Providence

COVID-19 Resource Desk

#111 | 6.12.2022 to 6.18.2022

Prepared by System Library Services Retraction Watch

New Research

*note, **PREPRINTS** have not undergone formal peer review

COVID-19 related publications by Providence caregivers – see Digital Commons

Diagnostics & Screening

1. **Benefit and Cost of Repeating a SARS-CoV-2 PCR after the Second Day of Hospitalization in 5 Hospitals during Various Community Prevalences and Vaccination Rates.** Bulnes R et al. *Infect Control Hosp Epidemiol.* 2022 Jun 16:1-14. doi: 10.1017/ice.2022.157. https://go.openathens.net/redirector/providence.org?url=https%3A%2F%2Fwww.cambridge.org%2Fcore%2Fjournals%2Finfection-control-and-hospital-epidemiology%2Farticle%2Fbenefit-and-cost-of-repeating-a-sarscov2-pcr-after-the-second-day-of-hospitalization-in-5-hospitals-during-various-community-prevalences-and-vaccination-rates%2FBB198C5726468632A318D07C195EE421

Universal SARS-CoV-2 PCR was performed upon admission and again after two inpatient days. As community-wide prevalence, admission, and vaccination rates varied, number-needed-to-benefit (NNB) and cost-per-additional-detection (Cd) fluctuated between 16-769 and $800-$29,400 respectively, and negatively associated with new hospital admissions. No other community indicator associated with NNB and Cd.

Epidemiology & Public Health

2. **Association of Omicron vs Wild-type SARS-CoV-2 Variants with Hospital-Onset SARS-CoV-2 Infections in a US Regional Hospital System.** Klompas M, et al. *JAMA.* 2022 Jun 15. doi: 10.1001/jama.2022.9609. https://jamanetwork.com/journals/jama/fullarticle/2793582

The SARS-CoV-2 Omicron variant is more contagious than prior variants, leading to large increases in community cases. Little is known, however, about the incidence of nosocomial SARS-CoV-2 infections with Omicron vs prior variants.

Healthcare Delivery & Healthcare Workers

3. **COVID-19 and Cancer: Special Considerations for Patients Receiving Immunotherapy and Immunosuppressive Cancer Therapies.** Jason D Goldman, et al. **[Providence author]**. *Am Soc Clin Oncol Educ Book.* 2022 Apr;42:1-13. doi: 10.1200/EDBK_359656. https://doi.org/10.1200/edbk_359656

In patients undergoing cancer immunotherapy or other immunosuppressive cancer treatments, we summarize the evidence on outcomes from COVID-19; address the safety, immunogenicity, and efficacy of COVID-19 vaccination; and review COVID-19 antiviral therapeutics for the patient with cancer. Despite higher mortality for patients with cancer, treatment with immune checkpoint inhibitors does not seem to increase mortality risk based on observational evidence. Inhibitory therapies directed toward B-cell lineages, including monoclonal antibodies against CD20 and CAR T-cell therapies, are associated with poor outcomes in COVID-19; however, the data are sparse. Regarding vaccination in patients receiving immune checkpoint inhibitors, clinical efficacy comparable to that in the general population can be expected. In patients undergoing B-cell-depleting therapy, immunogenicity and clinical efficacy are curtailed, but vaccination is not futile, which is thought to be due to the cellular response. Vaccine reactogenicity and toxicity in all groups of patients with cancer are comparable to that of the general population. Preexposure prophylaxis with monoclonal antibodies directed against the viral spike may provide passive immunity for those not likely to mount an adequate vaccine response. If infected, prompt treatment with monoclonal antibodies or oral small molecule antivirals is beneficial, though with oral antiviral therapies, care must be taken to avoid drug interactions in patients with cancer.

4. **Notes from the Field: COVID-19-Associated Mortality Risk Among Long-Term Care Facility Residents and Community-Dwelling Adults Aged ≥65 Years - Illinois, December 2020 and January 2022.** Lee D, et al. *MMWR Morb Mortal Wkly Rep*. 2022 Jun 17;71(24):803-805. doi: 10.15585/mmwr.mm7124a4. https://www.cdc.gov/mmwr/volumes/71/wr/mm7124a4.htm?s_cid=mm7124a4_w

This report estimates the risk for death among LTCF residents by comparing COVID-19–associated mortality rates among LTCF residents aged ≥65 years and persons aged ≥65 years who are not LTCF residents (community-dwelling adults) in Illinois. Illinois infectious disease registry data and population data from state regulatory sources and the U.S. Census Bureau were used to calculate COVID-19 death rates among persons aged ≥65 years living within and outside of LTCFs during a prevaccination baseline month (December 2020) and a comparison month 1 year after COVID-19 vaccination began (January 2022).

5. **COVID-19 Cases and Hospitalizations Among Medicare Beneficiaries with and Without Disabilities - United States, January 1, 2020-November 20, 2021.** Yuan Y, et al. *MMWR Morb Mortal Wkly Rep*. 2022 Jun 17;71(24):791-796. doi: 10.15585/mmwr.mm7124a3. https://www.cdc.gov/mmwr/volumes/71/wr/mm7124a3.htm?s_cid=mm7124a3_w

To describe the impact of COVID-19 on persons with disabilities and whether and how age contributes to disease rates, CDC assessed COVID-19 cases and hospitalizations during January 2020-November 2021, among Centers for Medicare & Medicaid Services Medicare beneficiaries aged ≥18 years who were either eligible because of a disability (disability-eligible) or only eligible because of age ≥65 years (age-eligible). COVID-19 incidence and hospitalization rates were higher in the disability-eligible group (10,978 and 3,148 per 100,000 population, respectively) throughout the study period compared with the age-eligible group (8,102 and 2,129 per 100,000 population, respectively). Both COVID-19 incidence and hospitalization rates increased with age in both disability- and age-eligible beneficiaries. American Indian or Alaska Native (AI/AN) persons had the highest disability-eligible (4,962 per 100,000) and age-eligible (5,024 per 100,000) hospitalization rates. Among all other racial and ethnic groups,

hospitalization rates were higher among disability-eligible than among age-eligible patients. COVID-19 incidence and hospitalization rates among disability-eligible Medicare beneficiaries were disproportionally higher than rates among age-eligible beneficiaries. Collection of disability status as a core demographic variable in public health surveillance data and identification, as well as the addition of disability questions in other existing data sources can guide research and development of interventions for persons with disabilities. Efforts to increase access to and use of COVID-19 prevention and treatment strategies, including activities that support equitable vaccine access regardless of the substantial challenges that older adults and persons with disability face, are critical to reducing severe COVID-19-associated outcomes among these groups.

Prognosis

6. **Risk of severe COVID-19 outcomes associated with immune-mediated inflammatory diseases and immune-modifying therapies: a nationwide cohort study in the OpenSAFELY platform.** MacKenna B et al. *Lancet Rheumatol.* 2022 Jun 9. doi: 10.1016/S2665-9913(22)00098-4. https://www.sciencedirect.com/science/article/pii/S2665991322000984

COVID-19 deaths and hospital admissions were higher in people with immune-mediated inflammatory diseases. We saw no increased risk of adverse COVID-19 outcomes in those on most targeted immune-modifying drugs for immune-mediated inflammatory diseases compared with those on standard systemic therapy.
FUNDING: UK Medical Research Council, NIHR Biomedical Research Centre at King's College London and Guy's and St Thomas' NHS Foundation Trust, and Wellcome Trust.

7. **Association of Statins for Primary Prevention of Cardiovascular Diseases With Hospitalization for COVID-19: A Nationwide Matched Population-Based Cohort Study.** Bouillon K, et al. *J Am Heart Assoc.* 2022 Jun 14:e023357. doi: 10.1161/JAHA.121.023357. https://www.ahajournals.org/doi/10.1161/JAHA.121.023357

Our findings support that the use of statins for primary prevention is associated with lower risks of hospitalization for COVID-19 and of in-hospital death from COVID-19.

Therapeutics

8. **Efficacy and safety of intramuscular administration of tixagevimab-cilgavimab for early outpatient treatment of COVID-19 (TACKLE): a phase 3, randomised, double-blind, placebo-controlled trial.** Montgomery H et al. *Lancet Respir Med.* 2022 Jun 7:S2213-2600(22)00180-1. doi: 10.1016/S2213-2600(22)00180-1. https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00180-1/fulltext

A single intramuscular tixagevimab-cilgavimab dose provided statistically and clinically significant protection against progression to severe COVID-19 or death versus placebo in unvaccinated individuals and safety was favourable. Treating mild to moderate COVID-19 earlier in the disease course with tixagevimab-cilgavimab might lead to more favourable outcomes.
FUNDING: AstraZeneca.

9. **Rebound Phenomenon after Nirmatrelvir/Ritonavir Treatment of Coronavirus Disease-2019 in High-Risk Persons.** Ranganath N, et al. *Clin Infect Dis*. 2022 Jun 14:ciac481. doi: 10.1093/cid/ciac481. https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac481/6607746

In a cohort of 483 high-risk patients treated with nirmatrelvir/ritonavir for coronavirus disease-2019, two patients (0.4%) required hospitalization by day 30. Four patients (0.8%) experienced rebound of symptoms, which were generally mild, at median of 9 days after treatment, and all resolved without additional COVID-19-directed therapy.

Vaccines / Immunology

10. **Rapid, scalable assessment of SARS-CoV-2 cellular immunity by whole-blood PCR.** Schwarz, M. et al. *Nat Biotechnol* (2022). https://doi.org/10.1038/s41587-022-01347-6

Our assays may allow large-scale monitoring of the magnitude and duration of functional T cell immunity to SARS-CoV-2, thus helping to prioritize revaccination strategies in vulnerable populations.

11. **Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims databases.** Wong HL et al. *Lancet.* 2022 Jun 11;399(10342):2191-2199. doi: 10.1016/S0140-6736(22)00791-7. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00791-7/fulltext

An increased risk of myocarditis or pericarditis was observed after COVID-19 mRNA vaccination and was highest in men aged 18-25 years after a second dose of the vaccine. However, the incidence was rare. These results do not indicate a statistically significant risk difference between mRNA-1273 and BNT162b2, but it should not be ruled out that a difference might exist. Our study results, along with the benefit-risk profile, continue to support vaccination using either of the two mRNA vaccines. FUNDING: US Food and Drug Administration.

12. **Immune responses after omicron infection in triple-vaccinated health-care workers with and without previous SARS-CoV-2 infection.** Blom K et al. *Lancet Infect Dis.* 2022 Jun 9:S1473-3099(22)00362-0. doi: 10.1016/S1473-3099(22)00362-0. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00362-0/fulltext

In this prospective cohort study, we analysed serological and T-cell responses following omicron infection in 56 triple-vaccinated health-care workers in Sweden with and without prior SARS-CoV-2 infection. A surrogate virus neutralisation test (sVNT) was used to assess neutralisation of SARS-CoV-2 variants. Immune responses of all participants had been regularly assessed since April, 2020, in the ongoing Swedish COMMUNITY study.3, 4 For this sub-study, participants were screened with qPCR twice a week for 4 weeks,5 with additional qPCR tests every other day for 14 days if positive. Blood samples were collected 1 week, 2 weeks, 3 weeks, 5 weeks, and 7 weeks after the first positive qPCR sample.

13. **Safety and immunogenicity of the FINLAY-FR-1A vaccine in COVID-19 convalescent participants: an open-label phase 2a and double-blind, randomised, placebo-controlled, phase 2b, seamless, clinical trial.** Ochoa-Azze R et al. *Lancet Respir Med.* 2022 Jun 9:S2213-

2600(22)00100-X. doi: 10.1016/S2213-2600(22)00100-X. https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00100-X/fulltext

A single dose of the FINLAY-FR-1A vaccine against SARS-CoV-2 strengthened the pre-existing natural immunity, with excellent safety profile.

FUNDING: Cuba's Ministry of Science, Technology, and Environment.

14. **Effect of priming interval on reactogenicity, peak immunological response, and waning after homologous and heterologous COVID-19 vaccine schedules: exploratory analyses of Com-COV, a randomised control trial.** Shaw RH et al. *Lancet Respir Med.* 2022 Jun 8:S2213-2600(22)00163-1. doi: 10.1016/S2213-2600(22)00163-1. Online ahead of print. https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00163-1/fulltext

These data support flexibility in priming interval in all studied COVID-19 vaccine schedules. Longer priming intervals might result in lower reactogenicity in schedules with BNT162b2 as a second dose and higher humoral immunogenicity in homologous schedules, but overall lower T-cell responses across all schedules. Future vaccines using these novel platforms might benefit from schedules with long intervals.

FUNDING: UK Vaccine Taskforce and National Institute for Health and Care Research.

15. **Comparison of Waning Neutralizing Antibody Responses Against the Omicron Variant 6 Months After Natural SARS-CoV-2 Infection (With/Without subsequent COVID-19 Vaccination) Versus 2-dose COVID-19 Vaccination.** Lim SY, et al. *Clin Infect Dis.* 2022 Jun 10:ciac435. doi: 10.1093/cid/ciac435. https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac435/6605068

Following SARS-CoV-2 infection, subsequent ChAdOx1 nCoV-19 induced similar neutralizing antibody levels against the original strain but significantly higher levels against the Omicron variant compared to those who were not vaccinated. Prior SARS-CoV-2 infection exhibited higher neutralization antibody titers than vaccination alone for both original strains and the Omicron variant.

16. **Comparative Safety of BNT162b2 and mRNA-1273 Vaccines in a Nationwide Cohort of US Veterans.** Dickerman BA, et al. *JAMA Intern Med*. 2022 Jun 13. doi: 10.1001/jamainternmed.2022.2109. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2793236

The findings of this cohort study suggest that there were few differences in risk of adverse events within 14 days of the first dose of either the BNT162b2 or the mRNA-1273 vaccine and small-magnitude differences within 42 days of the first dose. The 38-week risks of adverse events were low in both vaccine groups, although risks were lower for recipients of the mRNA-1273 vaccine than for recipients of the BNT162b2 vaccine. Although the primary analysis was designed to detect safety events unrelated to SARS-CoV-2 infection, the possibility that these differences may partially be explained by a lower effectiveness of the BNT162b2 vaccine in preventing the sequelae of SARS-CoV-2 infection compared with the mRNA-1273 vaccine could not be ruled out. These findings may help inform decision-making in future vaccination campaigns.

17. **Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections.** Altarawneh HN et al. *N Engl J Med.* 2022 Jun 15. doi: 10.1056/NEJMoa2203965. https://www.nejm.org/doi/10.1056/NEJMoa2203965

No discernable differences in protection against symptomatic BA.1 and BA.2 infection were seen with previous infection, vaccination, and hybrid immunity. Vaccination enhanced protection among persons who had had a previous infection. Hybrid immunity resulting from previous infection and recent booster vaccination conferred the strongest protection. (Funded by Weill Cornell Medicine-Qatar and others.).

18. **Comparative Safety of BNT162b2 and mRNA-1273 Vaccines in a Nationwide Cohort of US Veterans.** Dickerman BA et al. *JAMA Intern Med.* 2022 Jun 13. doi: 10.1001/jamainternmed.2022.2109. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2793236

The findings of this cohort study suggest that there were few differences in risk of adverse events within 14 days of the first dose of either the BNT162b2 or the mRNA-1273 vaccine and small-magnitude differences within 42 days of the first dose. The 38-week risks of adverse events were low in both vaccine groups, although risks were lower for recipients of the mRNA-1273 vaccine than for recipients of the BNT162b2 vaccine. Although the primary analysis was designed to detect safety events unrelated to SARS-CoV-2 infection, the possibility that these differences may partially be explained by a lower effectiveness of the BNT162b2 vaccine in preventing the sequelae of SARS-CoV-2 infection compared with the mRNA-1273 vaccine could not be ruled out. These findings may help inform decision-making in future vaccination campaigns.

Women & Children

19. **Safety and immunogenicity of the ChAdOx1 nCoV-19 (AZD1222) vaccine in children aged 6-17 years: a preliminary report of COV006, a phase 2 single-blind, randomised, controlled trial.** Li G et al. *Lancet.* 2022 Jun 11;399(10342):2212-2225. doi: 10.1016/S0140-6736(22)00770-X. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00770-X/fulltext

ChAdOx1 nCoV-19 is well tolerated and immunogenic in children aged 6-17 years, inducing concentrations of antibody that are similar to those associated with high efficacy in phase 3 studies in adults. No safety concerns were raised in this trial.

20. **Multisystem Inflammatory Syndrome in Children (MIS-C) During SARS-CoV-2 Delta and Omicron Variant Circulation- United States, July 2021 - January 2022.** Miller AD, et al. *Clin Infect Dis.* 2022 Jun 10:ciac471. doi: 10.1093/cid/ciac471. https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac471/6605071

We describe 2,116 multisystem inflammatory syndrome in children (MIS-C) cases reported to CDC during Delta and Omicron circulation from July 2021-January 2022. Half of MIS-C patients were aged 5-11 years, 52% received ICU-level care, and 1.1% died. Only 3.0% of eligible patients were fully vaccinated prior to MIS-C onset.

21. **Long COVID-19 Liver Manifestation in Children.** Cooper S et al. *Pediatric Gastroenterology and Nutrition:* June 10, 2022 doi: 10.1097/MPG.0000000000003521

https://go.openathens.net/redirector/providence.org?url=https%3A%2F%2Fjournals.lww.com%2Fjpgn%2FAbstract%2F9900%2FLong_COVID_19_Liver_Manifestation_in_Children.84.aspx

SARS CoV-2, the novel coronavirus responsible for coronavirus disease (COVID-19), has been a major cause of morbidity and mortality worldwide. Gastrointestinal and hepatic manifestations during acute disease have been reported extensively in the literature. Post-COVID-19 cholangiopathy has been increasingly reported in adults. In children, data are sparse. Our aim was to describe pediatric patients who recovered from COVID-19 and later presented with liver injury.

22. **Safety and immunogenicity of the ChAdOx1 nCoV-19 (AZD1222) vaccine in children aged 6-17 years: a preliminary report of COV006, a phase 2 single-blind, randomised, controlled trial.** Li G et al. *Lancet.* 2022 Jun 11;399(10342):2212-2225. doi: 10.1016/S0140-6736(22)00770-X. https://www.sciencedirect.com/science/article/pii/S014067362200770X

ChAdOx1 nCoV-19 is well tolerated and immunogenic in children aged 6-17 years, inducing concentrations of antibody that are similar to those associated with high efficacy in phase 3 studies in adults. No safety concerns were raised in this trial.
FUNDING: AstraZeneca and the UK Department of Health and Social Care through the UK National Institute for Health and Care Research.

23. **Epidemiology and Outcomes of SARS-CoV-2 Infection or Multisystem Inflammatory Syndrome in Children vs Influenza Among Critically Ill Children.** Shein SL, et al. *JAMA Netw Open*. 2022 Jun 1;5(6):e2217217. doi: 10.1001/jamanetworkopen.2022.17217. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793366

When assessing risks of SARS-CoV-2 and the need for public health measures for children, some cite its similarities to influenza.1-3 However, it is unclear whether pediatric critical illness differs between SARS-CoV-2 and influenza. Therefore, we used the Virtual Pediatric Systems database (VPS)4 to compare epidemiology and outcomes of patients in the pediatric intensive care unit (PICU) with SARS-CoV-2–related disease during the first 15 months of the COVID-19 pandemic vs children with critical influenza prior to the pandemic.

FDA / CDC / NIH / WHO Updates

FDA - EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 6 months through 4 years of age

FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age

CDC - Interim Clinical Considerations for COVID-19 Treatment in Outpatients Updated June 15, 2022

Commentary & Press Releases

Pfizer Reports Additional Data on PAXLOVID™ Supporting Upcoming New Drug Application Submission to U.S. FDA

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