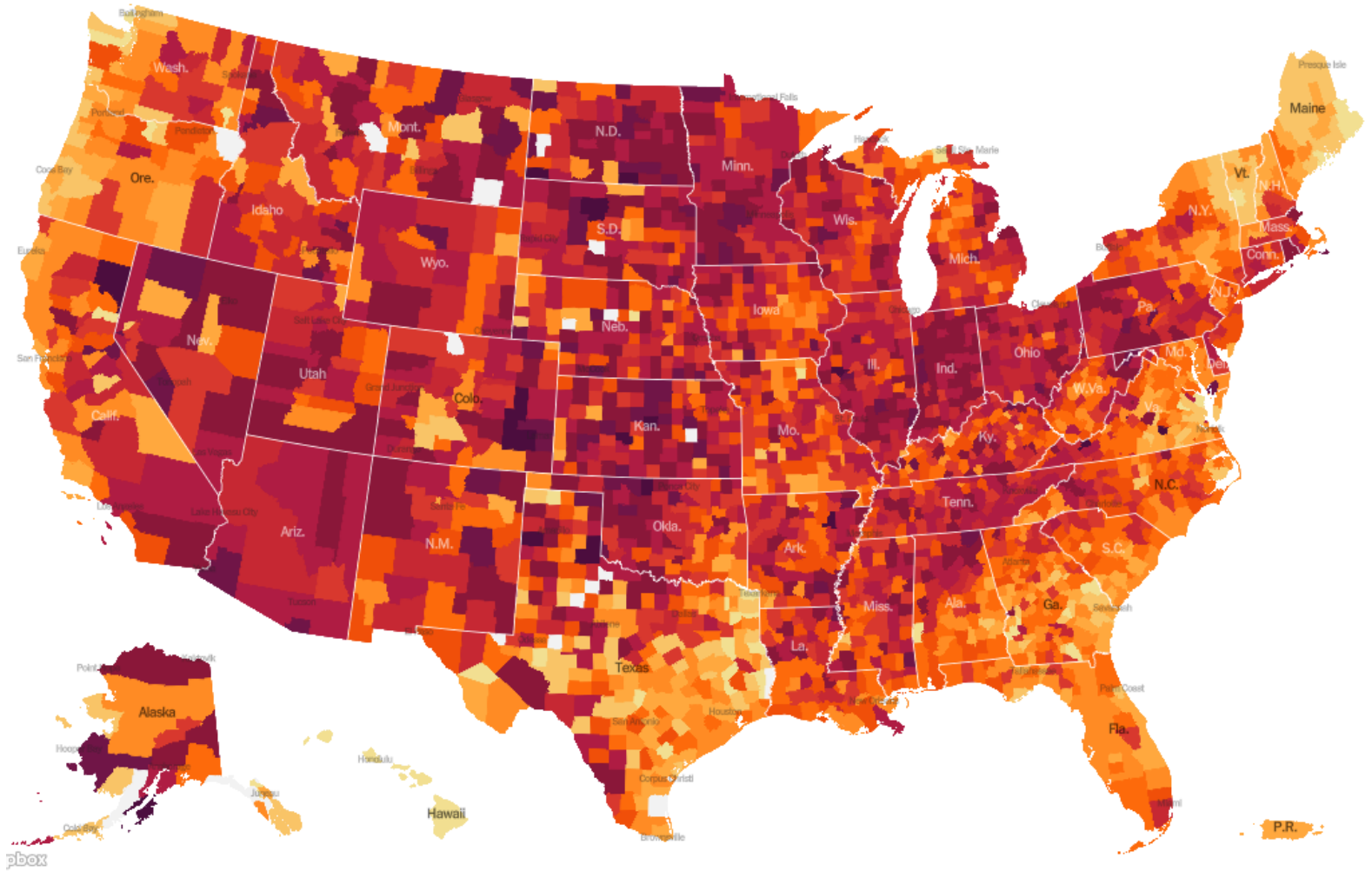
Hospitalized Covid-19 patients by day



	TOTAL REPORTED	ON DEC. 9	14-DAY CHANGE
Cases	15.4 million+	218,667	+19% ↗
Deaths	289,531	3,055	+36% →
Hospitalized		106,688	+21% →

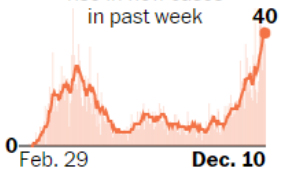
Day with reporting anomaly. Hospitalization data from the Covid Tracking Project; 14-day change trends use 7-day averages.





District of Columbia

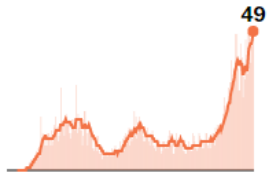
+35% rise in new cases in past week



3,521 reported per 100k

Maryland

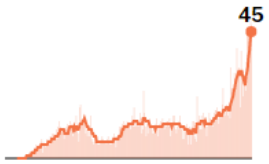
+37%



3,762 reported per 100k

Virginia

+70%



3,221 reported per 100k

https://www.washingtonpost.com/graphics/local/dc-maryland-virginia-coronavirus-cases/
https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

Fernando P. Polack, M.D., Stephen J. Thomas, M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Gonzalo Pérez Marc, M.D., Edson D. Moreira, M.D., Cristiano Zerbini, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., et al., for the C4591001 Clinical Trial Group*

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.

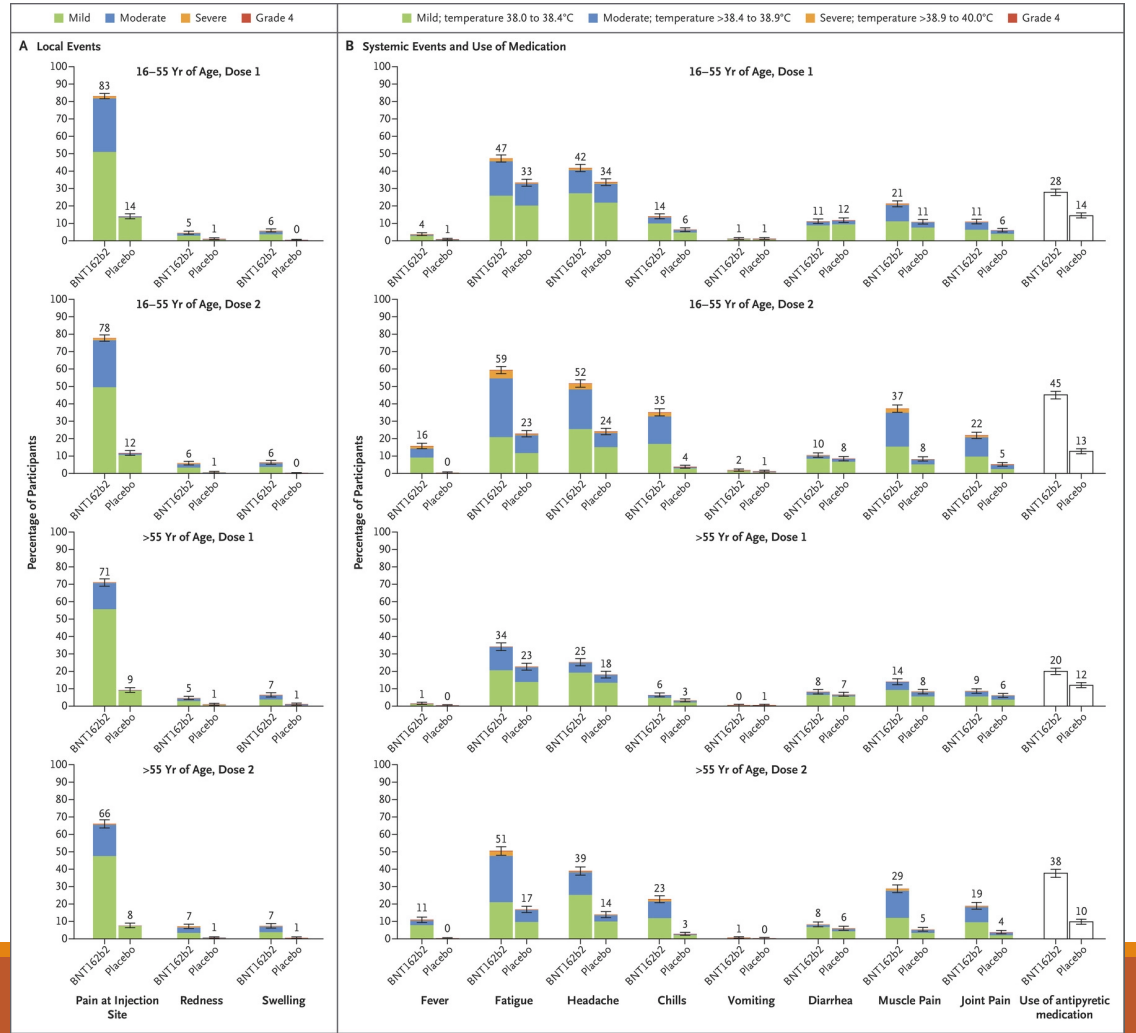
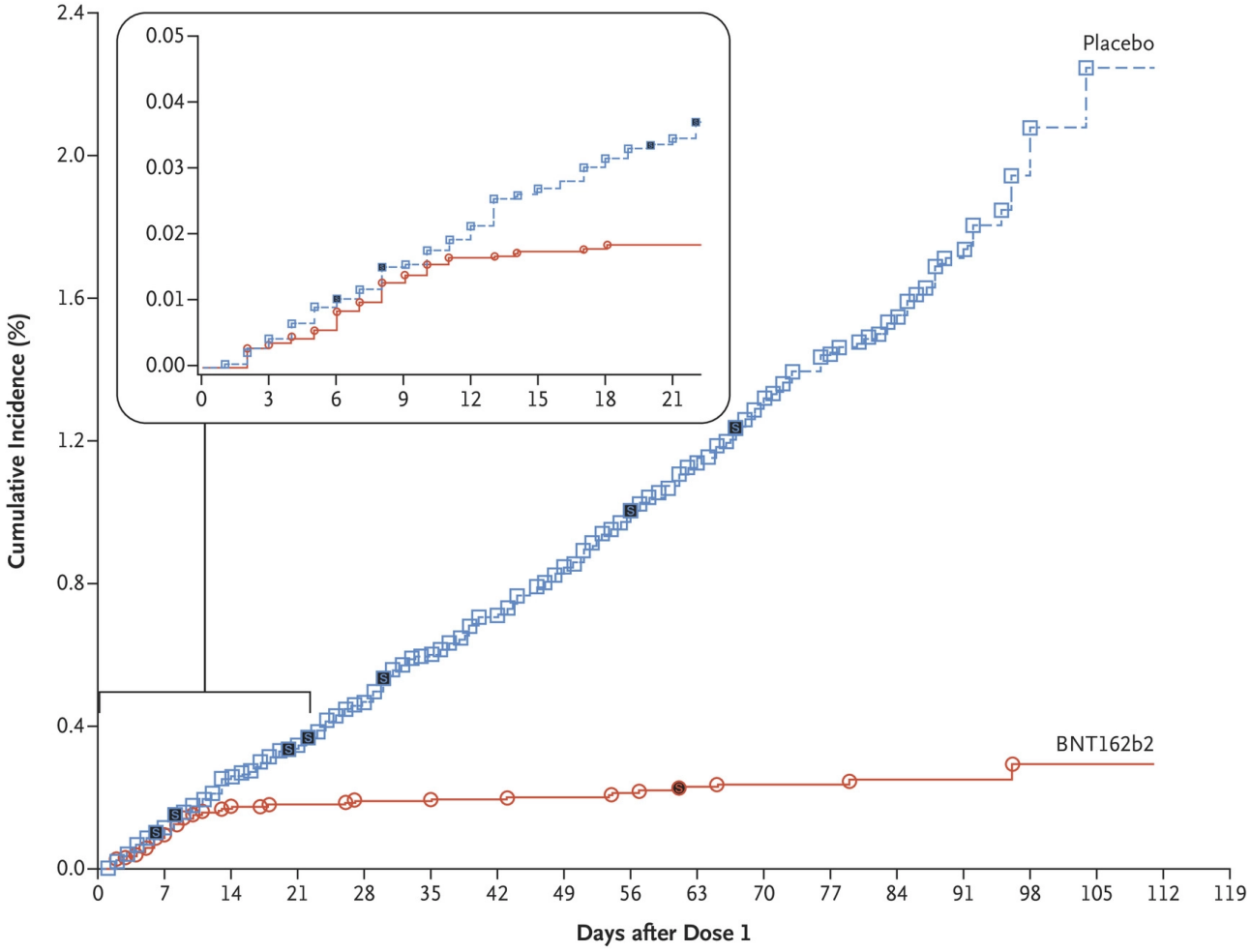


Table 3. Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection before 7 Days after Dose 2.

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)

https://www.nejm.org/doi/full/10.1056/NEJMoa2034577



Efficacy End-Point Subgroup	BNT162b2, 30 μg (N=21,669)		Placebo (N=21,686)		VE (95% CI)
	No. of participants	Surveillance time *person-yr (no. at risk)*	No. of participants	Surveillance time *person-yr (no. at risk)*	*percent*
Covid-19 occurrence					
After dose 1	50	4.015 (21,314)	275	3.982 (21,258)	82.0 (75.6–86.9)
After dose 1 to before dose 2	39		82		52.4 (29.5–68.4)
Dose 2 to 7 days after dose 2	2		21		90.5 (61.0–98.9)
≥7 Days after dose 2	9		172		94.8 (89.8–97.6)

Limitations:

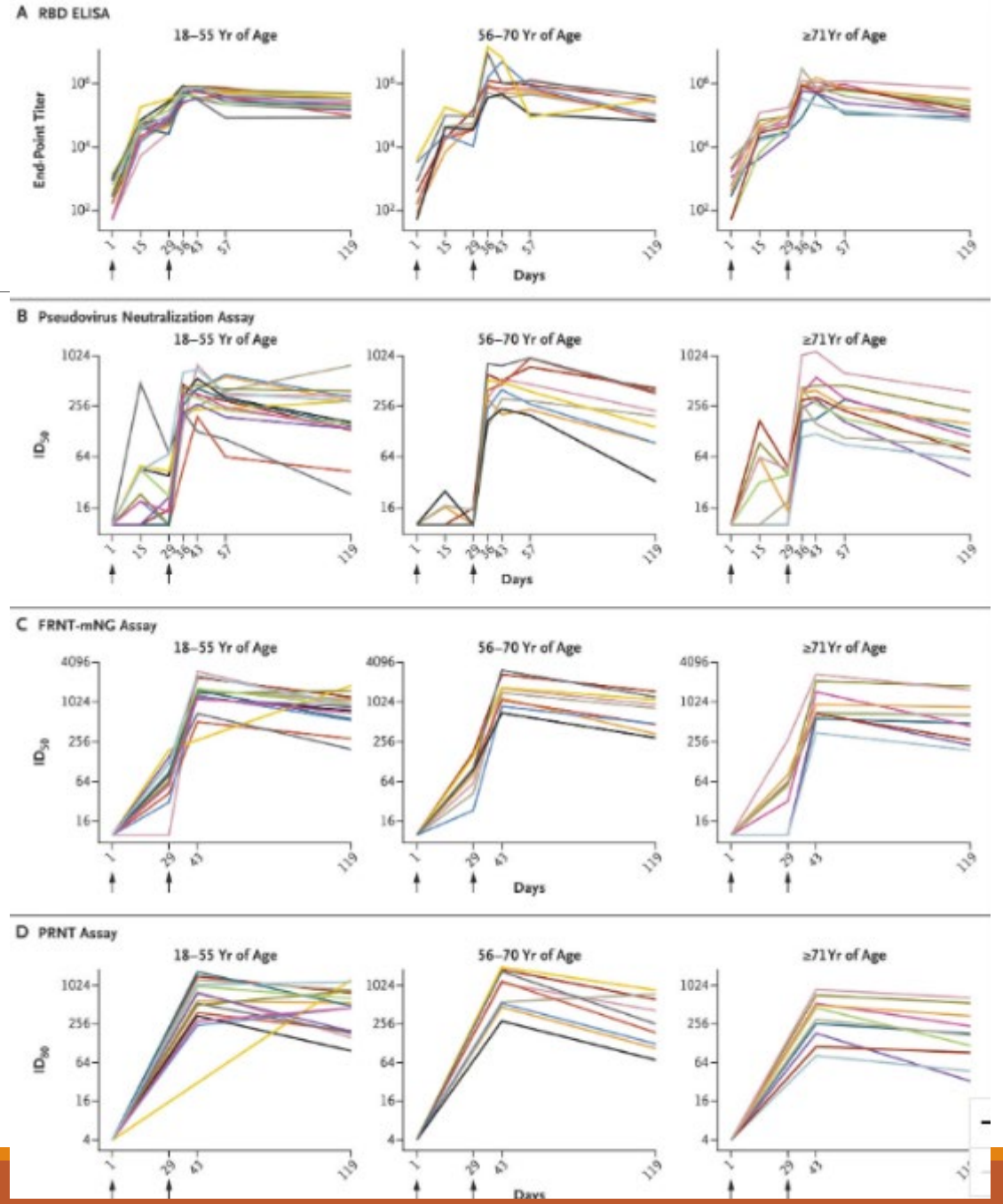
- Powered to detect AE with incidence of 0.01% (10 per 100,000) occurring within up to 3.5 months
- "Although the study was designed to follow participants for safety and efficacy for 2 years after the second dose, given the high vaccine efficacy, ethical and practical barriers prevent following placebo recipients for 2 years without offering active immunization, once the vaccine is approved by regulators and recommended by public health authorities."
- Does not address whether vaccination prevents asymptomatic infection; seroconversion data to be released later.
- TBD: efficacy in adolescents ages 12-15, children, pregnant women, and immunocompromised
- TBD: stability outside of extra-cold storage

After dose 1, before dose 2: 52.4%
After dose 2 (7+): 94.8%

https://www.nejm.org/doi/full/10.1056/NEJMoa2034577

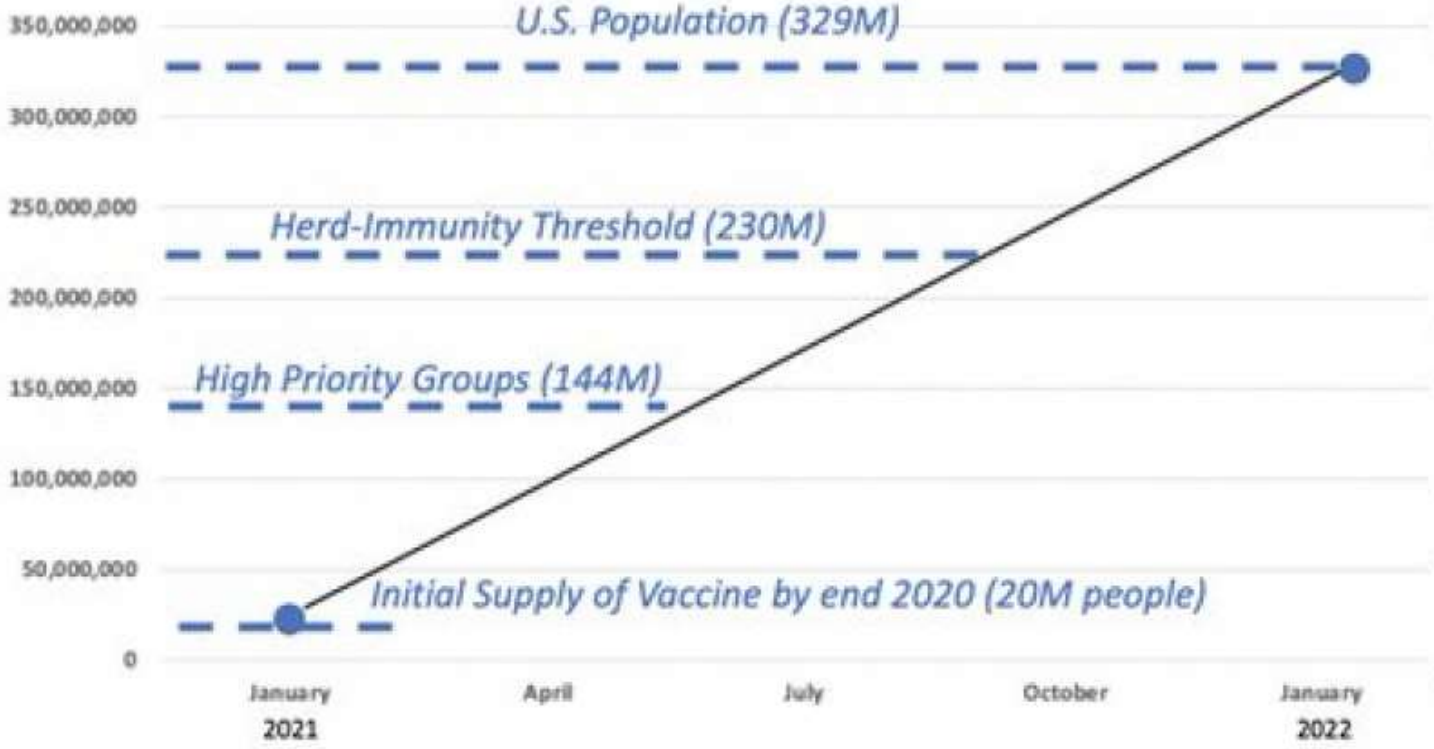
Durability of Responses after SARS-CoV-2 mRNA-1273 Vaccination

- High levels of binding and neutralizing antibodies declined slightly over time, as expected, but remained elevated in all participants 3 months after the booster vaccination
- Although the memory cellular response to mRNA-1273 is not yet defined, this vaccine elicited primary CD4 type 1 helper T responses 43 days after the first vaccination, and studies of vaccine-induced B cells are ongoing.
- Longitudinal vaccine responses are critically important, and a follow-up analysis to assess safety and immunogenicity in the participants for a period of 13 months is ongoing.
- Findings provide support for the use of a 100-µg dose of mRNA-1273 in an ongoing phase 3 trial, which has recently shown a 94.5% efficacy rate in an interim analysis.



https://www.nejm.org/doi/full/10.1056/NEJMc2032195

U.S. Vaccine Availability and Eligible Groups



Some Useful Numbers to Gauge Vaccine Timing (Ariadne estimates)

- Healthcare workers & first responders: 19.3M
- Patients with one or more comorbidities: 92M
- Patients over 65 with no comorbidities: 1.3M
- Over 65 in congregate settings: 2.3M
- Essential workers not fitting other categories: 22M
- Homeless: 6.7M
  Incarcerated: 0.7M

Total: ~144M

Number of people in U.S.: 329M

Herd immunity threshold (~70% of total population): 230M

@bob_wachter

https://www.sfgate.com/bayarea/article/COVID-vaccine-timeline-US-UCSF-Wachter-15770110.php

GW Updates

The GW Medical Faculty Associates

School of Medicine & Health Sciences
THE GEORGE WASHINGTON UNIVERSITY

THE GEORGE WASHINGTON UNIVERSITY HOSPITAL
UHS

GW MFA/SMHS and GW Hospital leaders will hold a Town Hall meeting to discuss what we know about the COVID-19 vaccine and address questions.

WHEN:
Wednesday, Dec. 9 at 1:00 pm

WHERE:
Event address for attendees: https://gwu.webex.com/gwu/onstage/g.php?MTID=e42e7f7e60fbab40a599fd3ec0778d7f2

There is no password required for this event. If you are prompted for a password, please use: *townhall*

The GW Medical Faculty Associates

School of Medicine & Health Sciences
THE GEORGE WASHINGTON UNIVERSITY

THE GEORGE WASHINGTON UNIVERSITY HOSPITAL
UHS

Dear Colleagues,

The GW Clinical Enterprise continues to monitor and respond to the ongoing COVID-19 pandemic. We are grateful to those who have been on the frontlines battling this virus and caring for those affected as well and to all who have adapted and continued to care for all our patients and our community in novel ways during this time. As an academic enterprise, we have been honored to work with our government officials and healthcare partners on research and education related to COVID-19 treatment, as well as potential vaccines. And, we thank those who have continued to serve our education and training missions despite many challenges.

As we begin to hear more news about the start of vaccinations in the United States, we acknowledge that you may have many questions about the vaccine and its arrival in Washington, D.C., as well as its plans for distribution to all members of our teams. We recognize this anticipation comes with a range of emotions from urgency to uncertainty. We have been carefully preparing for the arrival of the vaccines; and we are equipped to receive all forms of the vaccines as they become available. We will adhere to guidance from the CDC Advisory Committee for Immunization Practice (ACIP) which advised that the COVID-19 vaccination program (phase 1a) should be offered to both 1) health care personnel and 2) residents of long-term care facilities.

As an academic medical enterprise, we will also align our distribution with the efforts of the DC Health. We are in close communication with our government partner and awaiting information regarding the number of doses and timing of vaccine deliveries, hoping our first batch will arrive by mid-December.