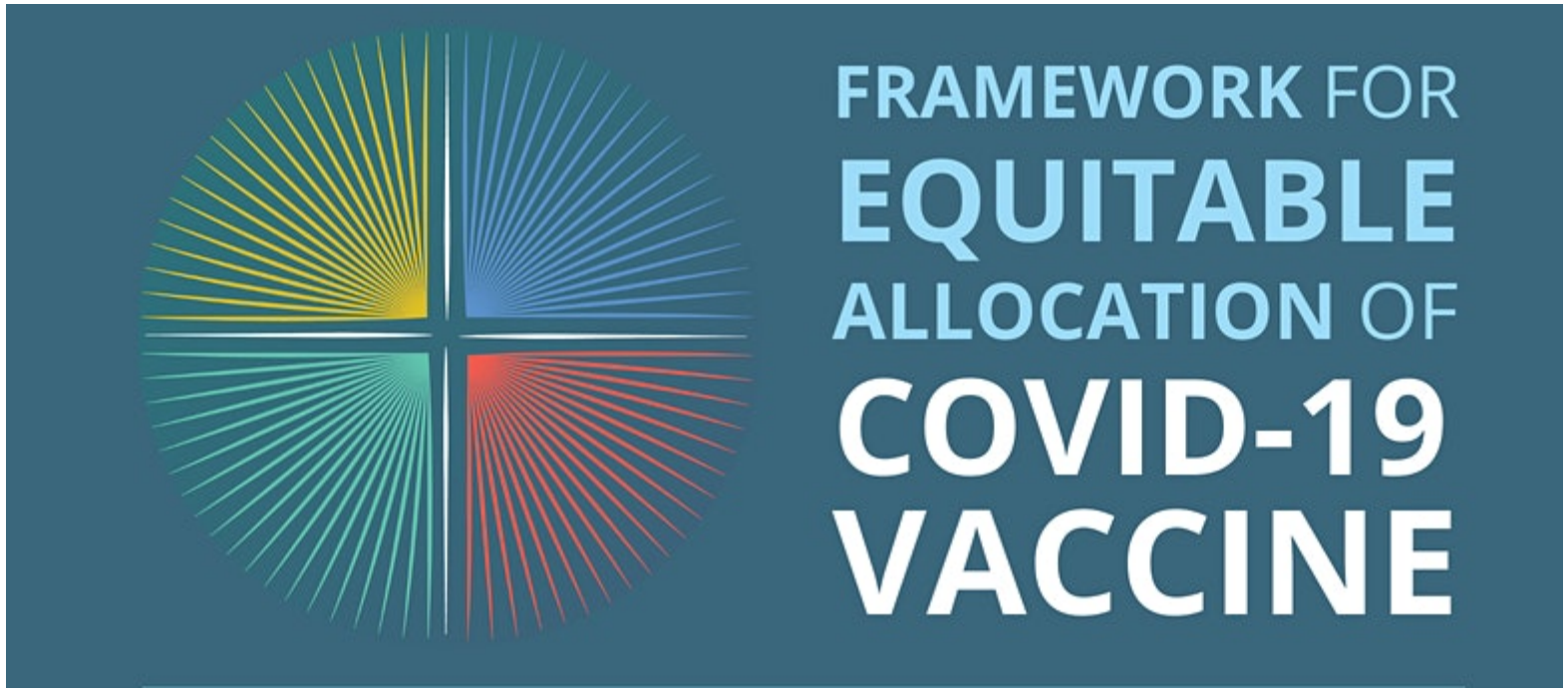
New/updated guidance of note



Report from National Academies of Sciences, Engineering, and Medicine

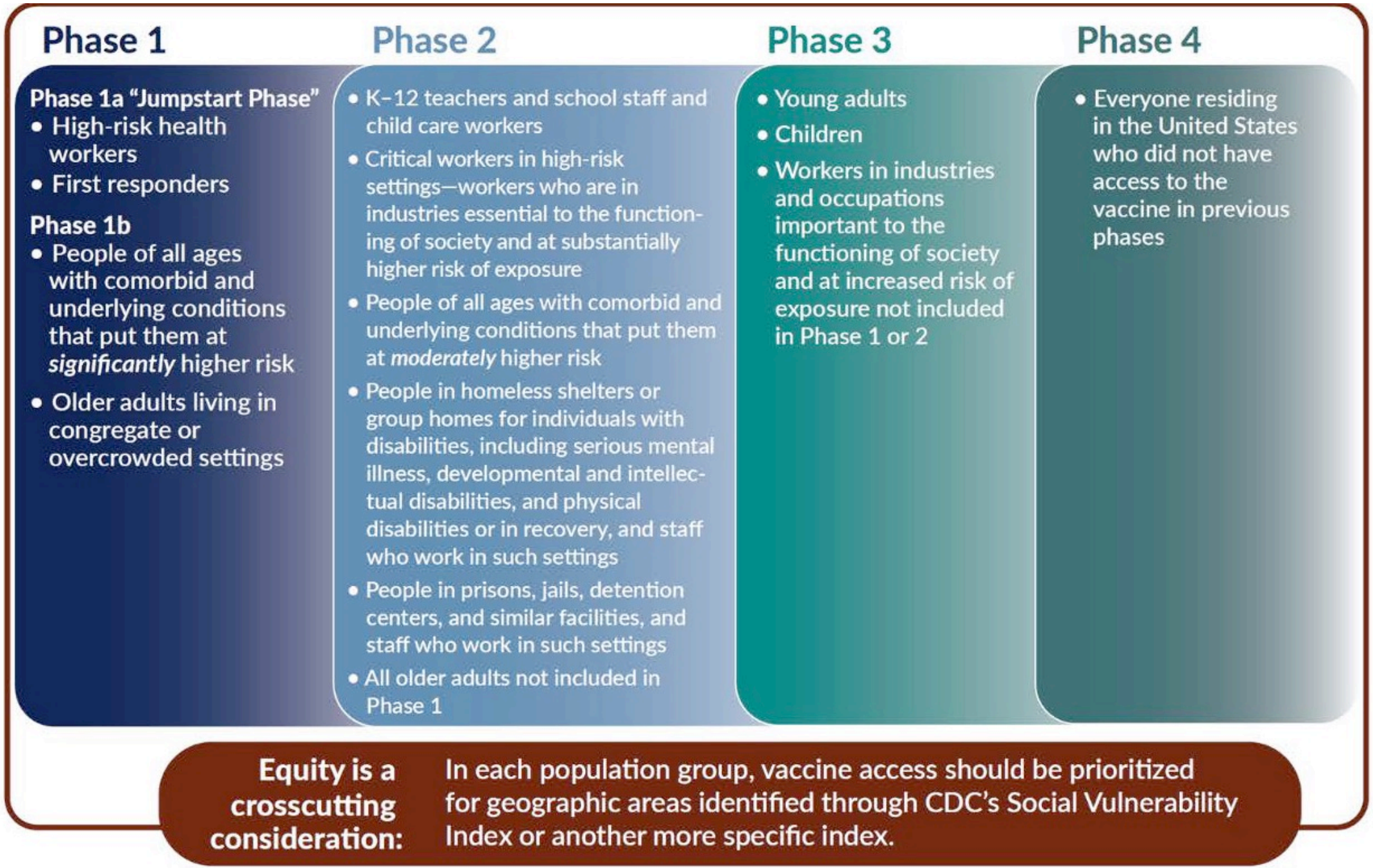
released Oct 2nd

- Requested by CDC and NIH

Allocation Criteria
Risk of: 1) acquiring infection; 2) severe morbidity and mortality; 3) negative societal impact; and 4) transmitting infection to others

- Allocation criteria based on 4 types of risk
- 4 phases of allocation
- 7 recommendations

Race itself not was considered as a risk factor, as the high burden of COVID-19 among some racial and ethnic groups is due to racism and social inequalities, not biological race.


Phase 1
Phase 1a "Jumpstart Phase"
• High-risk health workers
• First responders
Phase 1b
• People of all ages with comorbid and underlying conditions that put them at *significantly* higher risk
• Older adults living in congregate or overcrowded settings
Phase 2
• K–12 teachers and school staff and child care workers
• Critical workers in high-risk settings—workers who are in industries essential to the functioning of society and at substantially higher 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 disabilities, including serious mental illness, developmental and intellectual disabilities, and physical disabilities or in recovery, and staff who work in such settings
• People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings
• All older adults not included in Phase 1
Phase 3
• Young adults
• Children
• Workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Phase 1 or 2
Phase 4
• Everyone residing in the United States who did not have access to the vaccine in previous phases
Equity is a crosscutting consideration:
In each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index or another more specific index.

COVID-19 Rapid Point-Of-Care Test Distribution

The U.S. Department of Health and Human Services (HHS), in partnership with the Department of Defense (DOD), is providing rapid point-of-care tests to communities across the US in an effort to trace, contain, and combat the spread of COVID-19.

HHS is distributing 150 million rapid, Abbott BinaxNOW™ COVID-19 tests to expand strategic, evidence-based testing in the United States. → **300,000 to IHS**

- Lateral flow assay that detects SARS-CoV-2 protein antigens
- EUA for use in CLIA-certified labs and as a point-of-care test in patient care settings with CLIA certificate
- Nasal swab comes with test kit
  - Test <1 hour of collection
  - 15 minute read time
- Designed for use within 7 days of symptom onset
  - 34/35 (97%) positive agreement with RT-PCR **within** 7 days of onset
  - 9/12 (75%) positive agreement with RT-PCR **after** 7 days of onset

Updated Evidence to Support the Emergency Use of COVID-19 Convalescent Plasma – as of 9/23/2020

Four lines of evidence support the emergency use of COVID-19 Convalescent Plasma:

1) historical data on the use of convalescent plasma in other outbreak settings
2) data from animal studies
3) data in the published literature from clinical studies performed during the current outbreak
4) results obtained from the National Expanded Access Program
    - Over 100,000 patients enrolled across the US
    - No specific safety concerns identified
    - In patients who were not intubated, higher antibody levels were associated with fewer deaths (dose response)
    - No control group of untreated patients

FDA strongly encourages the continuation of randomized controlled trials to more definitively evaluate the potential benefits of this therapy

nature medicine

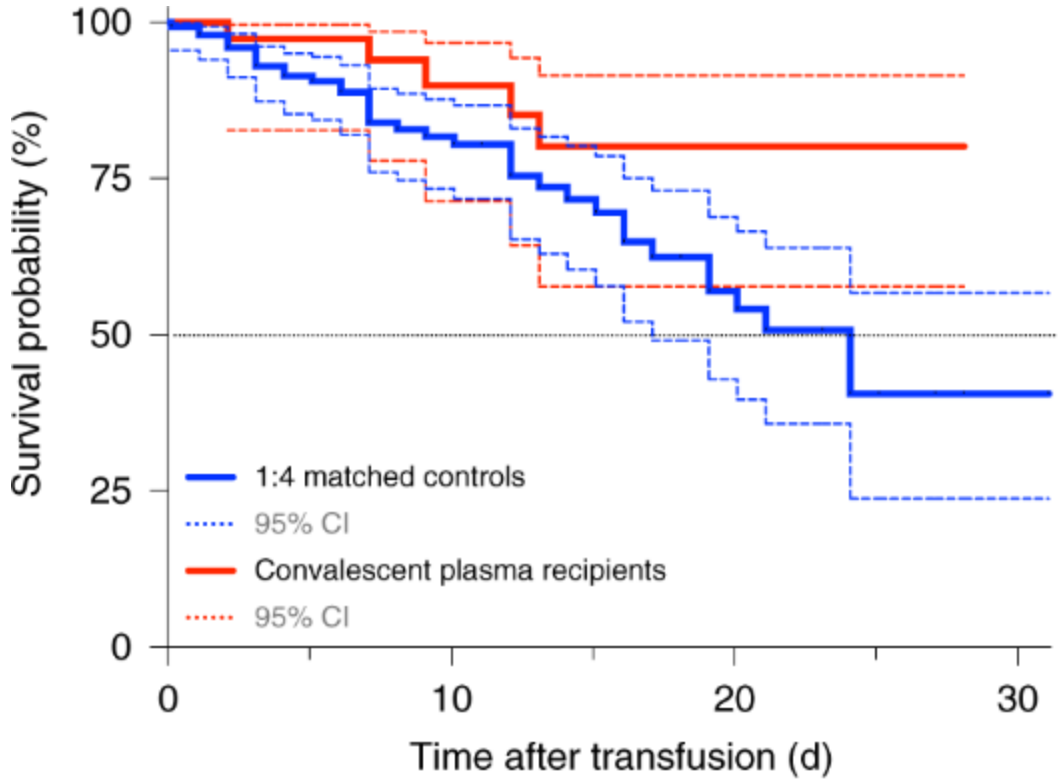
LETTERS

https://doi.org/10.1038/s41591-020-1088-9

Check for updates

Convalescent plasma treatment of severe COVID-19: a propensity score–matched control study

- Case-control study in hospitalized patients with severe or life-threatening COVID-19 at Mount Sinai Hospital in NYC
- 39 patients who received convalescent plasma therapy vs. 156 controls
- Improved survival in patients who received convalescent plasma



Updates from CDC

Guidance for fall holiday celebrations

How COVID spreads

MMWR:

- Changing age distribution of the COVID-19 pandemic
- COVID-19 trends in children
- COVID-19 in pregnancy
- COVID-19 in health care personnel
- Multisystem inflammatory syndrome in adults

YOUR HEALTH

Holiday Celebrations

Updated Sept. 21, 2020 Languages Print

Halloween

Día de los Muertos

Thanksgiving

Frequently Asked Questions

COVID-19 can sometimes be spread by airborne transmission

- Some infections can be spread by exposure to virus in small droplets and particles that can linger in the air for minutes to hours. These viruses may be able to infect people who are further than 6 feet away from the person who is infected or after that person has left the space.
- This kind of spread is referred to as **airborne transmission** and is an important way that infections like tuberculosis, measles, and chicken pox are spread.
- There is evidence that under certain conditions, people with COVID-19 seem to have infected others who were more than 6 feet away. These transmissions occurred within enclosed spaces that had inadequate ventilation. Sometimes the infected person was breathing heavily, for example while singing or exercising.
    - Under these circumstances, scientists believe that the amount of infectious smaller droplet and particles produced by the people with COVID-19 became concentrated enough to spread the virus to other people. The people who were infected were in the same space during the same time or shortly after the person with COVID-19 had left.
- Available data indicate that it is much more common for the virus that causes COVID-19 to spread through close contact with a person who has COVID-19 than through airborne

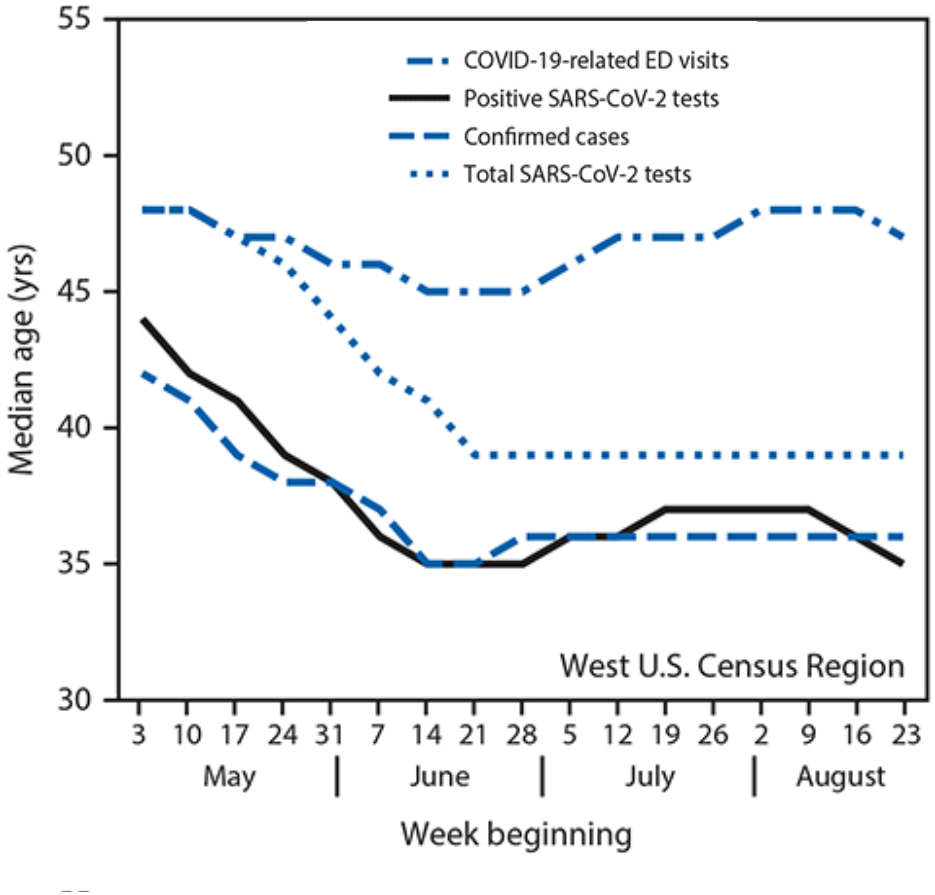
Morbidity and Mortality Weekly Report (*MMWR*)

CDC

Changing Age Distribution of the COVID-19 Pandemic — United States, May–August 2020

Weekly / October 2, 2020 / 69(39);1404–1409

- During Jun–Aug, COVID-19 incidence was highest in persons aged 20–29 years
- Younger adults likely contribute to community transmission of COVID-19
- Occupational and behavioral factors might put younger adults at higher risk for exposure to SARS-CoV-2



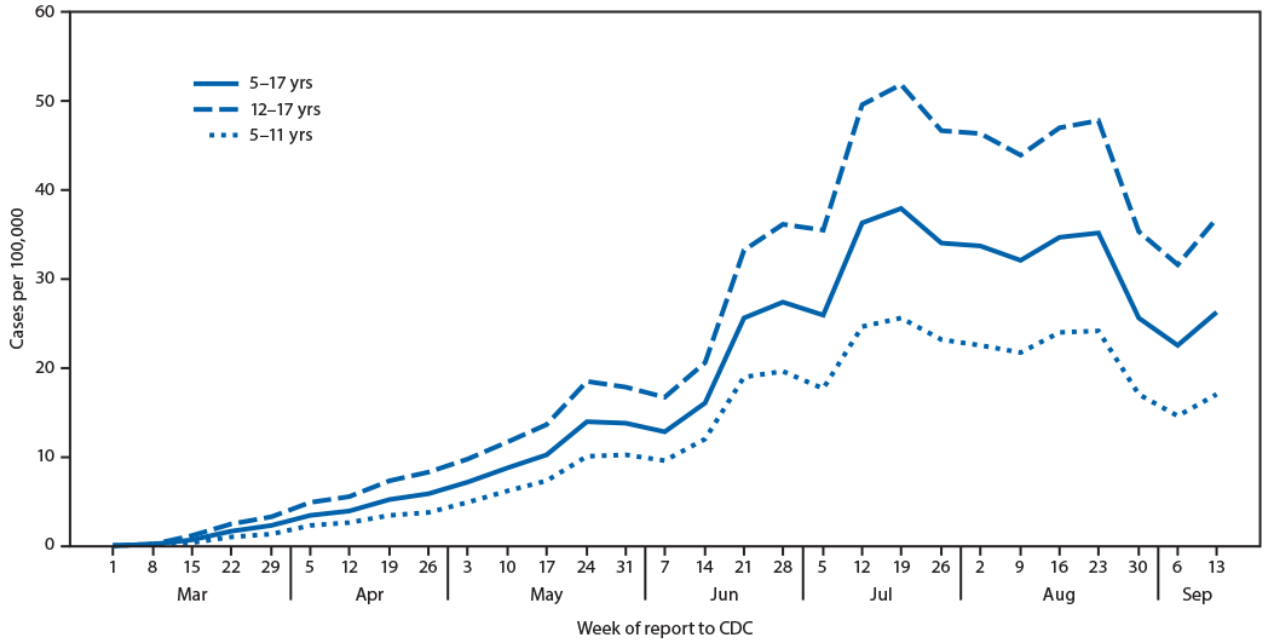
Morbidity and Mortality Weekly Report (*MMWR*)

CDC

COVID-19 Trends Among School-Aged Children — United States, March 1–September 19, 2020

Weekly / October 2, 2020 / 69(39);1410–1415

- Higher incidence in children aged 12–17 years vs. 5–11 years
- Lots of missing data but
  - 1.9% of cases in AI/AN
  - 2.8% had an underlying condition
  - 1.2% hospitalized
  - <0.1% died



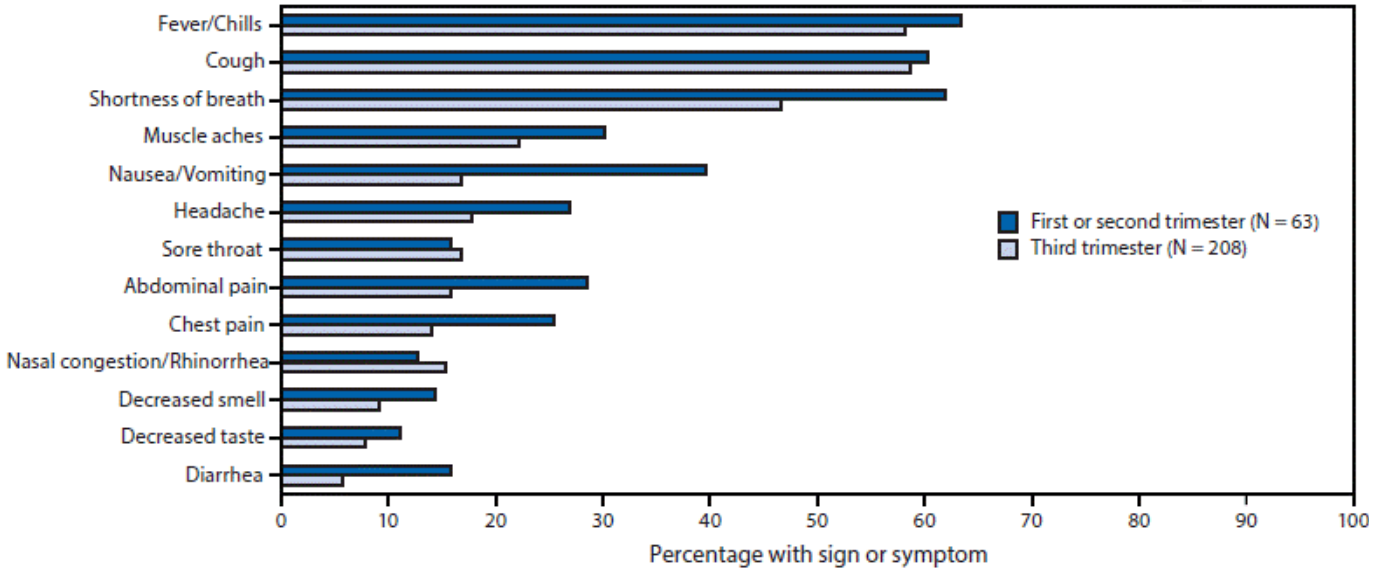
Morbidity and Mortality Weekly Report (*MMWR*)

CDC

Characteristics and Maternal and Birth Outcomes of Hospitalized Pregnant Women with Laboratory-Confirmed COVID-19 — COVID-NET, 13 States, March 1–August 22, 2020

Weekly / September 25, 2020 / 69(38);1347–1354

- ~1 in 4 hospitalized women aged 15–49 y with COVID-19 was pregnant
- 55% were asymptomatic at admission
- Among symptomatic women (n=272)
  - 16% admitted to ICU
  - 8% required mechanical ventilation
  - 1% died
- Preterm delivery: 23.1% of symptomatic women vs 8.0% of asymptomatic women
- Findings highlight importance of preventing and identifying COVID-19 in pregnant women



Morbidity and Mortality Weekly Report (*MMWR*)

CDC

Update: Characteristics of Health Care Personnel with COVID-19 — United States, February 12–July 16, 2020

Weekly / September 25, 2020 / 69(38);1364–1368

- 100,481 cases in HCP
  - median age 41 years
  - 79% female
  - 47% in non-Hispanic Whites
  - 26% were in Blacks
  - 12% were in Hispanics or Latinos
  - 9% were in Asians
- 8% hospitalized; 5% ICU
- 1% died
  - Compared with those who survived, decedents tended to be older (median age = 62 vs 40 years), male (38% vs 22%), Asian (20% vs 9%), or Black (32% vs 25%)

Job setting (6,955)	
Nursing and residential care facility	4,649 (66.8)
Hospital	1,231 (17.7)
Ambulatory health care service	804 (11.6)
Other	271 (3.9)
Occupation type (5,913)[§]	
Health care support worker[¶]	1,895 (32.1)
Nurse**	1,742 (29.5)
Administrative staff member	581 (9.8)
Environmental services worker	330 (5.6)
Physician	190 (3.2)

Case definition

1) severe illness requiring hospitalization in a person ≥21 y
2) positive test for SARS-CoV-2 (nucleic acid, antigen, or antibody) during admission or in the previous 12 wks
3) severe dysfunction of ≥1 extrapulmonary organ systems (e.g., hypotension or shock, cardiac dysfunction, thrombosis or thromboembolism, or acute liver injury)
4) laboratory evidence of severe inflammation (e.g., elevated CRP, ferritin, D-dimer, or IL-6)
5) absence of severe respiratory illness (to exclude patients in with inflammation and organ dysfunction due to tissue hypoxia)

- 27 MIS-A cases identified
  - 24 survived
  - 7 PCR-negative at the time of admission but antibody positive
  - most patients belonged to racial or ethnic minority groups
  - Treatment included i.v. immunoglobulin, corticosteroids, IL-6 inhibitor, therapeutic anticoagulation
- clinicians should consider MIS-A when caring for adult patients with clinical and laboratory findings consistent with the working MIS-A case definition

Research update

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults

- Phase 1, dose-escalation trial of an mRNA vaccine that encodes SARS-CoV-2 spike protein S-2P
- 40 participants, 2 age groups, two vaccine doses 28 days apart

Age of 56–70 Years		Age of ≥71 Years		All Participants (N=40)
25-μg Dose (N=10)	100-μg Dose (N=10)	25-μg Dose (N=10)	100-μg Dose (N=10)	

- Assessed safety, antibody binding, antibody neutralization, and T-cell responses

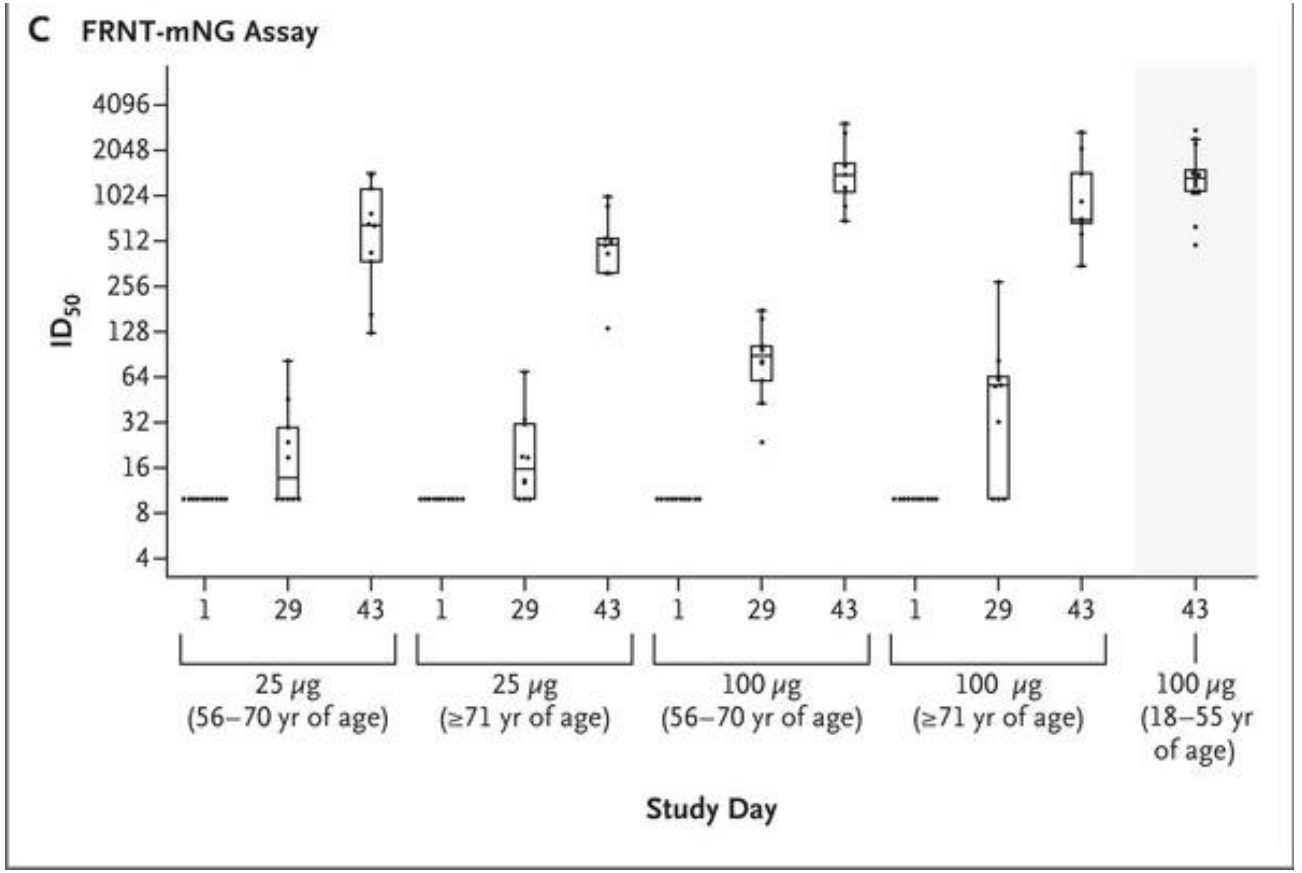
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults

- No serious adverse events (AEs), common AEs were mild to moderate (headache, fatigue, myalgia, chills, and injection site pain)
- Binding-antibody responses increased rapidly after 1st dose
- Serum neutralizing activity detected in all participants after 2nd dose
- Strong CD4 cytokine response involving Th1 cells

Neutralizing assay



The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Saliva or Nasopharyngeal Swab Specimens for Detection of SARS-CoV-2

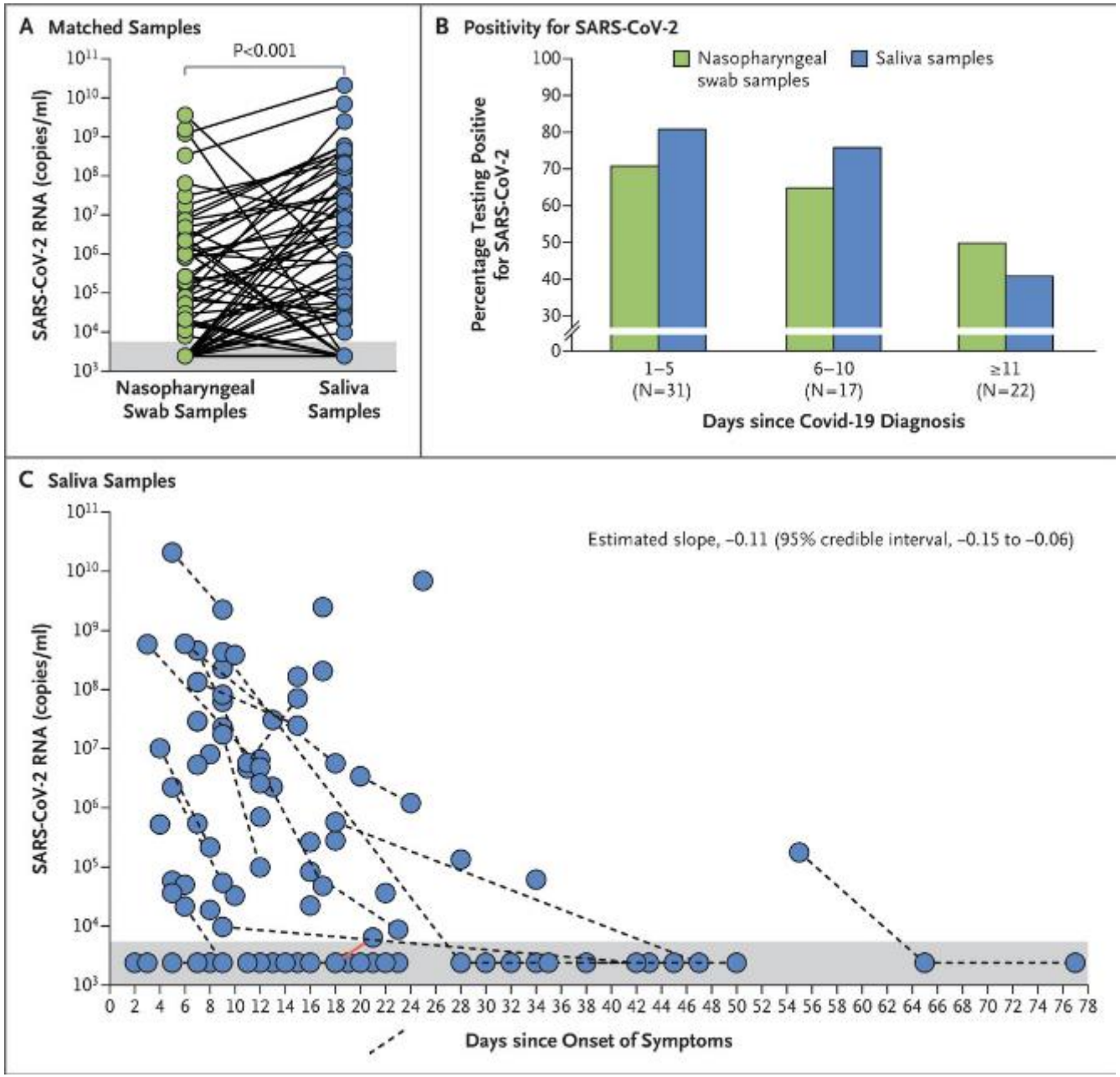
- Compared RT-qPCR detection of SARS-CoV-2 from 70 hospitalized patients with COVID-19 in saliva vs nasopharyngeal swab specimens

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Saliva or Nasopharyngeal Swab Specimens for Detection of SARS-CoV-2

- Saliva tended to have a higher viral load than NP swabs
- Saliva samples were positive for longer than NP swabs
- Findings support the use of saliva samples for diagnosis of COVID-19



References

Guidance documents

https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus (National Academies report on equitable vaccine allocation)

https://www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html (HHS announcement of Abbot BinaxNOW)

https://www.fda.gov/media/142386/download (FDA updated evidence supporting use of convalescent plasma)

https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/holidays.html (CDC guidance for fall holidays)

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html (updated CDC guidance on transmission including airborne transmission)

MMWR

Boehmer TK, et al. Changing Age Distribution of the COVID-19 Pandemic — United States, May–August 2020. MMWR Morb Mortal Wkly Rep 2020;69:1404–1409. DOI: http://dx.doi.org/10.15585/mmwr.mm6939e1

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Anderson EJ et al, Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. N Engl J Med. 2020 Sep 29. doi: 10.1056/NEJMoa2028436

Wyllie AL, et al. Saliva or Nasopharyngeal Swab Specimens for Detection of SARS-CoV-2. N Engl J Med. 2020 Sep 24;383(13):1283-1286. doi: 10.1056/NEJMc2016359

Thank you!

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