

September 30, 2021

Dr. Scott Morrow, Health Officer **Marc Meulman,** Director

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

CLINICAL PEARL

 The Western States Scientific Safety Review Workgroup reviewed the evidence concerning booster doses of the Pfizer-BioNTech COVID-19 vaccine presented at the meetings of the federal Vaccines and Related Biological Products Advisory Committee (VRBPAC) on September 17, 2021 and Advisory Committee on Immunization Practices (ACIP) on September 22 and 23, 2021 as well as the statement of CDC Director Rochelle Walensky on September 23, 2021.

To sustain protection against COVID-19, especially among those at increased risk for hospitalization and severe disease, the Workgroup concurred with CDC recommendations for a single Pfizer-BioNTech COVID-19 vaccine booster dose, given under FDA Emergency Use Authorization at least 6 months after a primary series for the following persons:

Those who **should** receive a booster dose:

- Age 65 years and older or residing in a long-term care facility, or
- Age 50 through 64 years with underlying medical conditions or at increased risk of social inequities.

Those who may receive a booster dose:

- o Age 18 through 64 years
 - with underlying medical conditions, or
 - who are at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting.

The Workgroup recognized that current federal authorization and guidance for a booster dose is currently limited to use of the Pfizer-BioNTech mRNA COVID-19 vaccine and asked FDA, CDC and ACIP to promptly find solutions to sustain the protection of vulnerable persons who have received the Janssen or Moderna COVID-19 vaccine, including the possible option of heterologous (mix and match) schedules.

PUBLIC HEALTH UPDATES

- Governors of California, Nevada, Oregon, and Washington State Statement on Pfizer Booster
- CDC <u>Statement on ACIP Booster Recommendations</u>
- FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations
- UK Government/ Public Health England
 - o JCVI issues updated advice on COVID-19 booster vaccination
 - o PHE: Duration of protection of COVID-19 vaccines against clinical disease, 9 September 2021
- WHO
 - o WHO calls on world leaders at the UN General Assembly to focus on vaccine equity, pandemic preparedness, and getting the SDGs back on track
 - International Organizations, Vaccine Manufacturers Agree to Intensify Cooperation to Deliver COVID-19 Vaccines
- IDSA and HIVMA Call for Greater U.S. Leadership in Accelerating Global Vaccine Equity
- PAHO selects centers in Argentina, Brazil to develop COVID-19 mRNA vaccines





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GUIDELINES/GUIDANCE

- CDC
 - o Who is Eligible For a COVID-19 Vaccine Booster Shot?
 - o <u>Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in</u> Nursing Homes
- CDPH
 - o COVID-19 Public Health Guidance for K-12 Schools in California, 2021-22 School Year (updated)
 - o K-12 Schools Guidance 2021-2022 Questions & Answers (updated)

RESOURCES

- CDC COCA Webinar:
 - What Clinicians Need to Know About the Latest CDC Recommendations for Pfizer-BioNTech COVID-19 Booster Vaccination
 - o Evaluating and Supporting Patients Presenting With Fatigue Following COVID-19
 - o <u>New Multisystem Inflammatory Syndrome in Children (MIS-C) Materials Available for Healthcare</u> Providers
- CDC/IDSA COVID-19 Clinician Call:
 - o Vaccine Boosters
 - o COVID-19 Treatment Update
- Center for Infectious Disease Research and Policy (CIDRAP) Osterholm Update:
 - o A Whole New Ball Game
 - o Corrected Science
- COVID-19 Scenario Modeling Hub
- Center on Reinventing Public Education School District Responses to COVID-19 Closures

ACADEMIC/RESEARCH PAPERS

- New England Journal of Medicine
 - o Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel
 - o Audio Interview: New Evidence on SARS-CoV-2 Vaccine Boosters
 - o SARS-CoV-2 Neutralization with BNT162b2 Vaccine Dose 3
 - o Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months
 - o Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel
- Nature
 - o <u>Safety and immunogenicity of SARS-CoV-2 variant mRNA vaccine boosters in healthy adults: an</u> interim analysis
 - o New-onset IgG autoantibodies in hospitalized patients with COVID-19
- medRxiv
 - o Effectiveness of the Single-Dose Ad26.COV2.S COVID Vaccine





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The Lancet

- o <u>Infections</u>, hospitalisations, and deaths averted via a nationwide vaccination campaign using the Pfizer–BioNTech BNT162b2 mRNA COVID-19 vaccine in Israel: a retrospective surveillance study
- Vaccination reduces need for emergency care in breakthrough COVID-19 infections: A multicenter cohort study
- o Considerations in boosting COVID-19 vaccine immune responses
- o Rapid COVID-19 vaccine rollout: immense success but challenges ahead
- Remdesivir plus standard of care versus standard of care alone for the treatment of patients admitted to hospital with COVID-19 (DisCoVeRy): a phase 3, randomised, controlled, open-label trial
- o Remdesivir, on the road to DisCoVeRy
- o <u>Daily testing for contacts of individuals with SARS-CoV-2 infection and attendance and SARS-CoV-2 transmission in English secondary schools and colleges: an open-label, cluster-randomised trial</u>
- Outpatient and inpatient anticoagulation therapy and the risk for hospital admission and death among COVID-19 patients

JAMA

- o <u>Safety and Antibody Response After 1 and 2 Doses of BNT162b2 mRNA Vaccine in Recipients of</u> Allogeneic Hematopoietic Stem Cell Transplant
- o <u>Humoral Immunity After mRNA SARS-CoV-2 Vaccination in Allogeneic HCT Recipients—Room for</u> Improvement and Much to Learn
- o <u>Assessment of Allergic and Anaphylactic Reactions to mRNA COVID-19 Vaccines With Confirmatory</u> Testing in a US Regional Health System
- o <u>Trajectory of COVID-19 Vaccine Hesitancy Over Time and Association of Initial Vaccine Hesitancy</u> With Subsequent Vaccination
- o Association of Nursing Home Characteristics With Staff and Resident COVID-19 Vaccination Coverage
- o Investigation of an Outbreak of COVID-19 in a French Nursing Home With Most Residents Vaccinated
- o Clinical Characteristics of Multisystem Inflammatory Syndrome in Adults A Systematic Review
- o <u>Assessment of a Program for SARS-CoV-2 Screening and Environmental Monitoring in an Urban</u> Public School District
- o <u>Risk Factors Associated With SARS-CoV-2 Infection Among Farmworkers in Monterey County,</u> California
- o <u>Factors Associated With Changes in Pregnancy Intention Among Women Who Were Mothers of</u> Young Children in New York City Following the COVID-19 Outbreak
- o Disrupted Family Plans and Exacerbated Inequalities Associated With COVID-19 Pandemic
- Evaluation of the Association Between Medicare Eligibility and Excess Deaths During the COVID-19
 Pandemic in the US
- o <u>Association of Patient Characteristics With Delivery of Ophthalmic Telemedicine During the COVID-19</u> Pandemic
- Trends in Outpatient Antibiotic Prescriptions in the United States During the COVID-19 Pandemic in 2020
- o Africa's COVID-19 Experience—A Window of Opportunity to Act

Emerging Infectious Diseases

- o <u>Effectiveness of BNT162b2 Vaccine in Adolescents during Outbreak of SARS-CoV-2 Delta Variant</u> Infection, Israel, 2021
- o <u>Large-Scale Screening of Asymptomatic Persons for SARS-CoV-2 Variants of Concern and Gamma Takeover, Brazil</u>



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COVID-19 Digest Issue 64

- o Multinational Observational Cohort Study of COVID-19-Associated Pulmonary Aspergillosis
- o Limited Protection of Inactivated SARS-CoV-2 Vaccine against Wuhan Strain and Variants of Concern
- o Postmortem Stability of SARS-CoV-2 in Mouse Lung Tissue
- Journal of Hospital Medicine
 - o Factors Associated With COVID-19 Disease Severity in US Children and Adolescents
- Clinical Infectious Diseases
 - o Infectious SARS-CoV-2 in Exhaled Aerosols and Efficacy of Masks During Early Mild Infection
 - o Risk of SARS-CoV-2 Transmission among Air Passengers in China
 - o <u>Understanding the Potential Impact of Different Drug Properties On SARS-CoV-2 Transmission and Disease Burden: A Modelling Analysis</u>
- Infection Control and Hospital Epidemiology
 - o <u>COVID-19 Vaccine Hesitancy among Physicians, Physician Assistants, Nurse Practitioners, and Nurses in Two Academic Hospitals in Philadelphia</u>
- International Journal of Epidemiology
 - o Quantifying impacts of the COVID-19 pandemic through life-expectancy losses: a population-level study of 29 countries
- Research Square
 - o <u>Coronaviruses with a SARS-CoV-2-like receptor-binding domain allowing ACE2-mediated entry into human cells isolated from bats of Indochinese peninsula</u>
- PLOS
 - o <u>Census tract socioeconomic indicators and COVID-19-associated hospitalization rates—COVID-NET surveillance areas in 14 states, March 1–April 30, 2020</u>
- PNAS
 - o Excess mortality from COVID and non-COVID causes in minority populations
- Peterson-KFF Health System Tracker
 - o <u>Unvaccinated COVID-19 hospitalizations cost billions of dollars</u>
- British Dental Journal
 - o New PPE mask range begins killing SARS-CoV-2 on contact

MMWR

- Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥16 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, September 2021
- Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in <u>Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions — United States, March—August 2021</u>
- Interim Estimates of COVID-19 Vaccine Effectiveness Against COVID-19—Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS-CoV-2 B.1.617.2 (Delta)
 Variant Predominance — Nine States, June—August 2021
- <u>Safety Monitoring of an Additional Dose of COVID-19 Vaccine</u> <u>United States</u>, <u>August 12–September 19</u>,
 2021
- New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status New York, May 3–July 25, 2021
- Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements United States, July 1— September 4, 2021



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- Association Between K–12 School Mask Policies and School-Associated COVID-19 Outbreaks Maricopa and Pima Counties, Arizona, July–August 2021
- COVID-19—Related School Closures and Learning Modality Changes United States, August 1—September 17,
 2021
- Post-Acute Sequelae of SARS-CoV-2 Infection Among Adults Aged ≥18 Years Long Beach, California, April
 1-December 10, 2020
- Outbreak of SARS-CoV-2 B.1.617.2 (Delta) Variant Infections Among Incarcerated Persons in a Federal Prison
 — Texas, July—August 2021
- <u>Disaggregating Data to Measure Racial Disparities in COVID-19 Outcomes and Guide Community Response</u> Hawaii, March 1, 2020–February 28, 2021
- <u>Longitudinal Trends in Body Mass Index Before and During the COVID-19 Pandemic Among Persons Aged 2–19 Years United States, 2018–2020</u>

HOT OFF THE (LAY) PRESS

- New York Times
 - Boosters for Moderna and Johnson & Johnson vaccine recipients weren't up for debate during a C.D.C. panel.
 - o <u>The F.D.A. authorized Covid booster shots for Pfizer vaccine recipients who are over 65 or at high risk, including because of job-related exposure.</u>
 - o The F.D.A. has made its move. Next question: Exactly who should get Pfizer boosters?
 - o Fauci urges Americans not to get booster shots until they are eligible
 - o Amid conflicting science on boosters, Biden's plan for extra shots is in flux
 - o Pfizer says its vaccine is safe for children 5 to 11. Will parents buy in?
 - Covid vaccine prompts strong immune response in younger children, Pfizer says
 - o <u>Pfizer said its coronavirus vaccine is safe and effective in young children. With F.D.A. authorization, millions of them may be immunized by Halloween.</u>
 - o Cuba will begin giving shots to children as young as 2.
 - o <u>The Biden administration will lift restrictions on fully vaccinated international travelers beginning in November.</u>
 - o Where are the tests?
 - o <u>'Every day is frightening': Working for the top U.S. employer amid COVID</u>
 - o Virus infections at a California jail quadruple in less than a week
 - o L.A. County will require proof of vaccination at drinking establishments.
 - o U.S. schools with mask requirements are seeing fewer outbreaks, the C.D.C. finds
 - o We Did the Research: Masks Work, and You Should Choose a Surgical Mask if Possible
- CDC Press Release
 - Studies Show More COVID-19 Cases in Areas Without School Masking Policies
- Pfizer Press Release
 - o PFIZER AND BIONTECH ANNOUNCE POSITIVE TOPLINE RESULTS FROM PIVOTAL TRIAL OF COVID-19 VACCINE IN CHILDREN 5 TO 11 YEARS
- Moderna Press Release
 - o Moderna Highlights New Clinical Data on its COVID-19 Vaccine
- Johnson and Johnson Press Release
 - o <u>Johnson & Johnson Announces Real-World Evidence and Phase 3 Data Confirming</u> Strong and Long-Lasting Protection of Single-Shot COVID-19 Vaccine in the U.S.





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- ABC News
 - o Pfizer CEO says it's possible to distribute both boosters and primary doses
- CBS News
 - o Gottlieb says vaccines could be approved for kids 5-11 by end of October
- Reuters
 - o England to offer COVID vaccine to all 12- to 15-year-olds
 - o British study to test mixed COVID-19 vaccine dose schedules in children
- The Economist
 - o Return to school has caused a surge in covid-19 cases in under-vaccinated counties
- The New Yorker
 - o <u>Teaching Without Masks and Vaccine Mandates</u>
 - o My Family Was a COVID Cluster
- The Washington Post
 - o Biden administration moves to stave off shortages of monoclonal antibodies
 - o White House lays out new global targets in coronavirus pandemic fight
 - o <u>The days of full covid coverage are over. Insurers are restoring deductibles and co-pays, leaving patients with big bills.</u>
- The Wall Street Journal
 - o NYC's Covid-19 Vaccination Proof Mandate for Restaurants and Dining: What to Know
 - o Biden Meets With Top Executives on Covid-19 Vaccine Mandate
 - o U.S. to Relax Covid-19 Travel Restrictions as Tensions Mount With Allies
- Politico
 - o Tensions mount between CDC and Biden health team over boosters
- AP News
 - o NY hospitals, schools fear staff shortage from vaccine rules
 - o Alaska's largest hospital implements crisis care standards
 - o COVID-19 creates dire US shortage of teachers, school staff
 - o Biden bets on rapid COVID tests but they can be hard to find
- NPR
 - o Is The Worst Over? Models Predict A Steady Decline In COVID Cases Through March
 - o The U.S. Will Require Would-Be Immigrants To Prove They've Been Vaccinated For COVID
- Bloomberg
 - o U.S. Racial Vaccine Gaps Are Bigger Than We Thought
 - o U.S. Covid Vaccinations Slide Again Ahead of Biden Mandates
- Medscape
 - o Doctors Divided About Need for COVID-19 Boosters: Poll
- Kaiser Health News
 - o Over Half of States Have Rolled Back Public Health Powers in Pandemic
- The Atlantic
 - o <u>Six Rules That Will Define Our Second Pandemic Winter</u>
- AXIOS
 - o America's mismatched COVID fears
- Los Angeles Times
 - o CDC endorses Pfizer booster shots for seniors and healthcare workers
 - o F.D.A. backs Pfizer COVID-19 vaccine boosters for seniors and those at high risk





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- o How California turned the tide and achieved the lowest coronavirus transmission rate in the U.S.
- o Average age of Californians dying of COVID-19 getting younger
- o Can California avoid another COVID-19 surge? Britain offers a sober warning
- o California COVID cases dropping, CDC says
- o Contra Costa County requires COVID vaccine proof or negative test for indoor restaurants, gyms
- o Big gap between Pfizer, Moderna vaccines seen for preventing COVID hospitalizations
- Mercury News
 - o Marin school families to get free at-home COVID test kits
- SF Gate
 - o SF schools have had no major COVID outbreaks. Here's why.
- San Francisco Chronicle
 - o CDC leader adds people with risky jobs to the booster list
 - o What COVID boosters mean for California's healthcare worker vaccination mandate
 - o One Bay Area county is approaching 100% of eligible residents with one COVID vaccine dose
 - o Here's what Bay Area children's hospitals are seeing a month after school reopened

EPIDEMIOLOGY UPDATES

- CDC COVID Data Tracker
 - o COVID-19 Vaccinations in the United States
- **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)
 - California COVID-19 Statewide Update as of September 30, 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
- Children and COVID-19: State-Level Data Report (New data!)
- HHS Coronavirus Data Hub
- COVID-19 Nursing Home Data

