

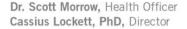
March 5, 2021

Dr. Scott Morrow, Health Officer Cassius Lockett, PhD, Director

Public Health, Policy & Planning 225 37th Avenue San Mateo, CA 94403 smchealth.org

CLINICAL PEARL

- What clinicians need to know about the Janssen COVID-19 vaccine and the mRNA COVID-19 vaccines that are currently approved for use in the United States:
 - o The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Johnson & Johnson/Janssen Biotech COVID-19 (Ad.26.COV2.S) vaccine on February 27, 2021.
 - The Janssen COVID-19 vaccine is the third COVID-19 vaccine authorized under an EUA for the prevention of COVID-19 in the United States.
 - The Janssen COVID-19 vaccine is a recombinant, replication-incompetent adenovirus serotype 26
 (Ad26) vector vaccine. It encodes the stabilized prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19.
 - \circ Vaccination with the Janssen COVID-19 vaccine consists of a **single dose** (5 × 10¹⁰ virus particles per 0.5-mL dose) **administered intramuscularly.**
 - o The Janssen COVID-19 vaccine is authorized for persons aged ≥18 years.
 - The body of evidence for the Janssen COVID-19 vaccine was primarily informed by one international Phase III clinical trial initiated in September 2020 that enrolled approximately 40,000 participants aged 18–100 years(median age = 52 years), using two coprimary endpoints: prevention of symptomatic, laboratory-confirmed COVID-19 among persons without evidence of previous SARS-CoV-2 infection occurring a) ≥14 days and b) ≥28 days after vaccination.
 - Interim findings from this clinical trial indicate that the Janssen COVID-19 vaccine efficacy against symptomatic, laboratory-confirmed COVID-19 was 66.3% ≥14 days after vaccination and 65.5% ≥28 days after vaccination.
 - o **Efficacy varied geographically and was highest in the United States (74.4%),** followed by Latin America (64.7%) and South Africa (52.0%). Regional differences in SARS-CoV-2 variants were noted; in South Africa, 94.5% of virus sequences from trial participants were from the B.1.351 lineage, whereas in Brazil, the P.2 lineage accounted for 69.4% of virus sequences.
 - Efficacy estimates for <u>severe outcomes</u> assessed ≥28 days post vaccination were high: 83.5% for <u>severe</u> disease.
 - Efficacy against severe disease remained high across all world regions (73-82%), suggesting protection against severe illness due to variant strains.
 - O Vaccine efficacy for the prevention of <u>COVID-19</u>—associated hospitalization was high. No COVID-19—associated hospitalizations occurred ≥28 days after vaccination in the vaccine group, and 16 occurred in the placebo group (vaccine efficacy = 100%).
 - Seven COVID-19—associated deaths occurred, all in placebo recipients (vaccine efficacy against death due to COVID-19 = 100%).
 - o Preliminary data suggest that the Janssen COVID-19 vaccine might also **provide protection against asymptomatic SARS-CoV-2 infection**, as measured by seroconversion to a non–spike protein. Among a subset of participants with SARS-CoV-2 serology results 71 days after vaccination, 0.7% of vaccine recipients had no symptoms of COVID-19 but had documented seroconversion to a non–spike protein, compared with 2.8% of placebo recipients (estimated efficacy = 74.2%).
 - Vaccine recipients frequently experienced reactogenicity symptoms, defined as solicited local injection site or systemic adverse reactions during the 7 days after vaccination.





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- Local reactions occurred in about 50% of vaccines recipients. Pain at the injection site was most common. Systemic reactions occurred in approximately 55% of vaccine recipients. Headache, fatigue and myalgia were most common.
- Symptoms were mostly mild to moderate and resolved 1–2 days after vaccination. Symptoms were more frequent among persons aged 18–59 years than among those aged ≥60 years.
- A detailed summary of safety data, including information on reactogenicity, is available at https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/reactogenicity.html.
- The Janssen COVID-19 vaccine only requires refrigerator temperatures (2°C–8°C) for transportation and storage.
- COVID-19 vaccines are not interchangeable. The safety and efficacy of a mixed series has not been evaluated.
 - In exceptional situations where a patient received one dose of an mRNA COVID-19 vaccine but is unable to complete the series with the same or a different mRNA vaccine, a single dose of the Janssen COVID-19 vaccine may be administered at a minimum interval of 28 days from the mRNA dose.
- COVID-19 vaccines should be administered alone with a minimum interval of 14 days before or after administration of other vaccines.
 - A shorter interval may be used in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks (e.g. tetanus toxoid vaccine for wound management) or to avoid barriers or delays to vaccination.
- Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindications to vaccination, including immunocompromised persons, people with autoimmune conditions, people with a history of Guillain-Barre syndrome, Bell's palsy, dermal filler use. Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions.
- o None of the currently authorized vaccines are live virus vaccines. All are non-replicating vaccines.
- o If they contract COVID-19, pregnant women are at increased risk of severe illness and there might be an increased risk of adverse pregnancy outcomes as well. Currently, there is limited but growing data on the safety of COVID-19 vaccines in pregnant women. No concerns have been demonstrated in animal development and reproductive toxicity (DART) studies. The Janssen adenovirus vector platform has been used for other clinical development programs that included pregnant women, including a large-scale Ebola vaccine trial. No adverse pregnancy-related outcomes, including infant outcomes, were determined to be related to the vaccine in these trials.
- The currently available vaccines were NOT studied in head-to-head trials.
 - No trials compared the efficacy between vaccines in the same study at the same time.
 - All Phase 3 trials differed by calendar time and geography.
 - Vaccines were tested against different circulating variants and in settings with different background incidence, which limits the ability to draw specific comparisons with each of the phase 3 trials.
 - All authorized COVID-19 vaccines demonstrated efficacy (65 to 95%) against symptomatic, laboratory-confirmed COVID-19.
 - All authorized COVID-19 vaccines demonstrated high efficacy against COVID-19 severe enough to require hospitalization.
 - In the vaccine trials, no participants who received a COVID-19 vaccine died from COVID-19.





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- The Moderna and Janssen trials each had COVID-19 deaths in the placebo arm
- ACIP does not state a product preference for any of the 3 authorized vaccines. Persons may receive any
 ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to
 them.

PUBLIC HEALTH UPDATES

- FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine
 - o FDA Vaccines and Related Biological Products Advisory Committee February 26, 2021
 - Meeting Video Recording
 - Meeting Presentation Slides
 - FDA Briefing Document
- FDA Allows More Flexible Storage, Transportation Conditions for Pfizer-BioNTech COVID-19 Vaccine
- NIH launches new initiative to study "Long COVID"
- Officer of Governor Gavin Newsom: <u>Governor Newsom Announces Federal Approval of Medicaid Funding for Expanded COVID-19 Testing for Low-Income Students</u>

GUIDANCE/GUIDELINES

- American Academy of Pediatrics COVID-19 Interim Guidance: Return to Sports and Physical Activity
- NIH COVID-19 Treatment Guidelines

RESOURCES

- CDC
 - o Janssen COVID-19 Vaccine (Johnson & Johnson)
 - Janssen COVID-19 Vaccine (Johnson & Johnson) Questions
 - o What Clinicians Need to Know About Johnson & Johnson's Janssen COVID-19 Vaccine (COCA webinar)
 - o COVID-19 ACIP Vaccine Recommendations
 - o <u>Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States</u>
 - o <u>Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Janssen COVID-19</u>
 Vaccine
 - o Independent Evaluation of SARS-CoV-2 Antibody Test Performance
 - o MMWR Weekly COVID-19 Briefing Podcasts
- CDC/IDSA
 - o COVID-19 Clinician Call: Johnson & Johnson/ Janssen Biotech, Inc. COVID-19 Vaccine EUA What You Need to Know
 - o Real Time Learning Network:
 - Johnson & Johnson/Janssen COVID-19 Vaccine
 - Therapeutics Under Early Investigation
- IDSA COVID-19 Podcasts:
 - o Masking After COVID-19 Vaccinations and the Multi-Layered Steps Still Needed
 - o Vaccinating Individuals with Prior COVID-19
- IDSA/hivma: COVID-19 Vaccines: What Are Your Concerns?



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- Society of Infectious Diseases Pharmacists
 - o COVID-19 Therapeutic Reviews
 - o SARS-CoV-2 Viral Vector Vaccines: Evidence-Based Health Information Related to COVID-19
 - o SARS-CoV-2 Protein Subunit Vaccines: Evidence-Based Health Information Related to COVID-19
 - o SARS-CoV-2 mRNA Vaccines: Evidence-Based Health Information Related to COVID-19
 - o SARS-CoV-2 Vaccines- General Information: Evidence-Based Health Information Related to COVID-19
- WHO Statement: Understanding and managing Long COVID requires a patient-led approach
- The COVID Tracking Project

ACADEMIC/RESEARCH PAPERS

- bioRxiv
 - o SARS-CoV-2 lineage B.1.526 emerging in the New York region detected by software utility created to guery the spike mutational landscape
- medRxiv
 - o A Novel SARS-CoV-2 Variant of Concern, B.1.526, Identified in New York
 - o <u>Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England</u>
- The Lancet
 - o <u>Safety and immunogenicity of S-Trimer (SCB-2019)</u>, a protein subunit vaccine candidate for COVID-19 in healthy adults: a phase 1, randomised, double-blind, placebo-controlled trial
- New England Journal of Medicine
 - BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting
 - o Tocilizumab in Hospitalized Patients with Severe Covid-19 Pneumonia
 - o Interleukin-6 Receptor Antagonists in Critically III Patients with Covid-19
- Science
 - o Lessons from applied large-scale pooling of 133,816 SARS-CoV-2 RT-PCR tests
- BMJ
 - o A living WHO guideline on drugs to prevent covid-19
- Journal of Thrombosis and Haemostasis
 - o <u>Pharmacologic Thromboprophylaxis and Thrombosis in Hospitalized Patients with COVID-19: A Pooled Analysis</u>
- Infection Control Hospital Epidemiology
 - o <u>Air contamination of households versus hospital inpatient rooms occupied by SARS-CoV-2 positive patients</u>
- Antimicrobial Agents and Chemotherapy
 - o <u>Limited Utility of Procalcitonin in Identifying Community-Associated Bacterial Infections in Patients</u>
 Presenting with Coronavirus Disease 2019
- American Journal of Obstetrics and Gynecology
 - o <u>Severe acute respiratory syndrome coronavirus 2 serology levels in pregnant women and their neonates</u>





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- JAMA
 - o Pregnancy, Postpartum Care, and COVID-19 Vaccination in 2021
 - o Pediatric Eye Injuries by Hydroalcoholic Gel in the Context of the Coronavirus Disease 2019 Pandemic
 - o Association of SARS-CoV-2 Seropositive Antibody Test With Risk of Future Infection
 - o <u>Effect of Layperson-Delivered, Empathy-Focused Program of Telephone Calls on Loneliness, Depression, and Anxiety Among Adults During the COVID-19 Pandemic A Randomized Clinical Trial</u>
- Radiology
 - o <u>Ocular MRI Findings in Patients with Severe COVID-19: A Retrospective Multicenter Observational Study</u>
- Journal of Dental Hygiene
 - o COVID-19 Prevalence and Related Practices among Dental Hygienists in the United States
- Nature
 - o Hospitalization and mortality associated with SARS-CoV-2 viral clades in COVID-19
 - o Reduction in mobility and COVID-19 transmission
 - o Years of life lost to COVID-19 in 81 countries
- Journal of Virology
 - o SARS-CoV-2 causes severe epithelial inflammation and barrier dysfunction
- Blood Advances
 - o The SARS-CoV-2 receptor-binding domain preferentially recognizes blood group A
- Clinical Infectious Diseases
 - o Persistence of antibodies to SARS-CoV-2 in relation to symptoms in a nationwide prospective study
 - o <u>Modeling effectiveness of testing strategies to prevent COVID-19 in nursing homes —United States,</u> 2020
- European Journal of Clinical Microbiology and Infectious Diseases
 - Nosocomial infections associated to COVID-19 in the intensive care unit: clinical characteristics and outcome
- Intensive Care Medicine
 - o <u>COVID-19</u> increased the risk of ICU-acquired bloodstream infections: a case—cohort study from the <u>multicentric OUTCOMEREA network</u>
- Emerging Infectious Diseases
 - o <u>Severe Acute Respiratory Syndrome Coronavirus 2 Seropositivity among Healthcare Personnel in</u> Hospitals and Nursing Homes, Rhode Island, USA, July–August 2020
 - o <u>Prevalence of SARS-CoV-2 Antibodies in First Responders and Public Safety Personnel, New York City,</u> New York, USA, May–July 2020
 - o <u>Prevalence and Clinical Profile of Severe Acute Respiratory Syndrome Coronavirus 2 Infection among</u> Farmworkers, California, June–November 2020
 - o Genomic Evidence of In-Flight Transmission of SARS-CoV-2 Despite Predeparture Testing
 - Antibody Responses 8 Months after Asymptomatic or Mild SARS-CoV-2 Infection
 - Use of US Public Health Travel Restrictions during COVID-19 Outbreak on Diamond Princess Ship, Japan,
 February—April 2020
 - o <u>Daily Forecasting of Regional Epidemics of Coronavirus Disease with Bayesian Uncertainty</u> Quantification, United States
 - o SARS-CoV-2 Exposure in Escaped Mink, Utah, USA
 - o <u>Animal Reservoirs and Hosts for Emerging Alphacoronaviruses and Betacoronaviruses</u>
 - o Local Transmission of SARS-CoV-2 Lineage B.1.1.7, Brazil, December 2020



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- o <u>COVID-19 Outbreak in a Large Penitentiary Complex, April–June 2020,</u> Brazil
- o Epidemiology and Clinical Course of First Wave Coronavirus Disease Cases, Faroe Islands
- o Excess All-Cause Deaths during Coronavirus Disease Pandemic, Japan, January–May 2020
- The Pediatric Infectious Diseases Journal
 - o <u>High Rates of SARS-CoV-2 Family Transmission in Children of Healthcare Workers During the First</u> Pandemic Wave in Madrid, Spain: Serologic Study
- European Journal of Clinical Investigations
 - o SARS-CoV-2 re-infection risk in Austria
- The Journals of Infectious Diseases
 - o Susceptibility and Attenuated Transmissibility of SARS-CoV-2 in Domestic Cats

MMWR

- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19
 Vaccine United States, February 2021
- First Identified Cases of SARS-CoV-2 Variant P.1 in the United States Minnesota, January 2021
- Travel from the United Kingdom to the United States by a Symptomatic Patient Infected with the SARS-CoV-2 B.1.1.7 Variant Texas, January 2021
- Estimated SARS-CoV-2 Seroprevalence Among Persons Aged <18 Years Mississippi, May–September 2020
- <u>SARS-CoV-2 Infection Risk Among Active Duty Military Members Deployed to a Field Hospital New York City, April 2020</u>
- Reduction in COVID-19 Patients Requiring Mechanical Ventilation Following Implementation of a National COVID-19 Vaccination Program Israel, December 2020–February 2021

HOT OFF THE (LAY) PRESS

- CDC News
 - Media Statement from CDC Director Rochelle P. Walensky, MD, MPH, on Signing the Advisory <u>Committee on Immunization Practices' Recommendation to Use Janssen's COVID-19 Vaccine in People</u> 18 and Older
- The White House
 - Remarks by President Biden on the Administration's COVID-19 Vaccination Efforts
- New York Times
 - o <u>President Biden said the United States would have enough vaccines available for every American adult</u> by the end of May.
 - o Merck will help manufacture Johnson & Johnson's coronavirus vaccine, under an unusual deal between rivals brokered by the White House.
 - o In Quest for Herd Immunity, Giant Vaccination Sites Proliferate
 - Thousands of Farmworkers Are Prioritized for the Coronavirus Vaccine
 - o <u>Canada authorized the Oxford-AstraZeneca vaccine. It has yet to be authorized in the U.S. but has</u> played a key role in Britain's rapid rollout.
 - o The Era of Vaccine Diplomacy Is Here
 - o Decline in Coronavirus Cases 'May Be Stalling,' C.D.C. Director Warns
 - o Federal Scientists Plead for Pandemic Controls as Infection Declines Stall
 - Texas's governor ended a statewide mask mandate and said businesses could fully reopen, despite federal warnings that states not ease restrictions yet





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- o <u>California Today: What Can Reopen in the Red Tier?</u>
- o American life begins to return to normal, even as some fear it's too soon.
- o The Coronavirus Is Plotting a Comeback. Here's Our Chance to Stop It for Good
- o A New Coronavirus Variant Is Spreading in New York, Researchers Report
- o <u>'Everything Seems So Tenuous'</u>: Variants Threaten N.Y.C.'s Progress on Virus
- A variant originally found in California has picked up speed in San Francisco, scientists say.
- o The rapid rise of P.1
- o Why has coronavirus testing slumped in the U.S.? It's complicated
- o Nursing Homes, Once Hotspots, Far Outpace U.S. in Covid Declines
- Virus Did Not Bring Financial Rout That Many States Feared
- o Will Fish Sauce and Charred Oranges Return the World Covid Took From Me?
- o Plan to Ditch the Mask After Vaccination? Not So Fast.
- MedPage Today
 - o How Long Do COVID Olfactory Problems Last?
- The Atlantic
 - o A Simple Rule of Thumb for Knowing When the Pandemic Is Over
- CIDRAP News
 - o COVID-19 cases rebound globally as COVAX immunizations begin in Africa
 - o With COVID vaccine maker pact, Biden vows wide vaccine access by May
- The Hill
 - o Biden administration buys 100,000 doses of Lilly antibody drug
- Bloomberg
 - o U.S. Steps Up Key Genetic Analysis for Covid Variants by 5,500%
 - o More Than 271 Million Shots Given: COVID-19 Tracker
- NPR
 - o Alaska Town Now Vaccinating Everyone 16 And Older
 - 'Neanderthal Thinking:' Biden Says Too Soon For States To Lift Mask Mandates
- The Wall Street Journal
 - How to Score a Vaccine Appointment: Recruit a College Kid with Tech Skills and Patience
 - o Some Covid-19 Tests' Blind Spots Point to Fast-Spreading U.K. Variant
 - o Covid-19 Vaccine 'Passports' Raise Ethics Concerns, Logistical Hurdles
 - o Support for Covid-19 Vaccine Passports Grows, With European, Chinese Backing
 - o Don't Be So Quick to Count on National Herd Immunity
 - o In Hunt for Covid-19 Origin, Patient Zero Points to Second Wuhan Market
- University of Edinburgh News
 - o Scottish vaccine roll-out working, data suggests
- Nature News
 - o J&J's single-dose COVID vaccine raises hopes for faster rollout
 - o Can COVID vaccines stop transmission? Scientists race to find answers
 - o Massive Google-funded COVID database will track variants and immunity
- Science News
 - o Unprotected African health workers die as rich countries buy up COVID-19 vaccines
 - o California coronavirus strain may be more infectious—and lethal
- BMJ News
 - o <u>Covid-19: Where are we on vaccines and variants?</u>



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STAT News

- o Johnson & Johnson's Covid-19 vaccine to start shipping soon, but early supply could be uneven
- o Moderna ready to test version of Covid-19 vaccine aimed at worrisome variant
- o Is more simply better? Why Pfizer thinks a booster of its Covid vaccine might work against new variants
- o To get ahead of variants, Covid-19 drug makers use evolutionary biology as a guide
- o STAT-Harris Poll: 1 in 4 Americans were unable to get a Covid-19 test when they wanted one

Medscape

- o Fauci Introduces New Acronym for Long COVID at White House Briefing
- Science Speaks: Global ID News
 - o Moderna to test a "multivalent" COVID vaccine as well as single-valent boosters
 - o <u>In March NIH will start the first variant-specific COVID vaccine study: Will this B.1.351-variant vaccine also induce some immunity to the P.1 variant?</u>

Moderna Press Release

- o <u>Moderna Announces it has Shipped Variant-Specific Vaccine Candidate, mRNA-1273.351, to NIH for Clinical Study</u>
- Pfizer Press Release
 - O PFIZER AND BIONTECH INITIATE A STUDY AS PART OF BROAD DEVELOPMENT PLAN TO EVALUATE COVID-19 BOOSTER AND NEW VACCINE VARIANTS
- Merck Press Release
 - o Merck Statement on Ivermectin use During the COVID-19 Pandemic
- AP News
 - o <u>Drug executives: Big jump in vaccine supply is coming soon</u>
 - High court tells Santa Clara it can't bar in-person worship
- KQED
 - o California Ends Coronavirus Testing Contract With Verily
 - o Newsom, Legislative Leaders Reach Deal Encouraging Schools to Reopen
 - o San Mateo County Leaders Push to Prioritize East Palo Alto for COVID-19 Vaccine

Los Angeles Times

- o <u>UC says Blue Shield sought 'expansive' patient data as part of its COVID-19 work for California.</u>
- o Harris coaxes Black communities to get vaccines, but distrust remains high.
- o California will reserve 40% of COVID-19 vaccine for disadvantaged areas to speed reopenings

San Francisco Chronicle

- o California, Bay Area officials hail Johnson & Johnson vaccine authorization
- o California's vaccine sites don't all require proof of eligibility, leaving room for line jumpers
- o Second case of worrisome South Africa variant found in Alameda County
- Congress is investigating One Medical over its vaccine distribution in San Francisco and other cities
- o Sutter Health may cancel up to 90,000 vaccine appointments because of insufficient supply
- o CDC study shows 68% of a gym's patrons infected during indoor classes
- o CDC warns of national rise in cases, but Bay Area is still dropping and counties are reopening
- o Once-cautious Bay Area counties moving swiftly to reopen. What's going on?





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EPIDEMIOLOGY UPDATES

- CDC COVID Data Tracker
 - o CDC COVID-19 Forecasts: Deaths
 - o United States COVID-19 Cases and Deaths by State
 - o CDC COVID Data Tracker: Vaccinations
 - o **NEW** CDC US COVID-19 Cases Caused by Variants
- US Leads the World in Confirmed COVID-19 Cases per <u>Johns Hopkins University Center for Systems Science</u> and Engineering Dashboard Website
- Johns Hopkins COVID-19 in the USA daily summary of key data on COVID-19 in the U.S.
- California COVID-19 by the numbers are available on the <u>CDPH Website</u> and the <u>NYT Map and Table</u> (includes data by county)
 - o California COVID-19 Statewide Update as of March 5, 2021
- San Mateo County COVID-19 Dashboard
- Santa Clara County COVID-19 Dashboard

ADDITIONAL COVID-19 RESOURCES

- San Mateo County COVID-19 Guidance and Resources for Clinicians and Facilities COVID-19 Digests
- Palo Alto Online tracking the coronavirus in San Mateo and Santa Clara counties
- California COVID-19 Data and Tools
- CDPH COVID-19 Assessment and Modeling Tool
- California Department of Corrections and Rehabilitations Population COVID-19 Tracking Dashboards
- CDC Interactive Serology Dashboard for Commercial Laboratory Surveys
- HHS Coronavirus Data Hub
- COVID-19 Nursing Home Data
- CDC COVID-19 Forecasts: Deaths
- Children and COVID-19: State-Level Data Report

