

SERONEWS

Spring 2024

Clinical and Translational Serology Highlights

COVID-19 Vaccination in 2023 and Beyond

Limited Uptake of Updated
Vaccines Fuels Search for
More Options

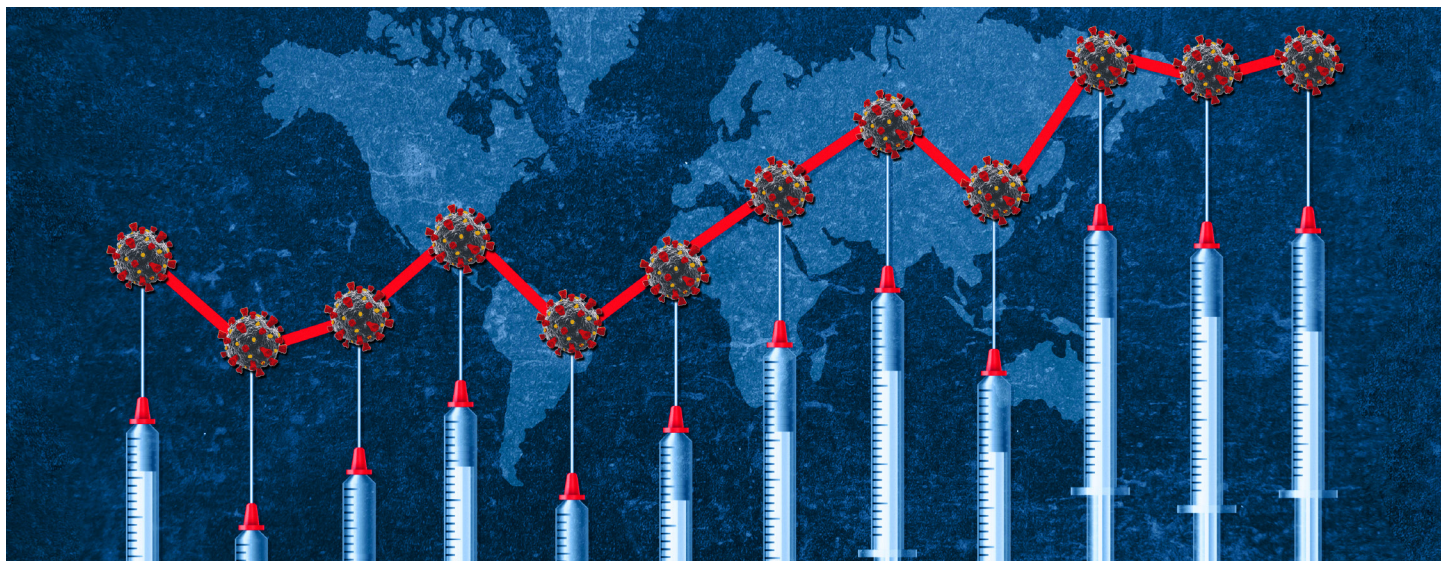


04 Hitting a
Moving Target

06 Living with HIV in the
Post-COVID-19 World

COVID-19 Vaccination in 2023 and Beyond

Limited Uptake of Updated Vaccines Fuels Search for More Options



The first updated monovalent SARS-CoV-2 vaccines were released last fall in anticipation of a winter COVID-19 surge. Since the U.S. government is no longer purchasing the vaccines for free distribution, vaccine rollout was uneven this time around as health care providers determined free-market pricing and consumers who were anxious to get the jab figured out which clinics and providers had them in stock.

However, as rollout challenges eased, it became evident that far fewer people than expected were making appointments to roll up their sleeves, leaving health care officials to puzzle out why, and how to address the problem.

The Clinical and Translational Serology Task Force hosted a meeting in December 2023 to hear from experts about the current vaccination landscape and the future of SARS-CoV-2 vaccine development.

Elisha Hall, Ph.D., R.D., and Megan Wallace, Dr.P.H., from the Centers for Disease Control and Prevention (CDC) presented current vaccine uptake statistics, strategies for increasing uptake, and a summary of the extensive process by which the new monovalent vaccine data were reviewed before approval.

John Beigel, M.D., from the National Institute of Allergy and Infectious Diseases (NIAID) presented a high-level overview of NIAID's trials to evaluate next-generation COVID-19 vaccines,

performed in support of [Project NextGen](#), a program designed to accelerate and streamline production of these next-generation vaccines via public-private collaborations.

The 2023–2024 Monovalent Vaccines

The U.S. Food and Drug Administration (FDA) [approved](#) updated COVID-19 vaccines (2023–2024 formula) from [Pfizer](#) and [Moderna](#) (monovalent mRNA-based) and the protein-based [Novavax](#) COVID-19 vaccine in fall 2023.

The [CDC recommends](#) that everyone aged 5 years and older get one dose of updated vaccine, and notes that children aged 6 months to 4 years need multiple doses to be up to date, including at least 1 dose of updated COVID-19 vaccine to protect from serious illness. People with immunocompromising conditions may also get additional doses.

The CDC developed these guidelines by reviewing information presented in its standard [Evidence to Recommendation Framework](#): the extent of the public health problem caused by the prevailing SARS-CoV-2 strains, the potential benefits and harms of the vaccines under evaluation, and the acceptability of those vaccines.

Also guiding the CDC were preliminary studies indicating that the [updated vaccines would be effective against many of the variants](#) circulating at the time.

Death and hospitalization rates due to COVID-19 were, and continue to be, a substantial concern to the CDC. Although lower than in previous years of the pandemic, [hospitalization rates](#) in January 2024 were 22,000–35,000 a week. In 2023, there were 75,692 [COVID-19-associated deaths](#) in the United States.

Finally, the CDC developed [platforms](#) to accurately measure COVID-19 vaccine effectiveness and inform critical COVID-19 vaccine policy decisions. [Modeling](#) published by the [COVID-19 Scenario Modeling Hub](#) in coordination with the CDC in June of 2023 demonstrated that universal vaccination would prevent 230,000 more hospitalizations and 21,000 more deaths over the next two years compared to only vaccinating patients aged 65 and older.

Uptake Is Concerningly Low

Despite CDC's extensive measures to ensure vaccine safety and efficacy and support vaccination efforts, uptake of the updated vaccines has been quite low.

As of the end of January, estimates indicated that around 12% of children in the United States aged [6 months to 17 years](#) old received the updated vaccine, with the youngest children having the lowest vaccination rates. Only an estimated 22% of [adults](#) took the vaccine, with rates ranging from about 9% in 18–29 year-olds to about 37% in patients 65 years and older.

COVID-19 Vaccination in 2023 and Beyond continues on next page.

COVID-19 Vaccination in 2023 and Beyond (cont.)

Wide disparities in vaccination rates also broke down along other lines.

Hispanic individuals had the lowest estimated coverage rate at about 13%, while White, non-Hispanic individuals had a coverage rate of about 25%.

Insured individuals had an estimated 23% coverage rate compared to 7% for the non-insured.

Individuals living below the poverty line had coverage estimates at 13%, while those with incomes greater than \$75,000 a year had roughly double the coverage at 27%.

These collective uptake numbers are severely low, and the CDC is implementing and recommending a number of strategies to increase uptake.

CDC Strategies for Increasing COVID-19 Vaccine Uptake

So, how to remedy this problem? Identify the challenges involved and tailor solutions to meet them.

Among the challenges to COVID-19 vaccine uptake, vaccine cost, vaccine coadministration, vaccine equity, and vaccine demand are of particular importance to the CDC.

Vaccine cost issues were addressed fairly promptly after rollout. The vaccine's cost is covered for those enrolled in Medicaid and Medicare and most private insurance companies. For those without health insurance, the [Vaccines For Children](#) and [Bridge Access](#) programs currently provide no-cost vaccines for qualifying children and adults, respectively.

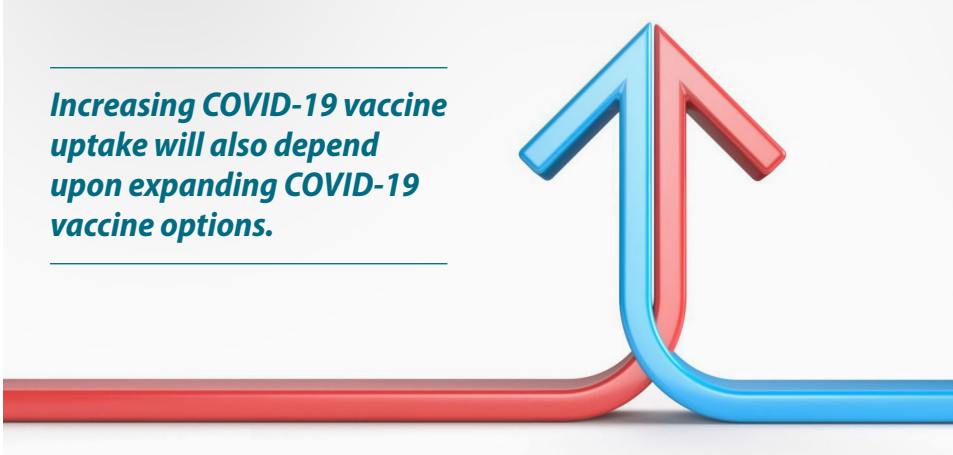
Vaccine coadministration, which officials believe [can increase overall vaccine uptake](#), proved to be a difficult sell for this winter's seasonal vaccines. Many people had already received the [flu vaccine](#) by the time the updated COVID-19 vaccines became available. In addition, those who were already skeptical of COVID-19 vaccine safety doubted the safety of combining it with another shot and declined to do so. The CDC is tackling this hurdle through providing education and [messaging](#) to the public and health care providers on the benefits of coadministration, specific guidance on coadministration decisions, and best practices for coadministration.

Racial and socioeconomic disparities in vaccine uptake are being addressed through partnerships with trusted messengers (such as community leaders) to provide culturally appropriate messaging and communications campaigns, as well as promoting the [Bridge Access Program](#) and [Vaccines for Children](#) as community resources.

Lastly, the largest and most reported challenge to vaccine uptake is low demand. Research shows that [COVID-19 vaccination rates increase when vaccine hesitancy decreases](#). However, some people still have concerns about vaccine safety, negative side effects, the rapid development of the vaccines, and uncertainty regarding its effectiveness. [Public confidence](#) in COVID-19

[Project NextGen](#) is based at the U.S. Department of Health and Human Services (HHS) and led by the Administration for Strategic Preparedness and Response (ASPR) [Biomedical Advanced Research and Development Authority](#) (BARDA) and NIAID. The [program](#) coordinates federal government and private sector resources to advance the pipeline of new, innovative vaccines and therapeutics into clinical trials, as well as potential review by the FDA for authorization or approval for commercial availability to the American people.

Project NextGen included a call from BARDA for companies and products in, or ready for, clinical trials. More than 64 respondents have submitted candidates for the program



Increasing COVID-19 vaccine uptake will also depend upon expanding COVID-19 vaccine options.

vaccine safety is still an issue, and uptake is [lower](#) than for other routine adult vaccines, such as influenza.

To deal with this complex issue, the CDC is employing extensive outreach strategies: monitoring and correcting inaccurate health information in the public domain, engaging in [evidence-based outreach efforts](#) to boost vaccine confidence, and utilizing intervention [strategies](#) such as vaccine ambassadors, medical reminders, motivational interviewing, financial incentives, and school and workplace vaccination programs.

Seeking More Options: Project NextGen

Increasing COVID-19 vaccine uptake will also depend upon expanding COVID-19 vaccine options.

thus far. NIAID and extramural investigators collaborate to prioritize candidates that meet Project NextGen criteria, and when a product is selected for the program, NIAID will sponsor further study for development and possible regulatory review.

What's in the Pipeline Now?

A few vaccine candidates [have already been selected for sponsorship](#) by Project NextGen: CastleVax (vector-based), Codagenix (live-attenuated intranasal), and Gritstone Bio (self-amplifying mRNA).

Project NextGen has also awarded funding for supporting resources and developing new technology. Funded supporting resources include American Type Culture Collection for cell culture and specimen management,

COVID-19 Vaccination in 2023 and Beyond continues on next page.

COVID-19 Vaccination in 2023 and Beyond (cont.)

BioInfoExperts for genomic sequencing, Meso Scale Diagnostics for COVID-19 antibody test kits, and Thermo Fisher Scientific's Pharmaceutical Product Development to provide central laboratory capacity.

New technologies for national preparedness under development with Project NextGen funding include Vir Biotechnology for mRNA-expressed monoclonal antibodies, Luminary Labs for vaccine patch development, ModeX Therapeutics for a prophylactic COVID-19 monoclonal antibody, Charles Stark Draper Laboratory for tissue chip platform

technology, Battelle and the UK Health Security Agency for human lung and airways tissue chip platforms, and Evidation for early respiratory illness detection wearables.

Tackling the issues of adapting vaccination approaches to protect against SARS-CoV-2 infection and developing effective COVID-19 treatments requires innovative thinking and collaborative efforts to produce the best available vaccines and therapeutics that will help fight back against this ever-changing virus.

Project NextGen's rigorous, agile process for responsibly pushing vaccine development, in

tandem with detailed review processes used by regulatory bodies and policymakers to develop vaccine recommendations, should improve confidence in approved vaccines. Public embrace of these health care tools will be key in mitigating SARS-CoV-2 transmission and preventing further hospitalization and death due to COVID-19.

Hitting a Moving Target

Scientists Grapple with SARS-CoV-2 Viral Mutation and Evolution Landscape



The U.S. made major strides in combating the COVID-19 pandemic when the FDA approved the original SARS-CoV-2 vaccines in 2021. Hospitalization rates and death due to COVID-19 significantly decreased in vaccinated populations.

However, infections continued to occur, and SARS-CoV-2's mutation rates resulted in several new variants of concern (VOCs) that were resistant to neutralization by antibodies elicited by the original vaccine. Booster vaccines formulated against these

variants provided updated protection, but the virus' continued evolution has made it hard to predict the most effective vaccine targets.

To respond to this challenge, scientists are working to track and better understand these

Hitting a Moving Target continues on next page.

Hitting a Moving Target (cont.)

different variants, with the goal of better mitigating future outbreaks.

Tracking SARS-CoV-2 Variants

The CDC, the nation's leading science-based, data-driven service organization that protects the public's health, [tracks SARS-CoV-2 variants](#) through several complementary surveillance systems.

The [National SARS-CoV-2 Genomic Surveillance System](#) provides a regular, comprehensive, population-based surveillance strategy to track viral evolution and identify emerging variants. Deidentified specimens from a portion of SARS-CoV-2-positive patients get shipped from public health laboratories to the CDC via the CDC National SARS-CoV-2 Strain Surveillance (NS3) System. Samples are processed and sequenced, and the resulting viral genomic data are submitted to public repositories as an open resource for the scientific community.

Since being established in September 2020, the CDC's [National Wastewater Surveillance System](#) (NWSS) has coordinated and built the nation's capacity to track SARS-CoV-2 virus shedding in community wastewater. It plays a large role in variant tracking in the U.S., as it allows for observation of viral signatures present in the population in real-time. Meant to work in conjunction with other surveillance systems, this program

partnership spans six international airports to promptly detect new SARS-CoV-2 variants (and other pathogens) and fill gaps in global biosurveillance. Staff administer a short survey and collect individual nasal swab samples from travelers who volunteer to participate. The samples are shipped to a laboratory network for RT-PCR viral testing, followed by viral genome sequencing of SARS-CoV-2-positive samples to classify the variant. Select samples are then shared with CDC laboratories for further viral characterization to understand a variant's transmissibility, virulence, and susceptibility to treatments or vaccines. The program also routinely tests airplane wastewater.

These strategies have kept the CDC up to date on the development and spread of SARS-CoV-2 variants while virologists work to understand the drivers of the virus' evolution.

Understanding SARS-CoV-2 Evolution

The evolution of SARS-CoV-2 has spawned an [extensive family tree](#), with different VOCs, such as Gamma, Delta, and Omicron, driving additional surges in infections. Omicron, which was first identified in late 2021, in turn generated multiple subvariants, several of which caused their own surges.

These branches in lineage are characterized by mutations in genes with important

behind [viral fitness advantage](#), as well as the forces driving the mutations that generate different variants and subvariants.

The [evolutionary pressures that host immunity](#) places on SARS-CoV-2 infection may in part drive the characteristics of emerging VOCs. In addition, long-term infections, such as those sometimes experienced by immunocompromised hosts, can be a potential source of variant emergence and are thought to influence the evolutionary dynamics of SARS-CoV-2. Different variants have also [evolved convergent strategies](#) to suppress the host's innate immune response, suggesting that this suppression is integral to SARS-CoV-2's success in the greater population.

There are [several theories](#) as to how Omicron developed such a unique mutation profile, but we're still far from fully understanding its emergence and predicting accurately what the next variants will look like.

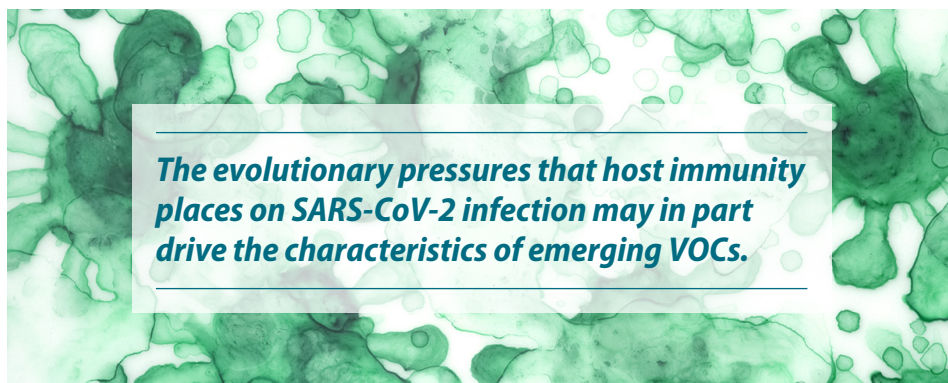
There are additional evolutionary pressures on the virus beyond those from the host. External interventions, such as isolation and quarantine practices, antiviral therapy, and vaccination, can also influence viral evolution.

For instance, isolating infected individuals can help contain and slow viral outbreaks, but can also [select for viral characteristics](#) that can circumvent these strategies, including a decreased incubation period and an increased proportion of asymptomatic infections.

In addition, antiviral treatments meant to help the severely ill or immunocompromised can introduce additional mutations. Molnupiravir, an antiviral drug licensed by several countries to treat COVID-19, functions by creating mutations in the virus that normally result in its death or dysfunction. Interestingly, studies have begun to [identify a mutational signature](#) of SARS-CoV-2 in populations treated with molnupiravir, suggesting that mutations from such therapies may also shape viral evolution.

Predicting the Future

Early detection strategies can [only make so much of a difference for rapidly spreading diseases](#). Consequently, the [continuing development](#) of SARS-CoV-2 vaccination technology, which depends on being able to



has enabled timely community sampling to add to the library of clinical samples used to track the virus.

Furthermore, the CDC has implemented its [Traveler-based SARS-CoV-2 Genomic Surveillance program](#). Led by the CDC's Travelers' Health Branch, this public-private

partnership spans six international airports to promptly detect new SARS-CoV-2 variants (and other pathogens) and fill gaps in global biosurveillance. Staff administer a short survey and collect individual nasal swab samples from travelers who volunteer to participate. The samples are shipped to a laboratory network for RT-PCR viral testing, followed by viral genome sequencing of SARS-CoV-2-positive samples to classify the variant. Select samples are then shared with CDC laboratories for further viral characterization to understand a variant's transmissibility, virulence, and susceptibility to treatments or vaccines. The program also routinely tests airplane wastewater.

Scientists have evaluated these variant lineages to try to understand the mechanisms

Hitting a Moving Target (cont.)

predict future important viral targets, is our best defense.

Multiple groups have been working to develop prediction or forecasting models based on [pre-pandemic data](#), [population immunity patterns](#), and [viral structure](#). One example of a model designed to forecast viral escape is called [VEscape](#), which uses a deep learning model to study the population-level

evolution of past viruses and predict how dangerous specific SARS-CoV-2 variants could be. This model could also be used to study other viruses, such as influenza or HIV.

Other models use [within-host diversity](#) from single patients to develop more accurate and comprehensive genetic tracing of viral variants through a population. In addition, some models predict variant trends based

on [pressures from the host immune system](#), including immunity from previous vaccination or infection. In the meantime, the mutation patterns seen in SARS-CoV-2 VOCs further highlight the importance of vaccination.

Living with HIV in the Post-COVID-19 World

Boosters Are Key but Underutilized



While the entire world felt the impact of the COVID-19 epidemic, some patient populations, such as the immunocompromised, were at the highest risk. PLWH, or people living with the human immunodeficiency virus (HIV), were particularly vulnerable as the medical community they already heavily relied on became even more stretched by SARS-CoV-2 infections and hospitalizations.

Efforts were undertaken to help. For instance, the [President's Emergency Plan for AIDS Relief \(PEPFAR\)](#), which was instituted by the U.S. government in 2003 as the largest

commitment by any nation to address a single disease, quickly began plans to ensure continued HIV care.

PEPFAR [announced four priorities](#) in the context of the pandemic: ensure continuity of care for PLWH, leverage PEPFAR-supported health systems and infrastructure to strengthen the COVID-19 response, reduce exposure of staff and PLWH to health care settings that may be overburdened and/or sources for potential COVID-19 exposure, and provide flexibility for PEPFAR programs to optimally serve PLWH in areas affected by

COVID-19. PEPFAR also received an additional [estimated \\$3.8 billion](#) in emergency funding in the 2021 fiscal year to help combat COVID-19.

Still, much research was needed to comprehend and directly target the effects of COVID-19 in PLWH. The understanding of this complex issue has begun to crystallize.

Does COVID-19 Vaccination Work for PLWH?

Studies have shown that the outcome of a SARS-CoV-2 infection in unvaccinated PLWH heavily depends on [how well controlled](#) the

Living with HIV continues on next page.

Living with HIV in the Post-COVID-19 World (cont.)

HIV is. For vaccinated PLWH, the antibody response following the primary COVID-19 vaccination series seems to be significantly lower in PLWH with [low CD4 T-cell counts](#) or [CD4/CD8 ratios](#) compared to those with preserved CD4 T-cell counts. A [booster dose of vaccine](#) increased antibody responses in PLWH, although, again, antibody titers [appear to be lower](#) in those with lower CD4 T-cell counts and more severe immunosuppression.

Current Vaccine Recommendations for PLWH

The [CDC](#) recommends that everyone follow the current universal vaccine [guidance for COVID-19](#): either an initial, one-dose vaccination with one of the new vaccines (two doses if 6 months to 4 years old) or, in people who've already been vaccinated, a booster shot. However, people with acquired immunodeficiency syndrome (AIDS) or PLWH who are not on anti-HIV therapy are [advised](#) to follow [CDC recommendations for immune-compromised people](#), meaning that unvaccinated people should receive two to three doses of the updated monovalent 2023–2024 vaccine.

[NIH COVID-19 treatment guidelines](#) recommend COVID-19 vaccination for PLWH regard-

less of their CD4 counts, as the potential benefits outweigh the potential risks, but also note that clinicians treating COVID-19-positive PLWH should consult with an HIV specialist before adjusting or switching the person's antiretroviral therapy (ART) medications.

Vaccination Rates in PLWH Are Concerningly Low

Vaccination [rates](#) in PLWH have varied greatly globally, depending on demographics and geographical region, but remain low overall. [PLWH in resource-limited areas](#) are less likely to be fully vaccinated, whereas those who live in high-income areas are more likely to be vaccinated. In addition, [among PLWH](#), those who are older, are White or male, of higher body mass index or cardiovascular risk, and who've been taking ART for a longer period are also more likely to be vaccinated. PLWH vaccination rates did not appear to differ by CD4 T-cell counts.

Roughly [32%](#) of individuals in the United States with health conditions associated with a higher risk for COVID-19 had received the updated 2023–2024 COVID-19 vaccine by December 30, 2023. While higher than uptake in the general population ([~21%](#)), these

numbers fall short of the [current recommendation](#) that all PLWH receive at least one dose of the new monovalent vaccine. Similar trends of low adherence were seen for the monovalent mRNA boosters in [immunocompromised patients](#) from a large integrated U.S. health care system. In PLWH in this cohort, only about one-third received a fourth dose of monovalent mRNA booster vaccine, and less than 1% received a fifth dose (as of August 2022). This gap is especially concerning for people with uncontrolled HIV, as it puts them at risk for higher rates of breakthrough infections and hospitalization.

It is of particular importance that these populations receive targeted messaging and [vaccine uptake interventions](#) to be better served by the resources available to them.

NIH COVID-19 treatment guidelines recommend COVID-19 vaccination for PLWH regardless of their CD4 counts, as the potential benefits outweigh the potential risks...



Past Events



Monthly Meetings

- Tues, 11.14.23 ***SARS-CoV-2 Reservoir in Post-Acute Sequelae of COVID-19 (PASC)***
Dr. Amy Proal, PolyBio Research Foundation
Persistent Serum Protein Signatures Define an Inflammatory Subcategory of Long COVID
Aarthi Talla, Allen Institute for Immunology
Impact of Anti-SARS-CoV-2 Monoclonal Antibody Therapy on Post-COVID Outcomes in the ACTIV-2 Platform Trial
Dr. Teresa Evering, Weill Cornell Medicine
Effectiveness of Nirmatrelvir-Ritonavir Against the Development of Post-COVID-19 Conditions Among U.S. Veterans: A Target Trial Emulation
Dr. Kristina Bajema, VA Portland Health Care System
- Tues, 12.12.23 ***COVID-19 Vaccination Uptake and Efforts to Increase Coverage***
Dr. Elisha Hall, Centers for Disease Control and Prevention
Evidence to Inform COVID-19 Vaccine Policy
Dr. Megan Wallace, Centers for Disease Control and Prevention
NIAID Trials to Evaluate Next Generation COVID-19 Vaccines Part of Project NextGen
Dr. John Beigel, National Institute of Allergy and Infectious Diseases
- Tues, 1.9.24 ***SARS-CoV-2 Variants Evolve Convergent Strategies to Remodel the Host Response***
Dr. Mehdi Bouhaddou, University of California, Los Angeles
A Signature of Molnupiravir Mutagenesis in Global SARS-CoV-2 Sequencing Databases
Dr. Theo Sanderson, Francis Crick Institute
- Tues, 2.13.24 ***Immunity to SARS-CoV-2 During the First Weeks and Months of Life***
Dr. Florian Wimmers, University of Tübingen
Open Aspects in Pediatric COVID-19: Adaptive Immunity Response to SARS-CoV-2 Infection
Dr. Gioacchino Andrea Rotulo, Bambino Gesù Children's Hospital
Texas Coronavirus Antibody REsponse Survey (CARES): Pediatric Key Findings to Date
Dr. Sarah Messiah, University of Texas Health
- Tues, 3.12.24 ***Characterization of the Antibody Response to SARS-CoV-2 in Lung Cancer Patients***
Dr. Ananda Rodilla, Icahn School of Medicine at Mount Sinai
Immune and Psychosocial Health of Patients with Cancer: Results from the SeroNet-CORALE Study
Dr. Jane Figueiredo, Cedars-Sinai
Exposure of Progressive Immune Dysfunction by SARS-CoV-2 mRNA Vaccination in Patients with Chronic Lymphocytic Leukemia
Dr. Randall Davis, University of Alabama at Birmingham



Round Table Meetings

- Mon, 2.26.24 **Topic: COVID-19 and HIV**
Persistent SARS-CoV-2 Infection in the Immunocompromised Host
Dr. Anna Riddell, Barts Health NHS
Association Between SARS-CoV-2 RNAemia, Skewed T-Cell Response, Inflammation, and Severity in Hospitalized COVID-19 People Living with HIV
Dr. Giulia Marchetti, University of Milan
The COVAXHIV Study: Vaccine Immunogenicity and Vaccine Effectiveness in People with HIV in Canada
Dr. Cecilia Costiniuk, McGill University Health Centre
Dr. Ann Burchell, St Michael's Hospital, Unity Health Toronto and the University of Toronto
Post-Acute COVID Symptoms, Cognition, and Antibodies in People Living with and without HIV
Dr. Annie Antar, Johns Hopkins University

Upcoming Events

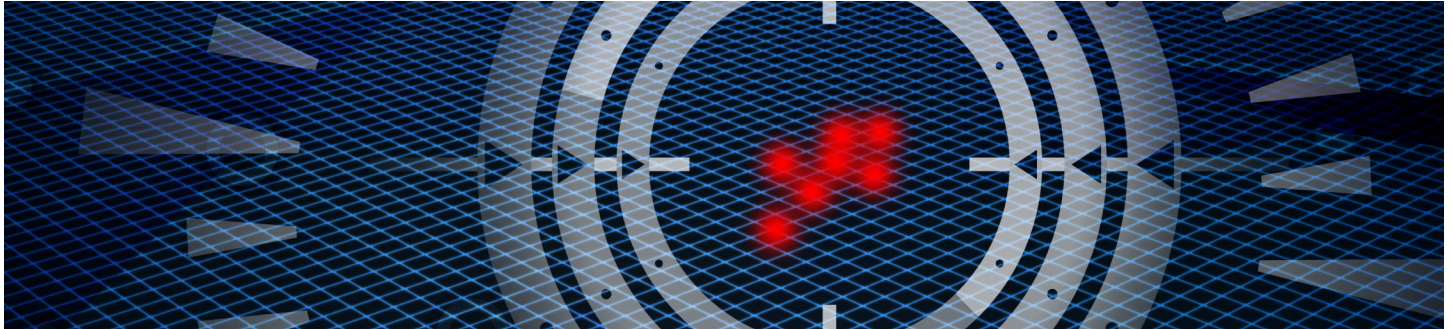
Monthly Meeting: Tuesday, April 9, 2024

Round Table Meeting: Monday, April 22, 2024



The Target Continues to Move, and We Must Move with It

Four Years into the Pandemic, Increased Vaccine Uptake Remains Crucial to Combating an Evolving Virus



The Clinical and Translational Serology Task Force has been regularly meeting to discuss SARS-CoV-2 viral evolution, the scientific community's understanding of immune responses to vaccination in immunocompromised people, and advances in vaccine development.

In the last four years, SARS-CoV-2 has caused over 700 million infections, leading to over 7 million deaths globally. COVID-19 continues to circulate in the U.S., where it resulted in more than 22,000 hospitalizations and over 900 deaths during the last week in January.

Since its emergence, SARS-CoV-2 has continued to mutate and spread. As of

February 2024, most new COVID-19 cases in the U.S. were caused by the emerging JN.1 variant. Although protection gained through past COVID-19 infection or vaccination declines over time, vaccination remains the best defense against COVID-19-related hospitalization and death. Recent data from the CDC demonstrate that the updated 2023–2024 COVID-19 vaccine provides enhanced protection against symptomatic infection caused by the variants currently responsible for most infections and hospitalizations in the U.S., including JN.1.

However, the vaccination rate with the new shot has been quite low in the U.S., with only

22% of adults and 12% of children having received it by the end of January despite it being recommended for everyone aged six months and older. Although it would have been better for more people to be vaccinated earlier, it's not too late to get vaccinated.

We continue to look forward to meeting and continuing the unique discussion, engagement, and collaboration afforded by this community. As always, we welcome your suggestions, comments, and requests!



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Editorial note: The data and hyperlinks provided in this issue of SeroNews are accurate as of the publication date, but may be subject to change in the future.