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GW Infectious Disease Updates

GW Covid-19 Collection

11-18-2021

Covid-19 Clinical Update 11/18/2024

George Washington University

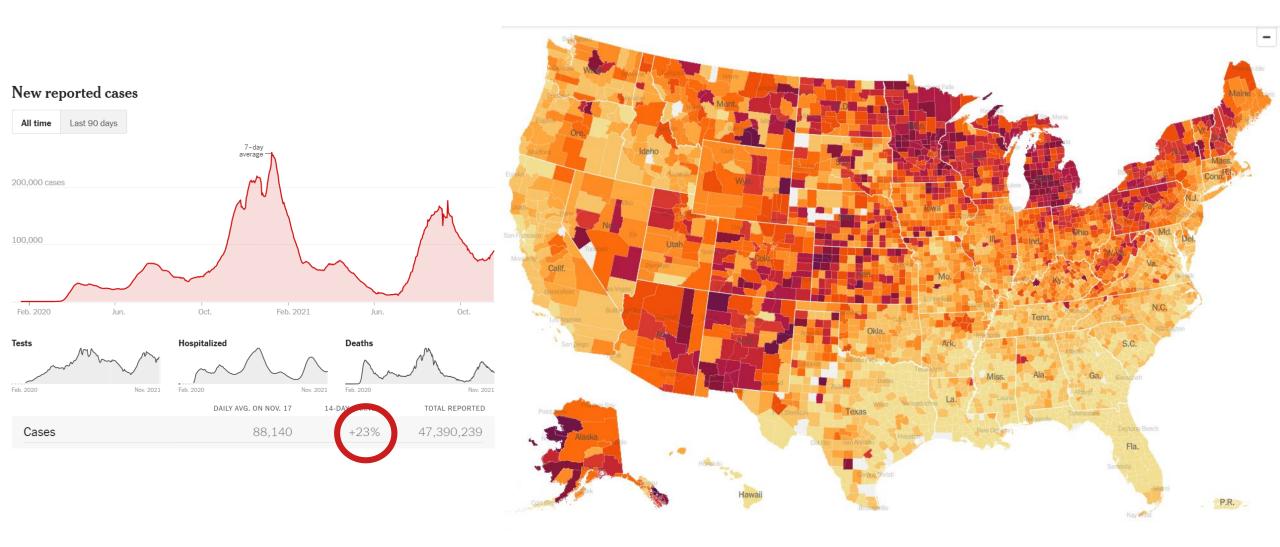
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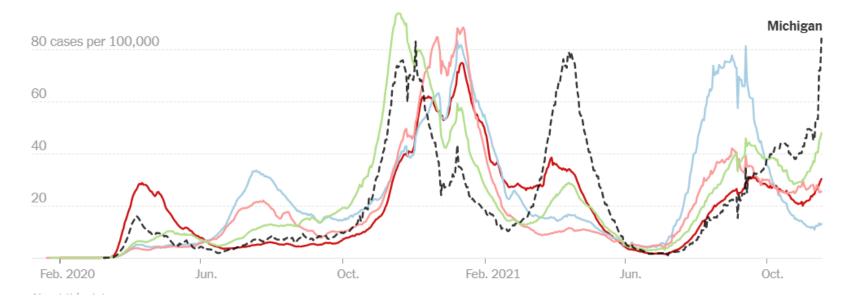
COVID-19 UPDATE

HANA AKSELROD, MD, MPH GW DIVISION OF INFECTIOUS DISEASES MFA COVID-19 LEAD 11/18/2021 EPIDEMIOLOGY
PREVENTION
TREATMENT
GW UPDATES

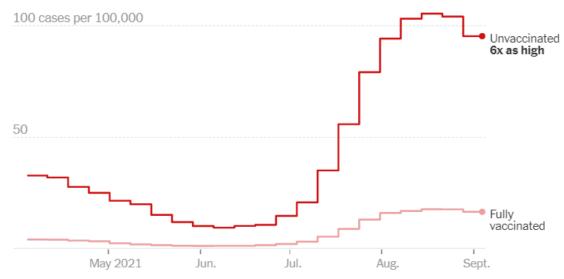
No Financial COI. Investigator on ongoing clinical trials as part of GW ID Division and Clinical Trials Unit. Preprints are marked as such.



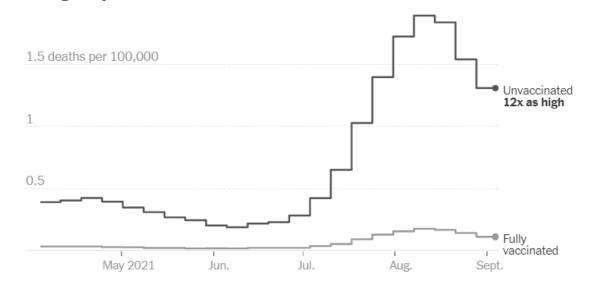
■ West ■ Midwest ■ South ■ Northeast



Average daily cases



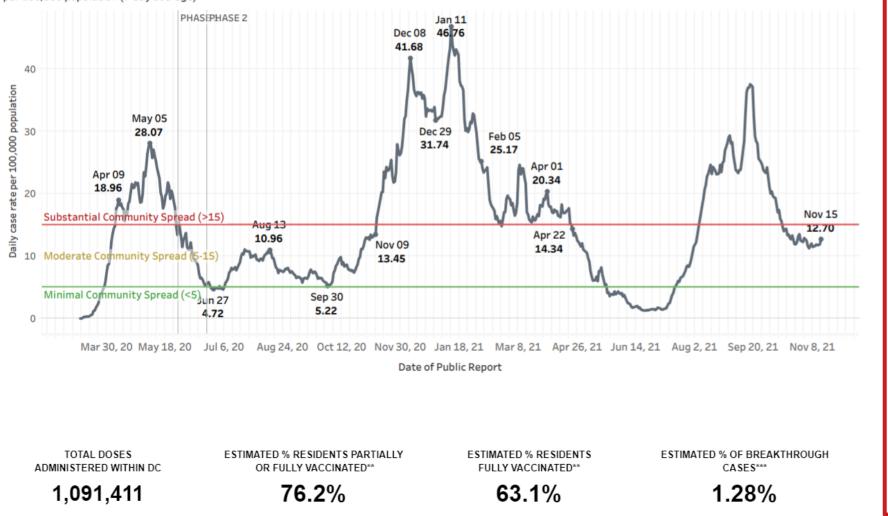
Average daily deaths

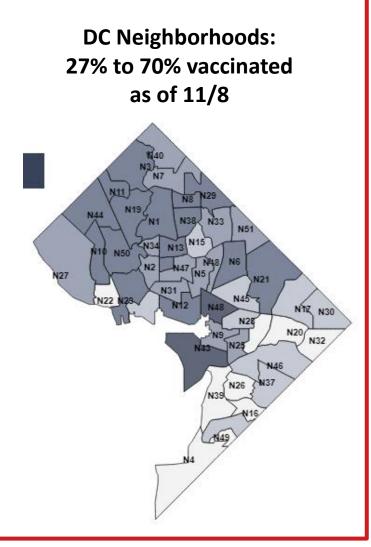


https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html

District of Columbia COVID-19 Daily Case Rate

per 100,000 population (7-day average)





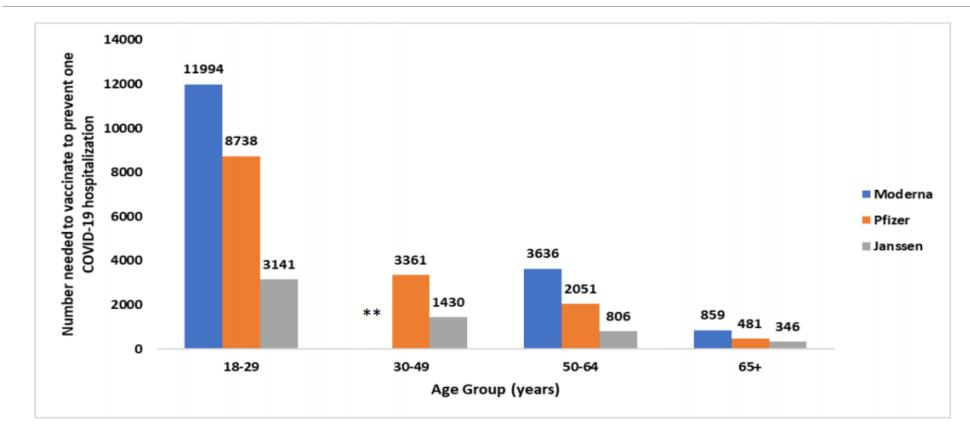
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COVID-19 Vaccine Boosters Recap

- **1.** Significantly immunocompromised: need 3rd dose, give ≥1 month after #2.
- **2.** J&J recipients: need 2^{nd} dose, give ≥ 2 months after #1.
- 3. High-risk **Pfizer-BioNTech** or **Moderna** recipients, boost at ≥6 months:
 - 65 years and older
 - Age 18+ who live in long-term care settings
 - Age 18+ who have <u>underlying medical conditions</u>
 - Age 18+ who work or live in <u>high-risk settings</u>
- All others: May soon be eligible for booster at ≥6 months regardless of risk level. Pfizer data is first to be reviewed, others will follow.

"Eligible individuals may choose which vaccine they receive as a booster dose." – CDC

Number of Adults Needed to Boost to Prevent One Hospitalization over 6 Months

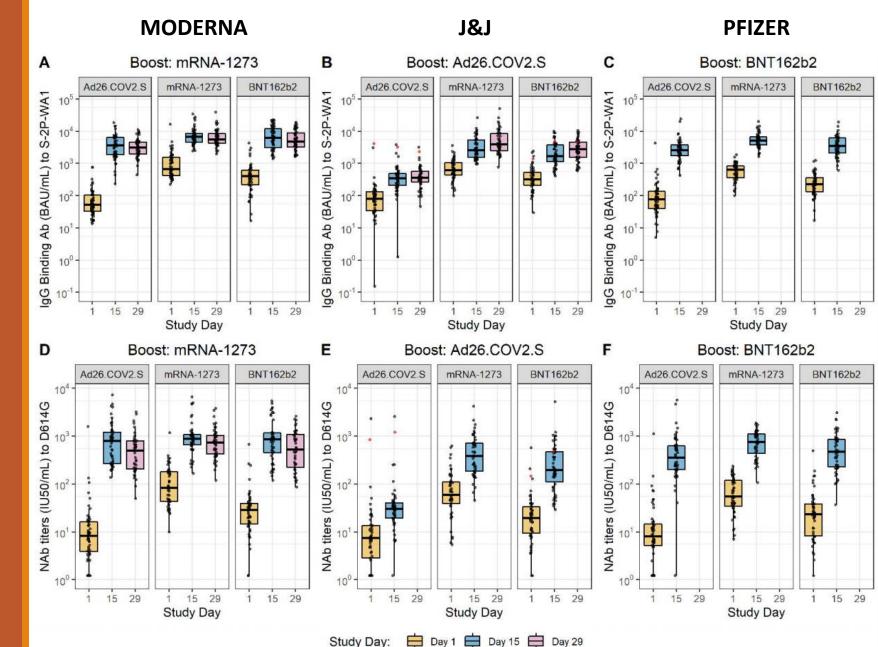


** Not estimable due to pre-booster efficacy estimated at >95%

"Mix and Match" Boosting

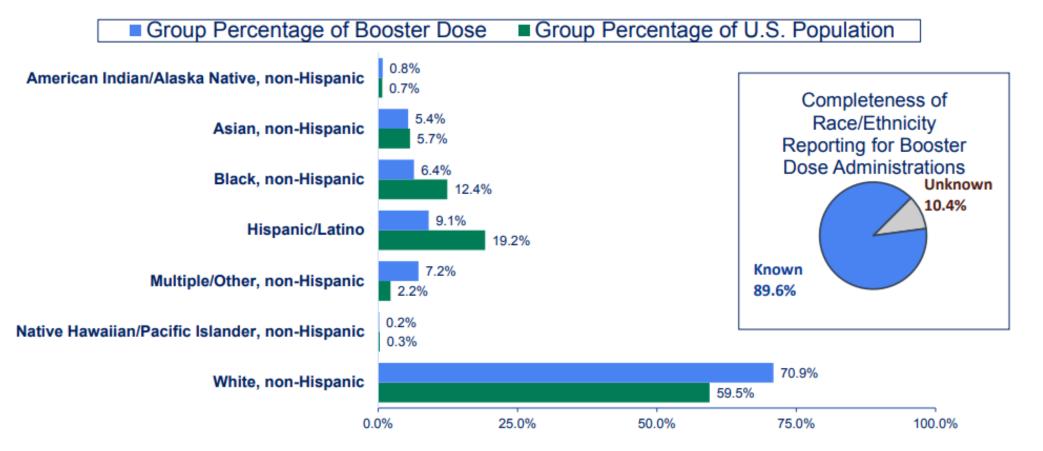
The "MixNMatch" Study Team Kaiser Permanent Washington Health Research Cincinnati Children' Institute **Jniversity** of Fred Hutch / SCHAI ittsburgh The Univ University of Maryland **Duke University Clinical Sites** Emory University labs ry, Data and Statistical Centers Moderna, Inc., Johnson&Johnson/Janssen, Pfizer/BioNTech University of Texas Medical Branch 1 D C R C NIH **Baylor College of Medicine**

https://www.cdc.gov/vaccines/acip/meetings/ slides-2021-10-20-21.html



https://www.medrxiv.org/content/10.1101/2021.10.10.21264827v2

Percentage of Booster Dose Administrations by Race/Ethnicity



Data shown for 9.8M people with a booster/additional dose administration and known race/ethnicity, vaccinated since August 13, 2021

Source: Immunization Data Lake Aggregate Dataset (includes TX). Data reported as of 19OCT2021 0600.

Notes: Census populations used to calculate Group Percentage of U.S. Population are from the Census 2019 Vintage files. The Multiple/Other category includes vaccine recipients that were identified as Multiple Race or Other Race. The Census populations used to calculate the Group Percentage of U.S. Population for this group represent the non-Hispanic Two or More Race population only, since Other is not a Census-recognized group.

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/11-COVID-Dooling-508.pdf

ORIGINAL ARTICLE

Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age

Emmanuel B. Walter, M.D., Kawsar R. Talaat, M.D., Charu Sabharwal, M.D., M.P.H., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., Grant C. Paulsen, M.D., Elizabeth D. Barnett, M.D., Flor M. Muñoz, M.D., Yvonne Maldonado, M.D., Barbara A. Pahud, M.D., M.P.H., Joseph B. Domachowske, M.D., Eric A.F. Simões, M.B., B.S., D.C.H., M.D., <u>et al.</u>, for the C4591007 Clinical Trial Group^{*}

- Phase 1: 48 children, selected dose 10 μg
- Phase 2-3: 2268 children, 2:1 randomization
- Two doses given 21 days apart
- VE 90.7% (95% CI: 67.7 to 98.3) starting 7 days post dose #2, followed for 2.3 months
- No serious adverse events reported AEs: 10.9% in vax arm, 9.2% in placebo arm Most common AE: sore arm
- Ongoing safety monitoring

CDC Recommends Pediatric COVID-19 Vaccine for Children 5 to 11 Years

Media Statement

For Immediate Release: Tuesday, November 2, 2021 Contact: <u>Media Relations</u> (404) 639-3286

Today, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation that children 5 to 11 years old be vaccinated against COVID-19 with the Pfizer-BioNTech pediatric vaccine. CDC now expands vaccine recommendations to about 28 million children in the United States in this age group and allows providers to begin vaccinating them as soon as possible.

COVID-19 cases in <u>children</u> can result in hospitalizations, deaths, MIS-C (inflammatory syndromes) and long-term complications, such as "long COVID," in which symptoms can linger for months. The spread of the

Treatment: Oral Antivirals Under Review

MOLNUPIRAVIR (MERCK)

- **MOVe-OUT** Phase 3 RCT: non-hospitalized adults with mild-to-moderate COVID-19, risk factors
- Interferes with RNA-dependent RNA polymerase
- At day 29 post randomization, hospitalization or death occurred in 28/385 (7.3%) of pts in intervention arm vs. 53/377 (14.1%) of control arm; p=0.0012; RRR = 50%; NNT = 15.
- Drug started within 5 days of symptoms onset
- No deaths in intervention arm vs. 8 in placebo
- 40% of SARS-CoV2 samples sequenced; consistent efficacy across Gamma, Delta, Mu variants
- Excluded vaccinated patients

PAXLOVID (PFIZER)

- **EPIC-HR** Phase 2/3 RCT: non-hospitalized adult patients with risk factors for severe illness
- PF-07321332 inhibits 3CL-like protease + ritonavir boosts levels
- Reported 6/607 hospitalizations and 0 deaths (composite 1%) in intervention arm, vs. 41/761 hospitalizations and 1/761 deaths (composite 6.7%) in placebo arm. RRR = 85%, NNT = 17.5.
- Reduction in risk of hospitalization or death by 89% if started within 3 days onset of symptoms, and by 85% if started within 5 days.
- Vaccinated patients excluded from this study but included in another ongoing one.



GW Updates

- COVID-19 Vaccine Clinic:
 - New location: 703 23rd St NW
 - Ages 12+ (soon: 5-11 yo as well)
 - Pfizer and J&J vaccines available
 - <u>https://www.gwdocs.com/patients-visitors/covid-19-updates/covid-19-vaccination-information/</u>
- Monoclonal antibodies for high-risk infected patients:
 - Available at GWUH ED
 - DHHS Locator: <u>https://combatcovid.hhs.gov/i-have-covid-19-now/monoclonal-antibodies-high-risk-covid-19-positive-patients</u>
- Travel advisory:
 - Check <u>https://onward.gwu.edu/covid-19-testing-after-travel-outside-dmv-region</u>
 - We anticipate a difficult COVID-19 & influenza season. If possible, celebrate outdoors, open windows, and limit size of gatherings. Avoid unvaccinated guests. Wear high-quality masks in transit. Ask family to support you.