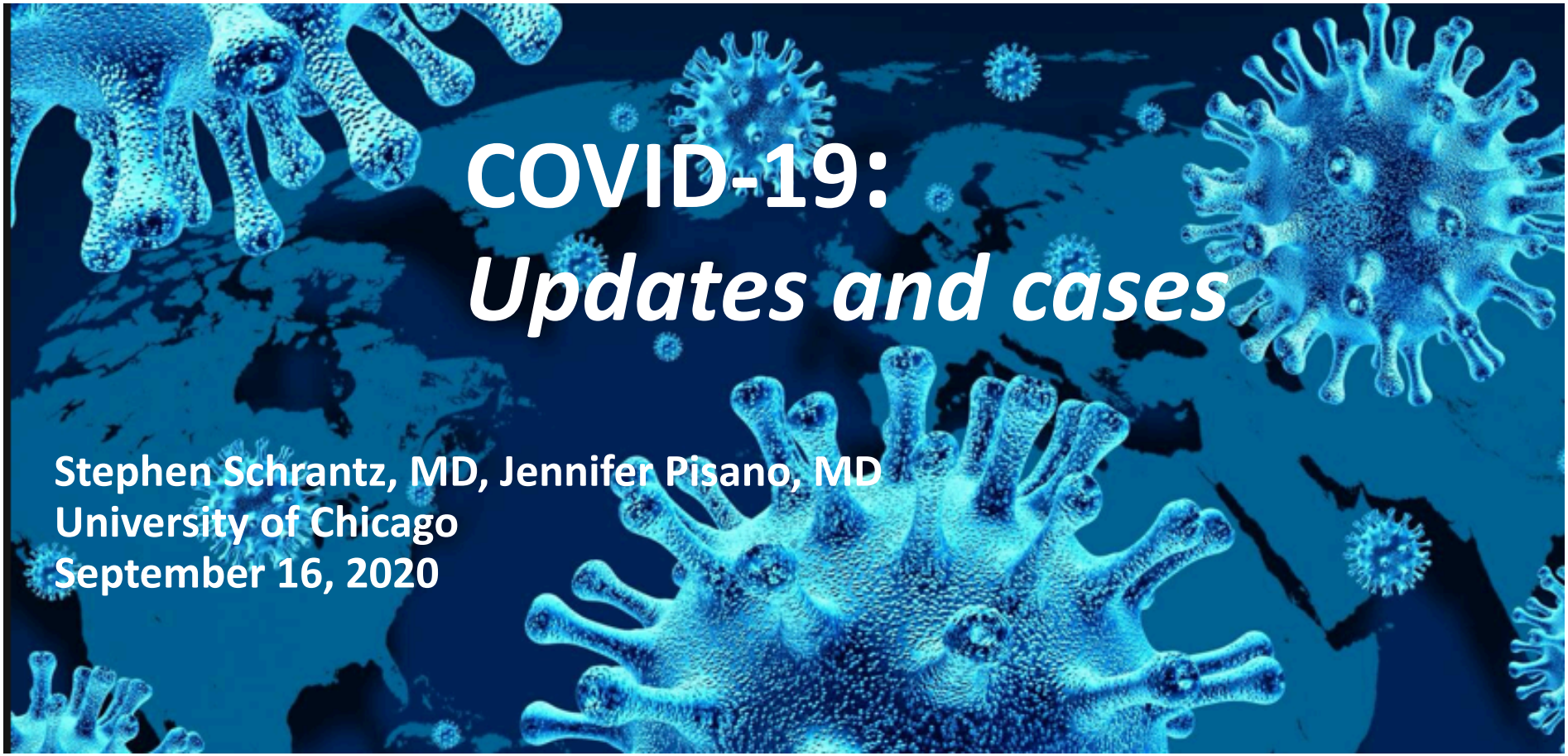


COVID-19:
Updates and cases

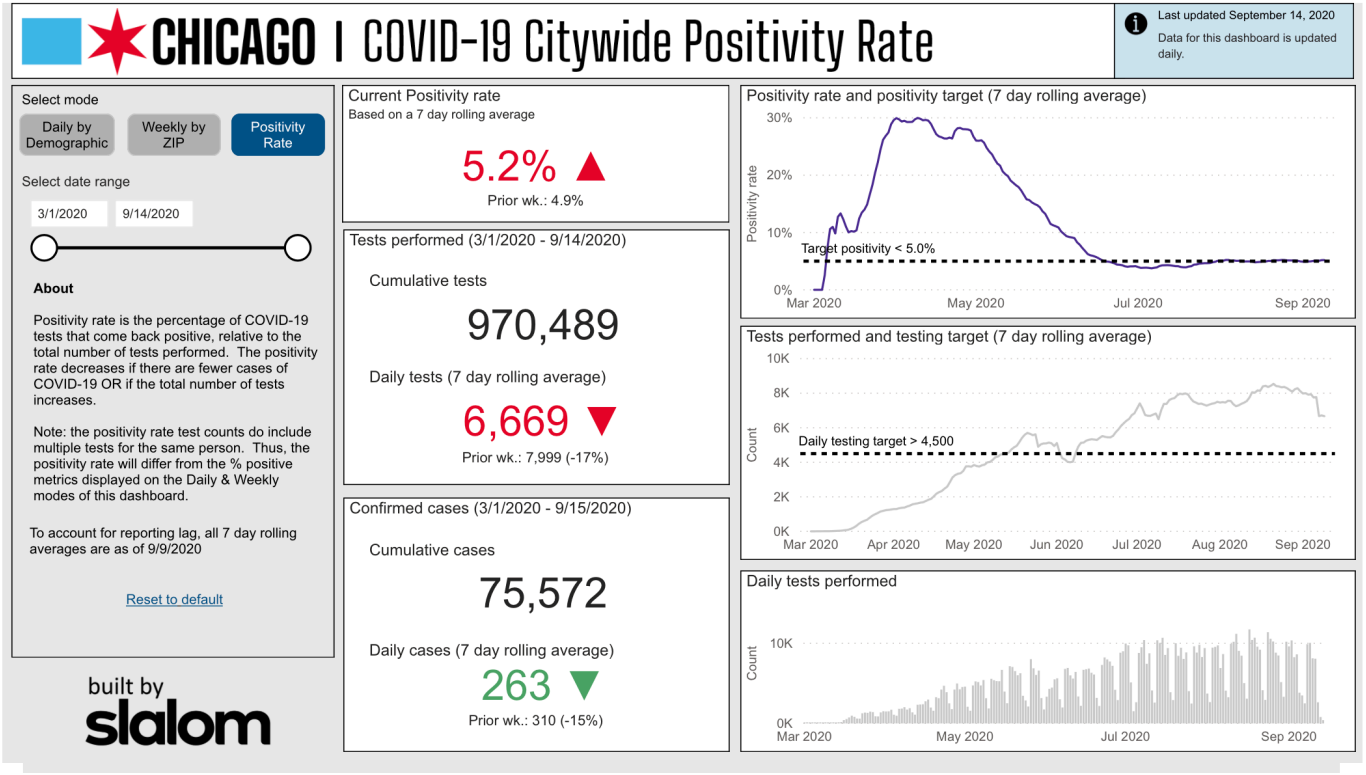
Stephen Schrantz, MD, Jennifer Pisano, MD
University of Chicago
September 16, 2020

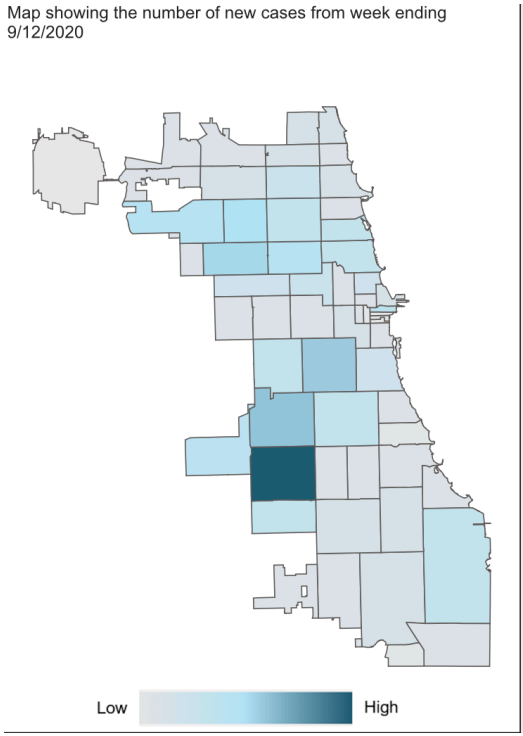
ECHO CHICAGO

Disclosures

- We have no relevant financial interests to disclose.

Local Epidemiology





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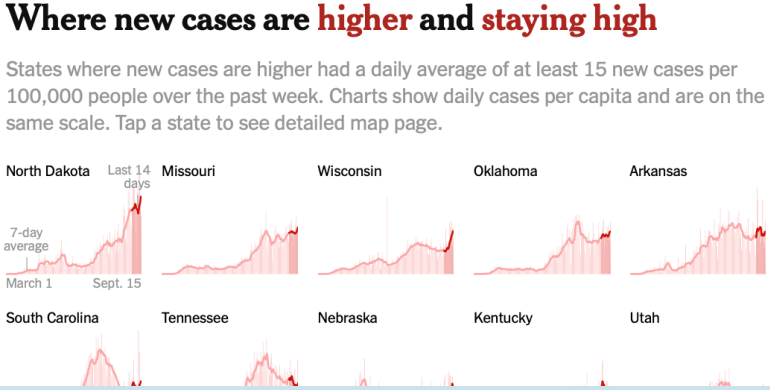
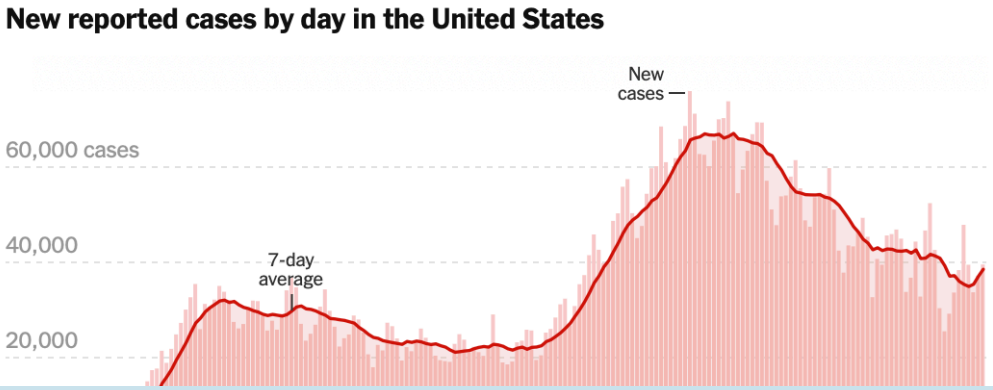
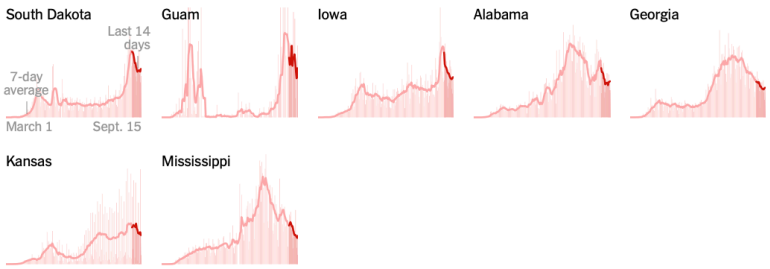
And Elsewhere…

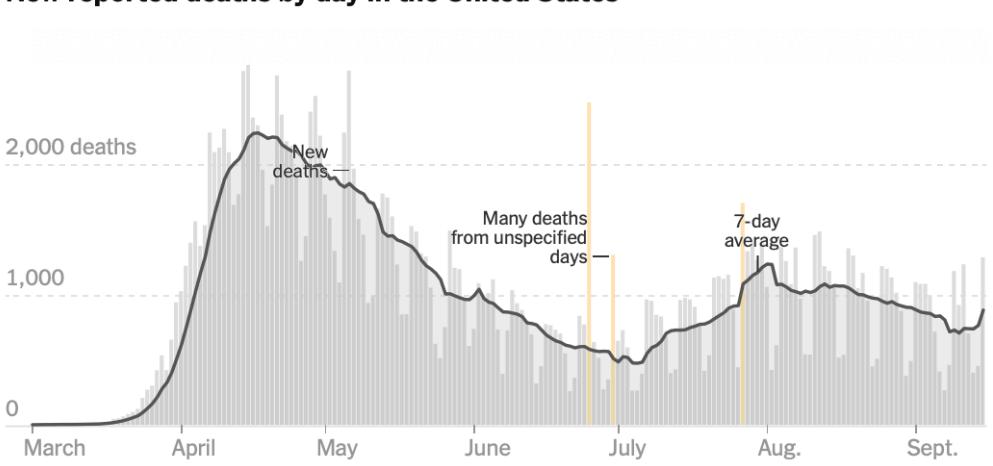




States Currently Covered by the Order

Travelers from the following states and territories should quarantine upon arrival in Chicago: Alabama, Arkansas, Georgia, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nebraska, North Dakota, Oklahoma, South Carolina, South Dakota, Tennessee, and Utah. The list will be updated every Tuesday and go into effect the following Friday at 12:01 a.m.

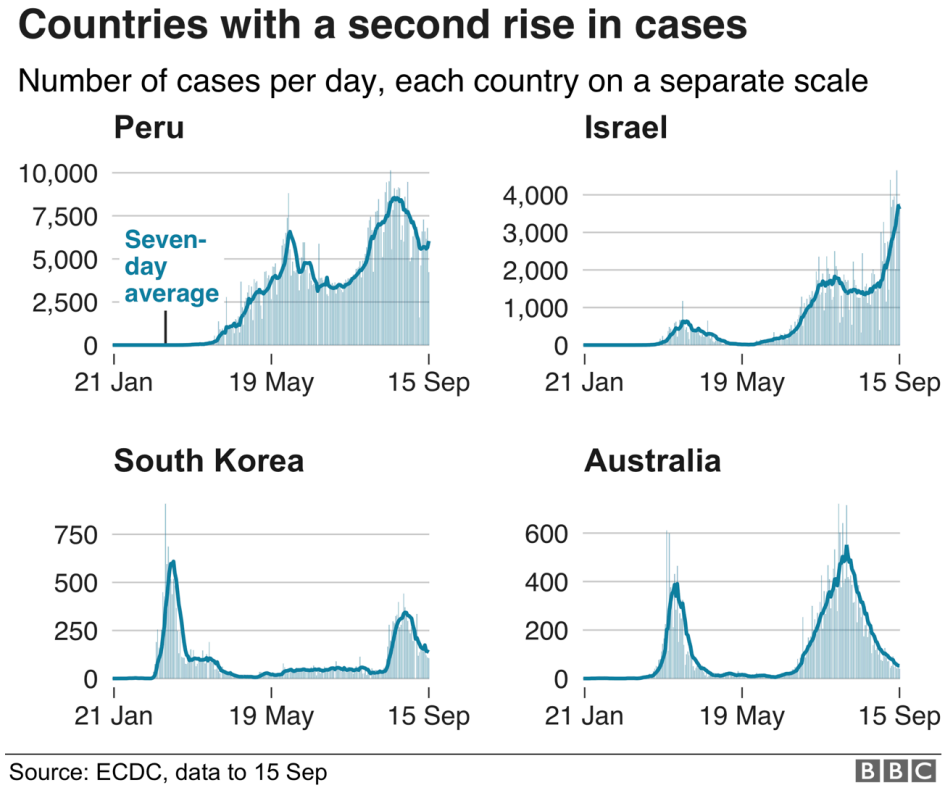




https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html?action=click&module=Top%20Stories&pgtype=Homepage

And Abroad…

- Countries with rising rates of COVID-19
- implementing new restrictions:
  - UK
  - Israel
  - India
  - Argentina
  - Indonesia
  - Ukraine
  - Iraq
  - Spain
  - France



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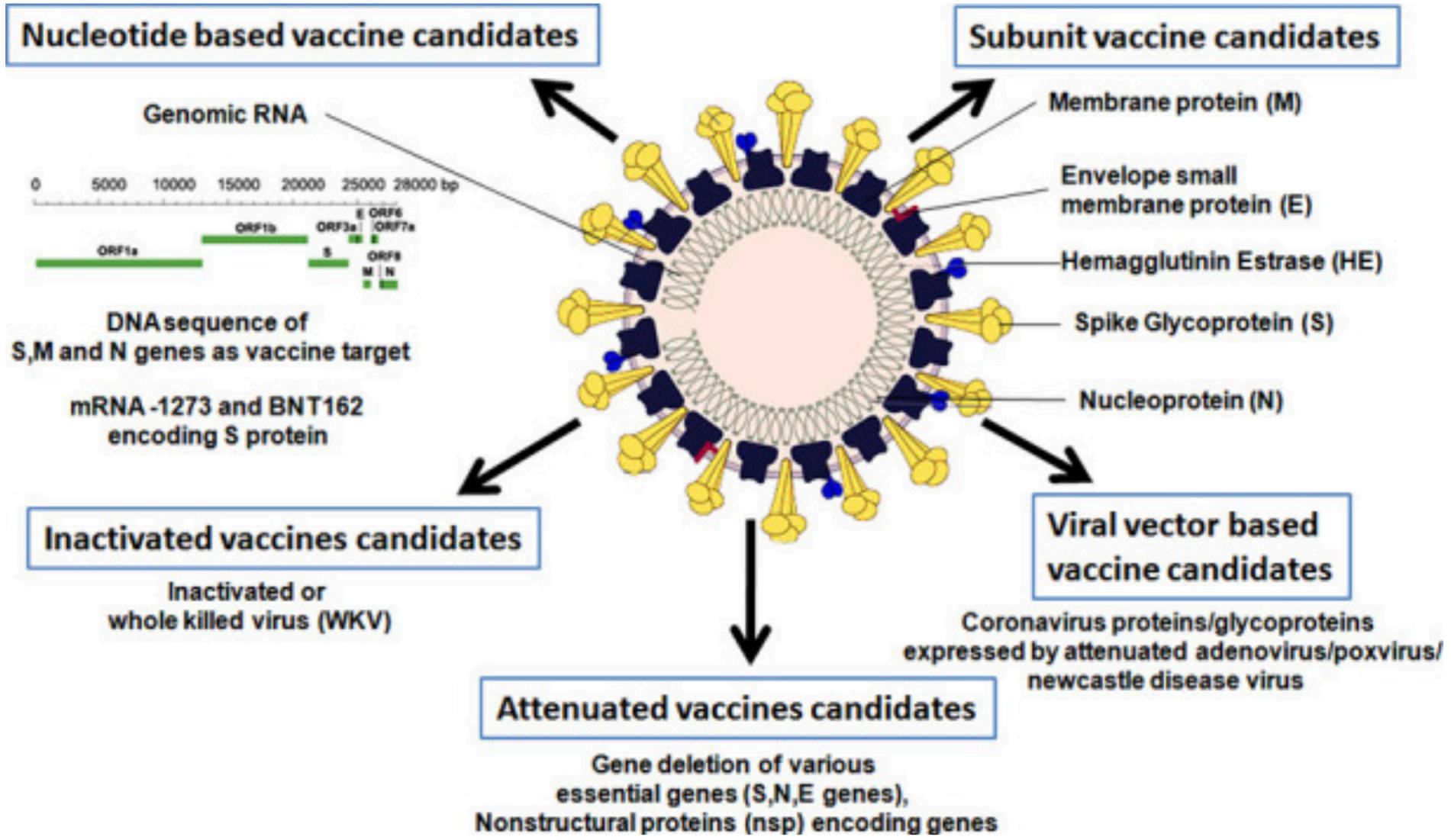

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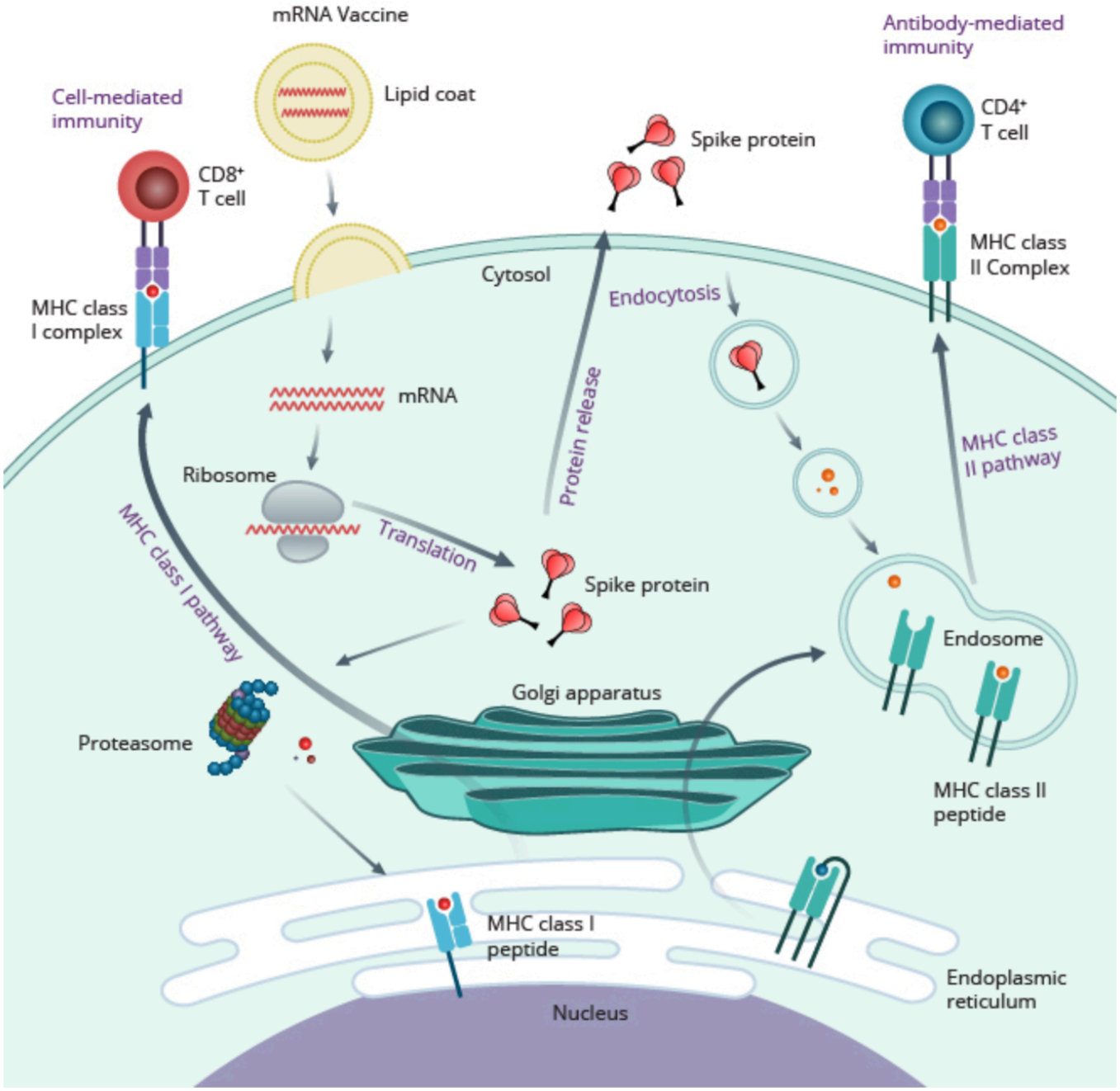
Pandey SC, Pande V, Sati D, Upreti S, Samant M. Vaccination strategies to combat novel corona virus SARS-CoV-2. *Life Sci*. 2020;256:117956. doi:10.1016/j.lfs.2020.117956

mRNA vaccines

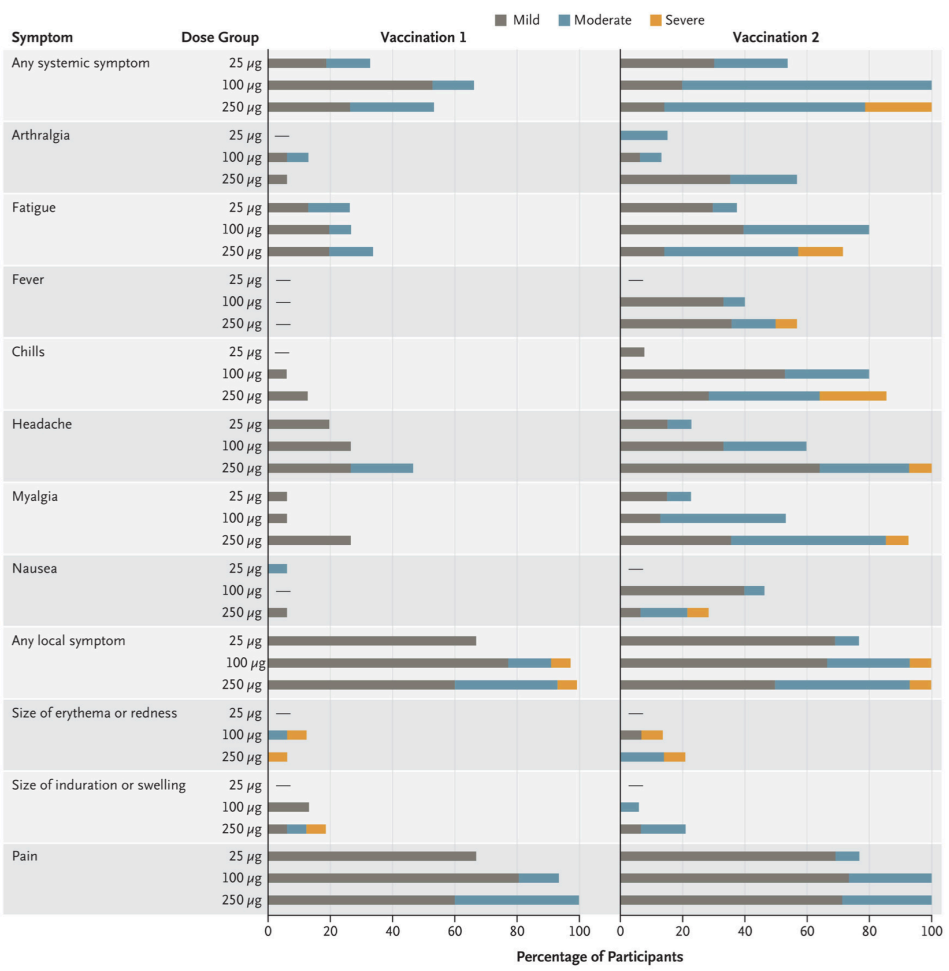
- 2 candidates in late stage trials: Moderna/NIAID mRNA-1273 and BioNTech/Fosun/Pfizer BNT162
- Advantages:
  - Development speed
  - Safety – no integration of into DNA, no viral particles
- Challenges:
  - Unintended immune reactions
  - Stability – need lipid nanoparticle to improve stability and get into cells



https://www.cas.org/blog/covid-mrna-vaccine

Moderna mRNA-1273

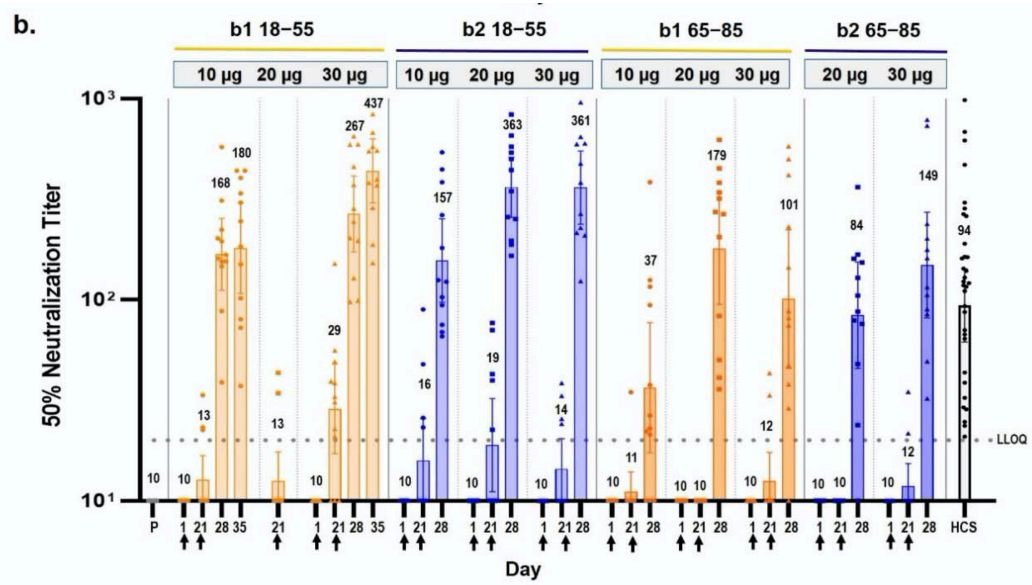
- 45 enrolled participants received their first vaccination between March 16 and April 14, 2020
- No serious adverse events were noted, and no prespecified trial halting rules were met
- Binding antibody IgG geometric mean titers (GMTs) to S-2P increased rapidly after the first vaccination, with seroconversion in all participants by day 15. Dose-dependent responses to the first and second vaccinations were evident
- After the first vaccination, neutralizing responses were detected in less than half the participants, and a dose effect was seen However, after the second vaccination, responses were identified in serum samples from all participants
- Elicited CD4 T-cell responses that on stimulation by S-specific peptide pools were strongly biased toward expression of Th1 cytokines



July 14, 2020
DOI: 10.1056/NEJMoa2022483

BioNTech/Fosun/Pfizer BNT162 b1/b2

- 195 healthy adults 18–55 and 65–85 years of age were randomized in an ongoing, placebo-controlled, observer-blinded dose-escalation study to receive 2 doses at 21-day intervals of placebo or either of 2 lipid nanoparticle–formulated, nucleoside-modified RNA vaccine candidates:
  - BNT162b1, which encodes a secreted trimerized SARS-CoV-2 receptor-binding domain
  - BNT162b2, which encodes a prefusion stabilized membrane-anchored SARS-CoV-2 full-length spike
- 2 vaccine candidates elicited similar dose-dependent SARS-CoV-2–neutralizing geometric mean titers (GMTs), comparable to or higher than the GMT of a panel of SARS-CoV-2 convalescent sera.
- BNT162b2 was associated with less systemic reactogenicity, particularly in older adults and was selected to advance to phase III study



RNA-Based COVID-19 Vaccine BNT162b2 Selected for a Pivotal Efficacy Study
doi: https://doi.org/10.1101/2020.08.17.20176651

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Updates as of 9/13…

- Moderna enrollment is slowing – trying to increase diversity on enrollment
- The fraction of white participants being enrolled in the study has decreased over the last four weeks, from 73% to 68% to 67%, and finally down to 59% for the most recent week. Meanwhile, enrollment of Hispanic or Latino participants jumped from 17% to 22%, and Black or African Americans increased from 5% of enrollment three weeks ago to 11% of enrollment in the most recent week.
- Moderna is trailing **Pfizer** and **BioNTech** which had enrolled 25,189 patients in the phase 2/3 clinical trial testing its coronavirus vaccine, BNT162b2, as of an update on Sep. 7. In terms of diversity though, Moderna is ahead with 27% of participants coming from diverse communities, compared to Pfizer and BioNTech's 24%
- U of Chicago to start enrollment this week; UIC is already enrolling

Adenoviral Vectored Vaccines

- All genetic vaccines mimic a natural viral infection by forcing our bodies to produce viral proteins inside our cells. That spurs the T cells of our immune system to attack these vaccinated cells, and in the process, they learn to seek and destroy cells infected with the real virus in the future.
- Genetic material is added to the adenoviral construct, which is used to make proteins from the SARS-CoV-2 coronavirus called Spike glycoprotein (S). This protein is usually found on the surface of SARS-CoV-2 and plays an essential role in the infection pathway of the SARS-CoV-2 virus.

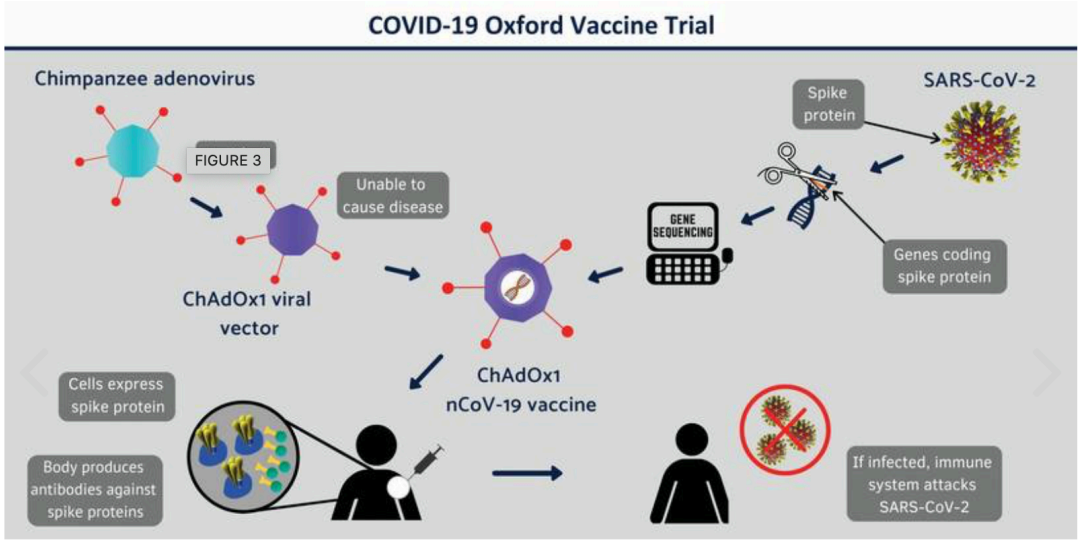
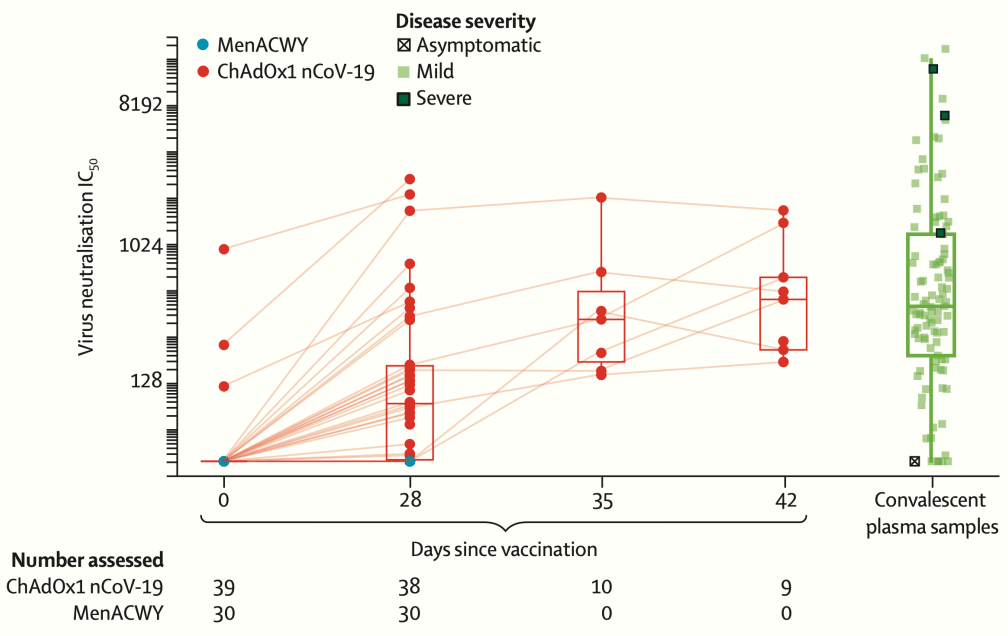


FIGURE 3 Photo: www.ovg.ox.ac.uk

AZD1222 SARS-CoV-2 Vaccine (AstraZeneca/Oxford)

- Formerly known as ChAdOx1 nCoV-19, is made from a virus (ChAdOx1), which is a weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees, that has been genetically changed so that it is impossible for it to grow in humans
- The vaccine was safe and tolerated, with reduced reactogenicity when paracetamol was used prophylactically for the first 24 h after vaccination.
- Reactogenicity was reduced after a second dose
- Humoral responses to SARS-CoV-2 spike protein peaked by day 28 post prime and cellular responses were induced in all participants by day 14.
- Neutralising antibodies were induced in all participants after a second vaccine dose. After two doses, potent cellular and humoral immunogenicity was present in all participants studied.



Lancet 2020; 396: 467–78
July 20, 2020 https://doi.org/10.1016/ S0140-6736(20)31604-4

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Updates as of 9/13…

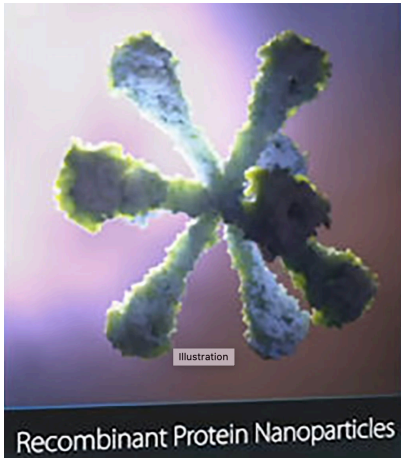
- September 8 – trial suspended due to SAE in one volunteer
- Volunteer in UK developed transverse myelitis
- Enrollment restarted 4 days later in the UK, but not in the US – FDA investigation result is still pending
- Three Chicago hospitals, Northwestern, Rush and Stroger, are among the facilities around the world set to take part in the trial

Johnson & Johnson/Janssen Ad26.COV2.S

- Only published study to date: Preclinical study on primates shows a production of neutralizing antibody to the Spike protein
- Phase I/IIa trials underway – preliminary results are supposedly good, though not published
- Monovalent vaccine composed of a recombinant, replication-incompetent adenovirus type 26 (Ad26) vector, wh encodes SARS-CoV-2 spike (S) protein.
- Adenoviral vectors:
- 1. Well characterized and easily manipulated
- 2. Exhibit broad tropism infecting many dividing and non-dividing cells
- 3. Platform allows for high yield
    - a. Adenovirus E1 region deleted (Ad26)
    - b. Clin/non-clin experience shows **strong humoral and Th1 CMI w acceptable safety**
- Previous Adenovial vectored vaccines: HIV, Ebola, RSV, Zika, malaria vaccines show good safety profile
    - Significant AEs: (>30%) malaise, fatigue, HA, myalgia.
- Planning underway for phase III study to begin later this month – University of Chicago will be a site

Sub-Unit Vaccines: Novavax NVX-CoV2373

- The company has received a $1.6 billion grant from the government's Operation Warp Speed to have 100 million doses ready by early 2021
- Novavax's technology turns moth cells into factories for the Spike protein, which studs the surface of coronaviruses. Its vaccine combines several of the spike proteins in a nanoparticle.
- Working with Takeda on production of vaccine
- Phase II studies ongoing; hope to produce results in 4th quarter



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Fairly Prioritizing Groups for Access to COVID-19 Vaccines

- First, prioritizing in-person health care workers and staff
  - Indirectly prioritizes disadvantaged groups because reducing disease spread facilitates the provision of treatments such as hemodialysis and chemotherapy, which disadvantaged individuals need more often.
- Second, prioritizing people engaged in essential high risk activities, such as in-person education, childcare, and food supply work
  - In-person workers are more likely to be socioeconomically disadvantaged than those able to work remotely. Prioritization among these workers should consider indirect benefit: if vaccination of those involved in education can contribute to reopening schools, this should precede vaccination of those involved in reopening other less beneficial venues, such as bars.
- Prioritizing people older than 65 years without high risk is ethically and legally more complex. Because early death correlates with disadvantage, prioritizing all patients 65 years and older is likely to exacerbate disadvantage. For instance, 30% of all non-White COVID-19 decedents are younger than 65 vs only 13% of White decedents. Although the risk of death fromCOVID-19 increases 7-fold between age 50 and 80, these estimates do not control for health conditions or exposure in residential settings.
- Prioritization should recognize that a healthy older person who can shelter in place is at different risk from a medically vulnerable older person in crowded housing. A preferable approach would reduce disparities by considering vulnerabilities

eTable. Ethical Values and Prioritizing Access to Scarce COVID-19 Vaccines

Ethical values	Potential dimensions	Priority groups
Benefiting people and limiting harm	Saving lives Preventing loss of future life Preventing medical complications Preventing socioeconomic harms	Health workers People in high-risk jobs and housing situations People at medical risk Older people (for some dimensions)
Prioritizing the disadvantaged	Addressing socioeconomic disadvantage and oppression Preventing deaths earlier in life Addressing medical vulnerability	Health workers People in high-risk jobs and housing People at medical risk Individual race-based prioritization[a]
Equal concern	Treating equals equally Identical treatment for all[a]	Any group where harm is prevented or the disadvantaged are prioritized Lottery or weighted lottery[a] (only achieves identical treatment)
Reciprocity[a]	Prioritizing worthy individuals[a]	Health workers People in high-risk jobs Research participants[a]

[a]These values, dimensions, or prioritizations are inappropriate for the allocation of vaccines in public health emergencies such as the COVID-19 pandemic.

Lilly announces proof of concept data for neutralizing antibody LY-CoV555 in the COVID-19 outpatient setting

September 16, 2020

- Primary endpoint of viral load change from baseline at day 11 was met for one of three doses; consistent effects of viral reduction seen at earlier time points

- Rate of hospitalizations and ER visits was 1.7 percent (5/302) for LY-CoV555 versus 6 percent (9/150) for placebo--a 72 percent risk reduction in this limited population

- LY-CoV555 was well-tolerated across all doses with no drug-related serious adverse events reported

Remdesivir Studies

Study	Population	intervention	Outcome
Wang Y et al. The Lancet, April 2020 Double blind, placebo-controlled, multi-center, RCT *stopped early	N=237 hospitalized patients with SARS-CoV2 virus, with CXR changes and O2<94% RA	Remdesivir 10 days vs. placebo, 2:1	• No associated difference in time to clinical improvement
Beigel JH et al. ACTT-1, NEJM May2020 Double blind, placebo-controlled, multi-center, RCT *stopped early	N=1063 hospitalized patients with SARS-CoV2 virus and CXR changes and O2<94% RA	Remdesivir x 10 days vs. placebo	• Recovery time of patients receiving 10d of Rem vs. placebo was shorter (11 vs 15 days) • No mortality difference bw drug (7.1%) and placebo (11.9%)
Goldman JD et al. NEJM, May 2020 Randomized, open-label, phase 3 trial	N=397 hospitalized patients with SARS-CoV2, CXR changes and O2<94% RA	Remdesivir 5 vs. 10 days, 1:1 *10d group sicker at baseline	• Clinical status assessed day 14, assessed by a 7-point ordinal scale found no significant difference 5 v 10d • Mortality lower 5d (8 v 11%)
Spinner, CD et al. JAMA, August 2020 Randomized, open-label,multi-center phase 3 trial	N=584 hospitalized adults with moderate COVID-19 (pulmonary infiltrates **and RA O2%>94**	10 days remdesivir vs. 5 days remdesivir vs. standard of care, 1:1:1 *Mean length of treatment 5d v 6 d (10-d arm)	• 5-day Rem group had statistically significantly higher odds of better clinical status (p=.02) vs. SOC on D11. • No difference between 10-d and SOC groups (p=.18) *difference of unclear clinical importance

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EDITORIAL

Efficacy of Remdesivir in COVID-19

Erin K. McCreary, PharmD; Derek C. Angus, MD, MPH

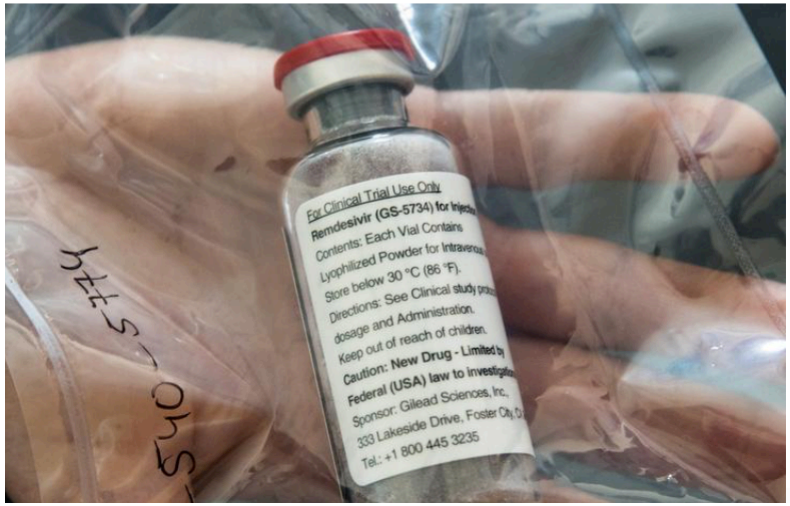
- Optimal patient population is not clear
- Optimal duration of therapy is not clear
- Outcomes vs. placebo or a standard of therapy are not clear
- The effect of remdesivir if given with dexamethasome or other steroids are not clear

HEALTHCARE & PHARMACEUTICALS SEPTEMBER 11, 2020 / 2:55 PM / UPDATED 5 DAYS AGO

Exclusive: U.S. hospitals turn down remdesivir, limit use to sickest COVID-19 patients

By Deena Beasley 4 MIN READ

(Reuters) - U.S. hospitals have turned down about a third of their allocated supplies of the COVID-19 drug remdesivir since July as need for the costly antiviral wanes, the Department of Health and Human Services (HHS) confirmed on Friday.



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Metabolic Syndrome and COVID-19 Mortality Among Adult Black Patients in New Orleans

https://doi.org/10.2337/dc20-1714

John Xie,[1] Yuanhao Zu,[2] Ala Alkhatib,[1] Thaidan T. Pham,[3] Frances Gill,[3] Albert Jang,[4] Stella Radosta,[4] Gerard Chaaya,[5] Leann Myers,[2] Jerry S. Zifodya,[1] Christine M. Bojanowski,[1] Nassir F. Marrouche,[6] Franck Mauvais-Jarvis,[7,8] and Joshua L. Denson[1]

- Patients divided into two groups
  - Metabolic syndrome (MetS) and non-Mets per WHO criteria
- Criteria for MetS (3 of 5)
- Primary outcome – hospital mortality
- Secondary outcomes – ICU, IMV, ARDS, LOW, hospital readmission
- 66% had metabolic syndrome, predominantly non-Hispanic black patients
- **MetS associated with increased odds of hospital mortality, ICU requirement, IMV and ARDS**

Criteria for MetS (3/5)

- Prediabetes or documented h/o diabetes
- Obesity BMI>30 kg/m^2
- History of hypertension or antihypertensive medication
- TG>150 mg/kL
- HDL<50mg/kL for women and <40 mg/kL for men OR use of cholesterol-lowering medication with history for hypercholesterolemia

Table 2—MetS characteristics

Characteristics	MetS (n = 188)	Non-MetS (n = 99)	P value
Age, mean ± SD, years	61.6 ± 13.9	61.2 ± 17.4	0.8181
Female, n (%)	111 (59.0)	52 (52.5)	0.2894
Race, n (%)			0.0009
Non-Hispanic black	171 (90.9)	74 (74.8)	
Non-Hispanic white	11 (5.9)	14 (14.1)	
Other[a]	6 (3.2)	11 (11.1)	
BMI[b], mean ± SD, kg/m^2	35.4 ± 8.5	30.8 ± 7.8	<0.0001
Charlson Index Score, mean ± SD	3.9 ± 2.3	2.8 ± 2.3	0.0002
MetS comorbidities, n (%)			
Prediabetes/diabetes[c]	169 (89.9)	31 (31.3)	<0.0001
Obesity[d]	136 (72.3)	51 (54.5)	0.0004
Hypertension[e]	176 (93.6)	54 (54.5)	<0.0001
TG >150 mg/dL	40/136 (29.4)	1/24 (4.1)	0.0090
Low HDL[f]	139 (73.9)	8 (8.1)	<0.0001
Laboratory values, mean ± SD (n measured)			
Ferritin, ng/mL	922 ± 1,503 (180)	771 ± 886 (95)	0.2958
CRP, mg/L	126 ± 88 (176)	96 ± 87 (94)	0.0079
LDH, units/L	403 ± 162 (177)	357 ± 173 (96)	0.0306

TG levels were available for a limited number of patients, and some were excluded if propofol had been administered prior. [a]Includes Hispanic, Asian, and unknown. [b]BMI is weight in kilograms divided by the square of height in meters. [c]Prediabetes defined by World Health Organization criteria: hemoglobin A_{1c} ≥5.7%. [d]BMI >30 kg/m^2. [e]Defined as history of hypertension or antihypertensive medication. [f]HDL <50 mg/dL for women and <40 mg/dL for men or those on a statin with documented history of hyperlipidemia.

Table 3—Multivariable analyses, MetS vs. non-MetS

Outcomes	MetS (n = 188)	Non-MetS (n = 99)	Risk difference, % (95% CI)	Adjusted OR[a] (95% CI)	P value
Hospital mortality, n (%)	48 (25.5)	10 (10.1)	15.4 (6.8–24.0)	3.42 (1.52–7.69)	0.0030
ICU requirement, n (%)	106 (56.4)	24 (24.2)	32.1 (21.1, 43.2)	4.59 (2.53–8.32)	<0.0001
ARDS[b], n (%)	69 (36.7)	11 (11.1)	25.6 (16.3–34.9)	4.70 (2.25–9.82)	<0.0001
IMV, n (%)	90 (47.9)	18 (18.2)	29.7 (19.3–40.1)	4.71 (2.50–8.87)	<0.0001
LOS, mean ± SD, days	14.1 ± 10.6	10.7 ± 10.1	n/a	n/a	0.0097
LOS, median (IQR), days	11 (7.0–20.5)	7 (4.0–14.0)	n/a	n/a	0.0062
Hospital readmission, n (%)	16/140 (11.4)	6/89 (6.7)	4.7 (−1.7 to 12.1)	1.19 (0.40–3.61)	0.7533

Hospital readmission data were available only for case subjects who survived to discharge. n/a, not available. [a]Multivariable logistic regression model adjusted for age, sex, race, hospital site, and Charlson Comorbidity Index. [b]ARDS defined according to Berlin criteria.

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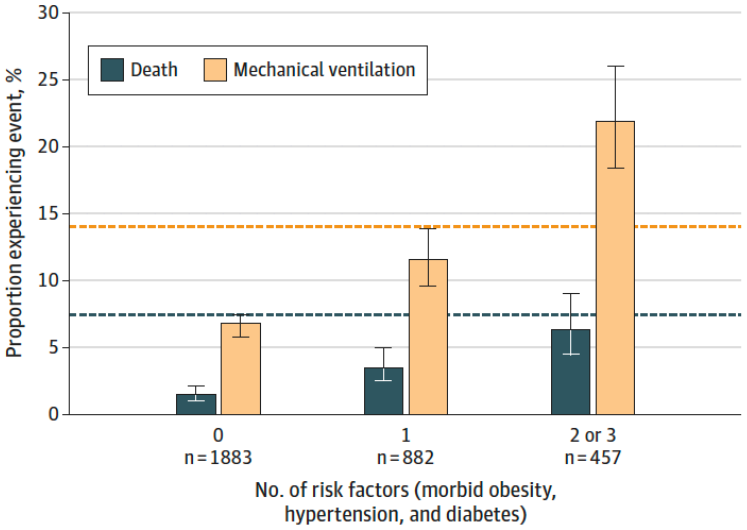
Table. Baseline Characteristics of Young Adults Age 18 to 34 Years With COVID-19[a]

Characteristic	No. (%) Full case series (N = 3222)	No death or ventilation (n = 2879)	Death or ventilation (n = 343)	*P* value
Age, mean (SD), y	28.3 (4.4)	28.3 (4.4)	28.3 (4.5)	.90
Men	1849 (57.6)	1626 (56.7)	223 (65.0)	.003
Race/ethnicity				
White non-Hispanic	536 (16.6)	479 (16.6)	57 (16.6)	
White Hispanic	350 (10.9)	324 (11.3)	26 (7.6)	
Black non-Hispanic	748 (23.2)	675 (23.4)	73 (21.3)	.14
Black Hispanic	14 (0.4)	13 (0.5)	1 (0.3)	
Other/unknown	1574 (48.9)	1388 (48.2)	186 (54.2)	
Black and/or Hispanic	1838 (57.0)	1669 (58.0)	169 (49.3)	.002
Discharge month				
April 2020	1680 (52.1)	1495 (51.9)	185 (53.9)	
May 2020	1063 (33.0)	936 (32.5)	127 (37.0)	.004
June 2020	479 (14.9)	448 (15.6)	31 (9.0)	
Region				
Northeast	1298 (40.3)	1161 (40.4)	137 (39.9)	
South	1130 (35.1)	1032 (35.9)	98 (28.6)	.002
Midwest	558 (17.3)	488 (17.0)	70 (20.4)	
West	233 (7.2)	195 (6.8)	38 (11.1)	
Any obesity, BMI ≥ 30	1187 (36.8)	1007 (35.0)	180 (52.5)	<.001
Morbid obesity, BMI ≥ 40	789 (24.5)	649 (22.5)	140 (40.8)	<.001
Asthma	545 (16.9)	495 (17.2)	50 (14.6)	.22
Hypertension	519 (16.1)	412 (14.3)	107 (31.2)	<.001
Smoking	513 (15.9)	472 (16.4)	41 (12.0)	.03
Diabetes	588 (18.2)	494 (17.2)	94 (27.4)	<.001

[a] Race/ethnicity groups include only patients whose race and ethnicity were reported. Patients with missing data for 1 or both were considered other/unknown.

Figure. Death and Mechanical Ventilation in Young Adults With and Without Morbid Obesity, Hypertension, and Diabetes



Morbid obesity, diabetes, and hypertension were determined by *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)* codes during coronavirus disease 2019 (COVID-19) admission. Proportions of patients experiencing death and mechanical ventilation were compared with a reference group of 8862 middle-aged (age 35-64 years) nonpregnant patients with COVID-19 with none of these conditions in the Premier database (dotted lines). Error bars refer to 95% CIs.

Cunningham J et al. Clinical Outcomes in Young Adults Hospitalized with COVID-19. JAMA Internal Medicine, Sept 2020.

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Morbidity and Mortality Weekly Report

Community and Close Contact Exposures Associated with COVID-19 Among Symptomatic Adults ≥18 Years in 11 Outpatient Health Care Facilities — United States, July 2020

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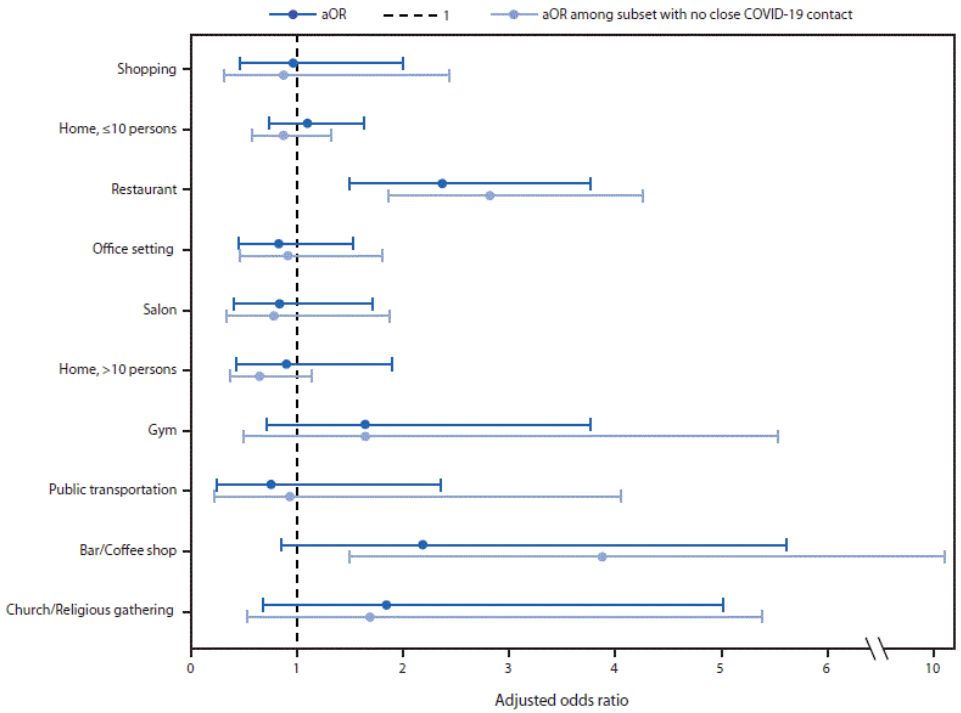
- Outpatient adults getting testing in July 2020
- Random sample of SARS-CoV2 positive case participants, each matched with 2 negative controls
- Compared with case-patients, control patients were more likely to be non-Hispanic white (<0.01), have a college degree or higher (p<0.01) and report at least one underlying chronic medical condition
- COVID-19 positive contacts reported by 42% of cases and 14% of controls
  - Half of contacts were family members
- Restaurants, gyms, coffee shops, bars and religious gatherings of highest risk if NO KNOWN contact

FIGURE. Adjusted odds ratio (aOR)* and 95% confidence intervals for community exposures† associated with confirmed COVID-19 among symptomatic adults aged ≥18 years (N = 314) — United States, July 1–29, 2020



Abbreviation: COVID-19 = coronavirus disease 2019.

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thebmj Visual summary

"Long covid" in primary care

Assessment and initial management of patients with continuing symptoms

Post-acute covid-19 appears to be a multi-system disease, sometimes occurring after a relatively mild acute illness. Clinical management requires a whole-patient perspective. This graphic summarises the assessment and initial management of patients with delayed recovery from an episode of covid-19 that was managed in the community or in a standard hospital ward.

An uncertain picture

The long term course of covid-19 is unknown. This graphic presesents an approach based on evidence available at the time of publication. However, caution is advised, as patients may present atypically, and new treatments are likely to emerge

Clinical assessment

Full history
From date of first symptom

Current symptoms
Nature and severity

Examination, for example:

Temperature | Heart rate and rhythm | Blood pressure | Respiratory examination | Functional status | Pulse oximetry | Clinical testing

If indicated

Investigations

Clinical testing is not always needed, but can help to pinpoint causes of contiuing symptoms, and to exclude conditions like pulmonary embolism or myocarditis. Examples are provided below:

Blood tests

Full blood count | Electrolytes | Liver and renal function | Troponin | C reactive protein | Creatine kinase | D-dimer | Brain natriuretic peptides | Ferritin – to assess inflammatory and prothrombotic states

Other investigations

Chest x ray | Urine tests | 12 lead electrocardiogram

Managing comorbidities

Many patients have comorbidities including diabetes, hypertension, kidney disease or ischaemic heart disease. These need to be managed in conjuntion with covid-19 treatment. Refer to condition specific guidance, available in the associated article by Greenhalgh and colleagues

Assess comorbidities

Social and financial circumstances

Social, financial, and cultural support

Prolonged covid-19 may limit the ability to engage in work and family activities. Patients may have experienced family bereavements as well as job losses and consequent financial stress and food poverty. See the associated article by Greenhalgh and colleagues for a list of external resources to help with these problems

Safety netting and referral

The patient should seek medical advice if concerned, for example:

Worsening breathlessness | PaO_2 < 96% | Unexplained chest pain | New confusion | Focal weakness

Specialist referral may be indicated, based on clinical findings, for example:

- **Respiratory** if suspected pulmonary embolism, severe pneumonia
- **Cardiology** if suspected

Medical management

Symptomatic, such as treating fever with paracetamol

Optimise control of long term conditions

Listening and empathy

Self management

Daily pulse oximetry

Attention to general health

Rest and relaxation

Diet | Sleep | Quitting smoking | Limiting alcohol | Limiting caffeine

Mental health

In the consultation:

Continuity of care

Avoid inappropriate medicalisation

Longer appointments for patients with complex needs

PRACTICE POINTER

Management of post-acute covid-19 in primary care

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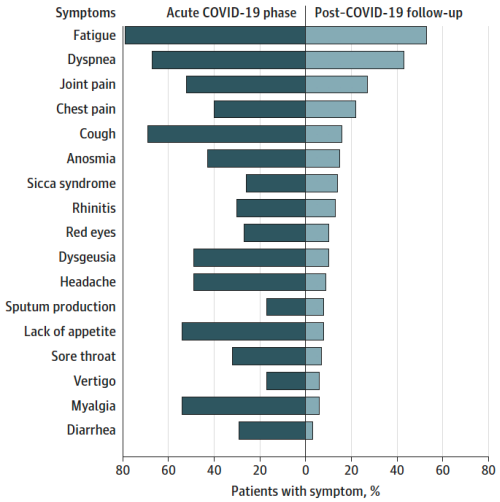
10-80% of people with the SARS-CoV2 virus experience symptoms >3 weeks after acute infections

Figure. COVID-19–Related Symptoms



The figure shows percentages of patients presenting with specific coronavirus disease 2019 (COVID-19)–related symptoms during the acute phase of the disease (left) and at the time of the follow-up visit (right).

Carfi A JAMA. Published online July 9, 2020. doi:10.1001/jama.2020.12603