

Getting to and Sustaining the Next Normal

A Roadmap for Living with COVID



March 2022
















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Executive Summary

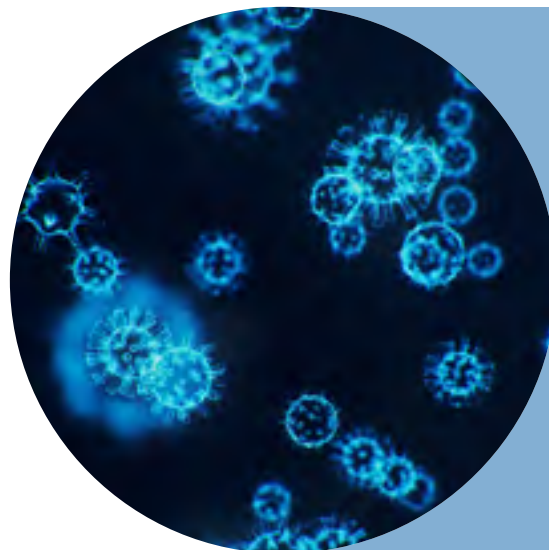
Covid has been raging for 2 years. Multiple variants have emerged. Worldwide, hundreds of millions of people have been infected, millions have died, and untold numbers have developed long Covid. Covid has disproportionately affected communities of color, those living in poverty, and those in less developed countries. Covid has disrupted education and led to significant learning loss. And, there has been tremendous economic dislocation, millions of people thrust into poverty, and the loss of tens of trillions of dollars from the world economy. Importantly, effective vaccines and therapeutics have helped make progress combatting the virus, but cases and deaths still remain high.

As the pandemic enters its third year, two factors have become critical. One is fatigue. People are tired of restrictions used to fight Covid. Simultaneously, the virus continues to surprise experts and make it challenging to anticipate what lies ahead. In all cases, the world must be better prepared.

In 2022, it is possible for a new variant of concern to emerge. But greater population immunity increases the probability of a lower disease burden, lower strain on the health system, and fewer deaths, if waning immunity or immune evasion do not become significant factors.

The United States' pandemic phase—with restrictive public health measures—can end when average daily deaths due to Covid and other major respiratory illnesses decline below 0.5 per 1 million Americans, or 165 deaths a day at a national level. At that point, the United States can transition into the next normal, although individual regions may be able to make earlier transitions, depending on local Covid metrics.

But on March 1, 2022, the nation is not yet at the next normal. The shift to the next normal should not induce complacency, inaction, or premature triumphalism. To rapidly reach and sustain the next normal, the country must implement a comprehensive and coordinated roadmap to both address this pandemic and develop the capacity to confront future biosecurity threats.



The following 12 elements constitute the fundamental core of this Roadmap and are elaborated in this report.

1. Major Respiratory Viral Illnesses

Shift the focus from Covid to major respiratory viral illnesses like flu and RSV infection, with the interim goal of reducing annual deaths below the worst influenza season in the last decade. Even in a pessimistic scenario, the next 12 months are likely to see about half the deaths from Covid compared to 2020 or 2021. But this should not lead to complacency, as unexpected viral changes may occur. There are concrete steps the U.S. can take to increase the chances of this outcome. (*Chapter 2: Possible Scenarios*)

2. Dashboard

Create, maintain, and disseminate a transparent infectious diseases dashboard to guide both the public and policymakers at the national, state, and local levels on the introduction, modification, and lifting of public health measures. The dashboard should also provide guidance on the distribution of therapeutics and other special protections for the immunocompromised, elderly, and other vulnerable populations. (*Chapter 1: Next Normal*)

3. Testing, Surveillance, and Data Infrastructure Increase

Increase surge production capacity for at-home rapid tests to 1 billion per month. Establish a test-to-treat infrastructure that links all testing with high sensitivity and specificity to immediate medical consults and appropriate treatment, clinical trial enrollment, and public health guidance. Invest in a substantial upgrade of the data collection and analysis infrastructure for pathogen surveillance at the local, state, and national levels. Implement standardization and timely collection, analysis, and public sharing of data from expanded and enhanced environmental, genetic, and zoonotic monitoring systems, including those involving wastewater and deer. In addition, establish and sustain infrastructure to rapidly collect and analyze population immunity data. (*Chapter 3: Testing and Surveillance; Chapter 9: Health Data Infrastructure*).

4. Indoor Air Quality

Direct the Environmental Protection Agency (EPA) and Occupational Safety and Health Administration (OSHA) to develop standards to improve indoor air quality and protect workers from inhalation exposure. Direct states and localities to use American Rescue Plan and other appropriated funds to upgrade ventilation and air filtration in schools, childcare facilities, and public buildings. (*Chapter 4: Cleaner, Safer Indoor Air*)



5. Vaccines and Therapeutics

Support the development of new, more effective therapeutics, especially multi-drug oral antivirals, and next generation vaccines, especially mucosal and pancoronavirus designs. Develop a test-to-treat platform to ensure rapid and equitable access to treatments for the most vulnerable populations and reduce disparities. (*Chapter 6: Vaccines; Chapter 7: Therapeutics*)

6. Global Investment

Shift the goal of U.S. contributions to the global vaccination effort from stopping infections through population vaccination coverage alone to improving the distribution and administration infrastructure necessary to fully vaccinate the most vulnerable people in low- and middle-income countries. (*Chapter 6: Vaccines*)

7. Long Covid

Rapidly coordinate and expand research on long Covid, to produce data and biospecimens available through open science, with specific emphases on the INSPIRE and RECOVER studies. Aim to generate definitive answers to fundamental questions on frequency, risk factors, prognosis, and the benefits of vaccines and therapies for long Covid, within the next year. Augment social, financial, and health supports for individuals affected by long Covid. (*Chapter 8: Long Covid*)



8. Equity

Better address health disparities by creating a permanent cadre of community health workers to support vulnerable populations highly susceptible to adverse outcomes from viral respiratory illnesses and leveraging trusted community groups such as faith-based organizations. (*Chapter 10: Public Health Infrastructure*)



9. Workforce

Expand and support the public health and health care workforces through improved wages, health benefits (including mental health), tuition assistance, loan forgiveness, and safe working conditions. Incentivize the accelerated adoption of automation for routine chores and paperwork. To institutionalize both virtual care and various forms of home care, extend and expand regulatory policies and reimbursement flexibilities. Ensure that a flexible pool of workers is available in emergencies. (*Chapter 10: Public Health Infrastructure; Chapter 11: Healthcare Workforce; Chapter 14: Worker Safety*)

10. Biosecurity and Pandemic Leadership

Create the post of Deputy Assistant to the President for Biosecurity (within the National Security Council), responsible for preparing for, monitoring, addressing, and coordinating responses to and communications about any biosecurity and pandemic threats. This post should coordinate efforts to counter foreign and domestic sources of anti-science misinformation on vaccines and drugs. (*Chapter 12: Communications and Education*)

11. Communication

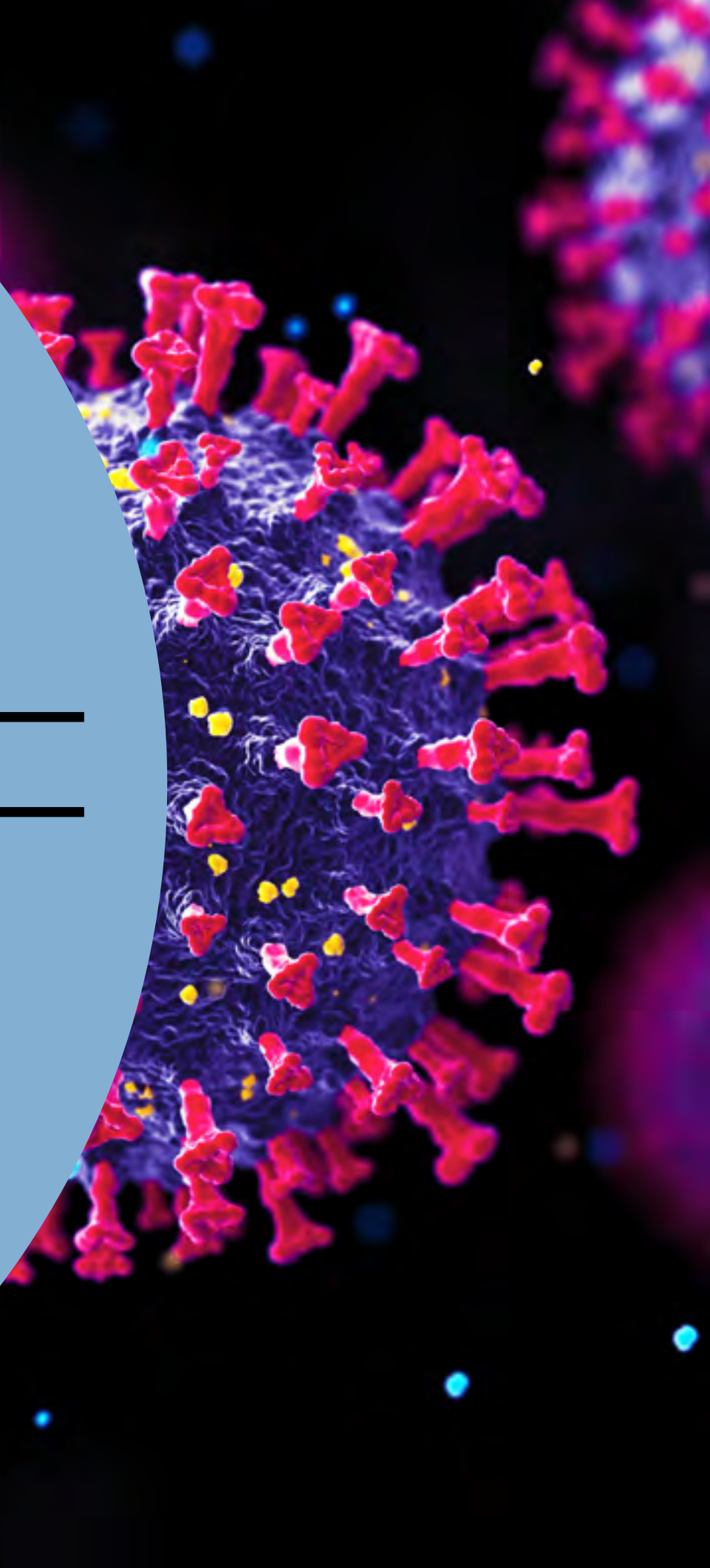
Implement a comprehensive, scientifically-tested communication and behavioral intervention infrastructure to increase vaccination, testing, and treatment, especially among vulnerable groups. (*Chapter 12: Communication and Education*)

12. Schools and Childcare

Governments should not close schools and childcare facilities unless all other community mitigation measures fail. Implement policies and programs, such as improved air filtration and expanded school nurse programs, that enable schools and childcare facilities to remain open and safe for in-person instruction and care without the need for special public health mitigation measures. Target program implementation assistance to schools in communities with the greatest need. (*Chapter 13: Schools and Childcare*)



Introduction



After nearly two years of tragic deaths, missed family reunions, shuttered schools, disrupted workplaces, and social isolation, Americans are exhausted with the Covid pandemic.

This fatigue has led *some* to throw caution to the wind. They are dining indoors at crowded restaurants, attending concerts and theaters, and even protesting vaccine and mask mandates. During Super Bowl LVI, millions gathered at homes and bars to watch the game with family and friends.

Many others are still deeply worried. They want to put Covid behind them but fret about their unvaccinated children, elderly family members, and their own risks of contracting long Covid. They remain vigilant — not yet dining indoors or inviting friends over for dinner. They withdraw their children from school and childcare when Covid cases arise. And they routinely swab their noses and those of their children to check infection status with at-home tests. Some immunocompromised individuals have had to alter their entire existence and fear they may never be able to go outside again.

Much of the country sits somewhere in between, with many making decisions on-the-fly about whether certain activities and gatherings are worth risking. These are the Americans who last summer cautiously began to travel, eat indoors, and resume social activities, only to hastily reverse course with the rise of Delta and then Omicron. Now that cases are declining again and the severity of symptoms from Omicron appear mild in the vaccinated or previously infected, they are venturing out despite high rates of death.

Everyone pines for their pre-pandemic routines and lives.

Regardless of where they fall on this spectrum, everyone pines for their pre-pandemic routines and lives. They want to know how and when they can return to those familiar and well-worn paths for themselves, their families, and their communities, even if they accept that some changes are likely permanent. They are looking for a roadmap of how to move forward, along with credible and understandable

guidance on when it will be safe and how to reduce their risks. And in the absence of a roadmap, they seem to follow whichever expert or outlet is closest to their preferences.

The purpose of this report is to offer Americans guidance and lay out a roadmap for how to advance to and sustain the next normal.

A New Threat

Two years ago, a new virus came roaring out of China. Hospitals filled and morgues were piled with bodies. In the United States, President Trump publicly expressed confidence that the resulting epidemic would soon pass while privately acknowledging the deadly risks.

President Trump launched Operation Warp Speed, a public-private partnership to accelerate the development of vaccines. In part because of the initiative’s investments and encouragement, the first vaccines were authorized just 10 months after the pandemic officially began—a record for vaccine development.

But much of the Trump Administration’s other efforts were plagued by disorganization, confusion, and an abiding refusal to face the severity of the pandemic. Scientific advisors were ignored and basic public health strategies were minimized. Communication was confused and frequently contradictory. The nation’s testing infrastructure buckled under the strain of soaring demand, supply shortfalls, and government neglect, in part because President Trump believed that positive Covid test results reflected poorly on him.

When President Biden assumed office, cases and deaths were at record highs and vaccines were in short supply. On January 20th, Inauguration Day, about 16 million Americans —only 4 percent of the U.S. population —had been vaccinated. The Administration ramped up vaccinations by opening mass vaccination sites, distributing vaccines in pharmacies, and ensuring that vaccines would be free and accessible for all. The Ad Council and COVID Collaborative initiated a \$250 million vaccination education campaign, coupled with administration efforts to boost vaccination uptake. And while efforts to improve testing faltered in some ways, the number of at-home tests grew exponentially.

The first vaccines were authorized just 10 months after the pandemic officially began—a record for vaccine development.

The Biden Administration also focused resources on global distribution of vaccines. The top supplier of Covid vaccines worldwide, the United States has already shipped more than 415 million of the 1.1 billion doses the country committed to provide to low- and middle-income countries. These donations are part of a \$4 billion allocation for global vaccine procurement, distribution, and administration. The Biden Administration rejoined the World Health Organization (WHO), helping to unify the global response to the virus, reinvigorate research networks that monitor viral variants, and signal the nation's willingness to lead once again.

There have been other achievements. A significant one has been a concerted push to make care accessible to all. Over the past year, significant racial disparities in Covid death rates have plunged and in some parts of the country been eliminated. But problems remain, with the most frustrating being the refusal by one in five Americans to receive even one dose of a vaccine. This cannot be entirely pinned on individuals: Most notably, the government has not fully investigated and addressed the higher Covid mortality rates amongst black Americans, which may have contributed to black Americans' lack of trust in the government's response and subsequently lowered vaccine uptake, versus other racial groups.

In April 2021, the U.S. government declared that all American adults were eligible for the Covid vaccine and in May 2021, the CDC declared that vaccinated Americans could go without masking and testing. Many Americans eased precautions and returned to social activities—traveling, eating in restaurants, and gathering with families. On July 4, President Biden declared “freedom from the virus.” And by July 29, 164 million Americans had been fully vaccinated and Covid cases dropped to near-record lows.

By mid-summer 2021, Delta emerged, followed by Omicron in November 2021. These variants infected even those who had been vaccinated. In the fall and winter, testing needs soared and again far outstripped supplies.

The Biden Administration established 20,000 free testing sites nationwide and mandated that private and public insurers pay for tests. Additionally, the Administration unveiled a plan to roll out 500 million at-home rapid tests free of charge, most of which have now arrived in American households. Finally, the Administration is also working to create a stockpile of four million doses of Covid therapeutics, including monoclonal antibodies, antivirals, and preventive drugs for immunocompromised patients.

Even as cases climbed, the vast majority of schools and businesses remained open, demonstrating a promising shift in school and workplace safety measures and public awareness on how to safely keep the economy open.

While trying to fight the SARS-CoV-2 virus, the federal government and scientists have had to contend with a politically motivated misinformation campaign about vaccines, therapeutics, and other aspects of the pandemic. This has inhibited an effective response and demoralized doctors, nurses, public health officials, and scientists, some of whom have been targeted in unusually vitriolic terms. Just as challenging, Americans are understandably fatigued and reluctant to continue mitigation measures.

Even as cases climbed, the vast majority of schools and businesses remained open.

Responding to an ever-evolving pandemic is intense, overwhelming, and endless work for public officials. Often, the sheer magnitude of things to do precludes long-term planning that the country needs to prepare for future variants of Covid, for other highly contagious viruses, and for facilitating a return to normal daily life.

Not Done Yet

Make no mistake, the United States is far from a normal situation. Going into March 2022, the country was still experiencing about 35,000 hospitalizations per day and 12,000 deaths per week from Covid, a toll exceeded only by the great modern killers of heart disease and cancer. To put this in perspective, the country has on occasion tolerated—meaning accepted without emergency mitigation efforts—as many as 1,150 deaths per week from major respiratory illnesses, including influenza and RSV. That Covid’s toll remains about 10 times higher than the flu’s modern worst is intolerable.

At the same time, many Americans wonder whether and when the current Omicron surge will fully subside, whether the number of cases and hospitalizations will continue to plateau, whether—or when—additional variants will emerge, and what this uncertainty means for 2022 and beyond. Some are not waiting to act. Several municipalities—including Boston, Philadelphia, and Denver—lifted vaccination requirements within certain indoor public settings based on only “improving” case counts but not near normal circumstances.

The mood of the American public, the demands of the economy and society, and the difficulties posed by a virus that constantly surprises the experts present new and unique challenges. Trying to eliminate Covid is not realistic. Instead, the nation must plan to mitigate its effects, prepare for variants, and build towards a next normal. This Roadmap’s authors envision that in the next normal, endemic Covid—or any other respiratory virus,

circulating or novel—does not necessitate the massive societal disruptions endured these past two years. This Roadmap reimagines how America may live with Covid, which requires getting to and sustaining the next normal, and allows for the return of the routines and joys of everyday life for a majority of the population.

This Roadmap reimagines how America may live with Covid.

Getting To and Sustaining a Next Normal

A roadmap for getting to a next normal with Covid must accomplish three goals. First, it must envision what the next normal is and specify indicators to monitor so that the country can understand when it is safe to reduce precautions. Second, it must describe the concrete steps needed to get to and sustain this next normal state. Third, it must learn from the mistakes and successes of the past few years to identify changes in policy and investments needed now to prepare for new variants, new viruses, and other biosecurity threats.

To contribute to such a roadmap, this Covid Roadmap Group, made up of health, scientific, and policy experts, came together to pool their knowledge. The Group is composed of private citizens with a diverse range of skills and experiences in various areas of the Covid response. They have different political affiliations and write in an independent capacity.

All the authors and reviewers contributed to this Roadmap with the greatest sense of shared purpose at this time of national need. There is consensus but not



unanimity. Not every author or contributor agrees with every recommendation. Some may differ with aspects of the Roadmap or stress other matters of primary focus. But none of these disagreements were so fundamental they declined to be an author or contributor.

Many of this report’s authors, contributors, and support team members are involved in Covid response and research that directly relates to this document. Because this is a consensus Roadmap, rather than the work of any individual author, the report’s recommendations are not driven by individual interests.

Equity must be a core tenet of solution design to mitigate health disparities made worse by the Covid pandemic.

Recognizing the luxury of a 30,000-foot view and the lack of responsibility for managing the day-to-day challenges of pandemic response, the Group tried to make its recommendations as actionable as possible. It focused only on critical areas and measures that could be fully implemented or at least initiated by the end of 2022. The focus is largely domestic, with some critical action steps targeted globally.

The objective of this document is to share suggestions with policy makers on practical steps needed at the federal, state, and local levels to get to and sustain the next normal. The intention is also to orient the American public by sharing ideas on what this next normal might actually look like and how to rapidly get there.

Parts of this transition will be complicated. Myriad areas need to be addressed simultaneously. There are public health considerations such as vaccines, therapeutics, testing and disease surveillance, the healthcare workforce, and air filtration. Communication and public education efforts need to be addressed. Equity must be a core tenet of solution design to mitigate health disparities made worse by the Covid pandemic and help restructure America’s healthcare system to better support all vulnerable populations.

Successfully implementing these various reforms and initiatives will require a whole-of-government approach that leverages various federal agencies working in combination with state and local governments, as well as close collaboration with industry, academia, faith-based organizations, the private sector, and the public. A balance should be struck—and will be demanded, by some—to balance public safety with respect for personal liberty.

Humility is essential. There are multiple characteristics of SARS-CoV-2 pathogenesis and epidemiology that remain unclear, including the precise duration of immunity from vaccination or infection, whether it will become a largely seasonal infection, and how to reduce the risk and impact of long Covid. Perhaps the biggest unknown of all—and the most concerning—is whether even more transmissible, immune-evading, or virulent variants will arise after Omicron. While the shift from pandemic to endemic may already be underway, the characteristics of that eventual state remain unknowable. This Roadmap attempts to account for these variables in each area of day-to-day pandemic response while contributing to groundwork for addressing many of these unanswered questions through research and surveillance.

Too often with epidemics, past becomes prologue. In 2003, SARS—the first-ever pandemic threat of a novel and deadly coronavirus—spread to more than 25 countries. Tragically, few structural investments were made to the United States’ surveillance, control, and research capacities in preparation for the potential emergence of another such threat, despite many warnings. SARS-CoV-2 is just a far more transmissible version of the original SARS virus. If recommended steps had been taken over the past 20 years to strengthen public health infrastructure, the American experience with Covid might have looked very different.

The United States cannot resort to its old habits. The nation cannot let this Covid moment pass and move on as it did in 2003.

The nation cannot let this Covid moment pass and move on as it did in 2003.

Beyond responding to the immediate crisis, the United States must finally commit to creating the infrastructure to respond to national biosecurity threats including pandemics. This Roadmap is geared primarily towards the current situation. But many of its recommendations are essential starting points for building towards a more secure future. Spending on these measures is a long-term investment in America’s public health and safety.

The national discussion needs to shift away from Covid alone to one that encompasses all major viral respiratory illnesses.

Summary of Key Recommendations

The next normal with Covid requires a basic re-orientation. The national discussion needs to shift away from Covid alone to one that encompasses major viral respiratory illnesses like influenza and respiratory syncytial virus (RSV). Several key metrics need to be tracked to know when this transition is occurring. These metrics include health care workforce shortages, hospital bed occupancy, the threat of health care systems being overwhelmed, and deaths from major viral respiratory infections (see *Chapter 1* for a proposed dashboard).

When hospitalizations caused by viral respiratory illnesses surge and force staffed bed occupancy to exceed 85%, the system begins to get overwhelmed. Patients suffer poor quality care. Avoidable complications and deaths increase. During the recent Omicron surge, many hospitals were over this staffed bed occupancy limit. Reducing cases of viral respiratory illnesses to a level that avoids such a high staffed bed occupancy rate is imperative.

The pandemic and its restrictive measures should end when Covid death rates decline to those of a bad influenza season. This is not to suggest that any deaths are acceptable. It is an interim period as approaches to addressing Covid change and the country transitions into the next normal.

The combined death toll from influenza and RSV can peak above 60,000 in a year—bad but still not considered an emergency or crisis. These numbers translate into an interim death threshold for the next normal of 0.5 deaths per one million people per day on average for major viral respiratory illnesses. In the United States, a country with 330 million people, the transition to the next normal can occur when the National Center of Health Statistics measures the direct mortality from major respiratory illnesses to average 165 deaths per day and 1,150 per week. The death toll from Covid going into March 2022 is over 10 times higher.

Making projections is always risky. The virus has repeatedly surprised scientists and evolved in unanticipated ways. Nevertheless, even in a pessimistic scenario, the outlook for the remainder of 2022 appears to be vastly better than the experiences of the past two years.

This report’s authors anticipate that a pessimistic scenario is likely if two things occur. First, the virus’ incidence or attack rate is high, with about 80 percent of Americans infected with a new SARS-CoV-2 variant. And second, the infection fatality rate, which is the number of infected people who die, hovers around 0.1 percent. Under these circumstances, the number of deaths from March 2022 through March 2023 would be approximately 264,000. In an optimistic scenario, a future annual death toll from Covid might be as low as 20,000.

This is less dire than many expected. Even the pessimistic scenario envisions deaths being about half the toll experienced in each of the past two years. This is mostly a result of higher population immunity through vaccination and infection rates.

While optimism is justified, inaction is not.

But while optimism is justified, inaction is not. After all, a more deadly variant could arise, there will be other novel viruses, and the country has yet to take many important steps to get to this next normal.

Indeed, getting to and sustaining the next normal requires serious work on many fronts. The Group identified 12 such areas, and each section includes specific recommendations. Several steps are critical for reducing virus transmission, mitigating adverse outcomes, and addressing long Covid.

Air Quality

Covid revealed the poor quality of the air inside many buildings, as well as the importance of improving air quality and filtration to reduce the transmission of Covid and other respiratory diseases. To start, all public buildings should have their air quality routinely monitored and publicly graded. The air handling systems of public buildings, schools, commercial buildings, and large apartment complexes should be upgraded to MERV 13. Going forward, building codes must require a minimum of MERV 13 filters on HVACs. Where heating and air conditioning systems cannot be upgraded, HEPA filters should be installed or portable HEPA air filtration machines deployed. Every classroom and childcare facility in the country should have either MERV 13 or HEPA filters.

Therapeutics

Fortunately, the nation now has some therapeutic interventions—oral antiviral pills, monoclonal antibodies, and immunomodulatory therapies—that can reduce hospitalizations and deaths. But the virus is expected to develop resistance to any single antiviral drug. Effective Covid therapy over the long term will most likely require a cocktail of two or three drugs. Hundreds of oral drugs are in development or clinical trials. The country needs a new Warp Speed-like program with advanced purchase agreements and other financial and regulatory incentives to

facilitate development and production of a multi-drug oral antiviral cocktail.

Another important element in therapeutics is to have a rapid test-to-treat pathway. All Americans who have a positive PCR test should be contacted within a day and offered a treatment, enrollment in a clinical trial of a potential therapy, and advice on how to isolate and stay safe.

These vaccines represent one of the most important tools on the road to the next normal.

Vaccines

The United States developed, manufactured, and distributed an ample supply of safe and effective vaccines in record time. These vaccines brought tremendous hope to Americans. Unfortunately, near universal uptake was hindered by confusing public health recommendations and a campaign of misinformation. The realization that vaccines were not as effective at preventing mild infections as initially believed created a wave of uncertainty and disappointment. Additionally, initial distribution challenges and decision-making that insufficiently addressed transportation and economic barriers to access vaccines likely contributed to the ongoing racial disparities in vaccine uptake. Nevertheless, these vaccines represent one of the most important tools on the road to the next normal.

Going forward, the United States should continue to use advance purchasing agreements and other incentives to rapidly develop novel vaccine platforms, including mucosal vaccines and combination vaccines, with the aim of creating a pancoronavirus vaccine. The country needs to expand the industrial base for domestic and international manufacturing of vaccines and bolster the availability of vaccines globally.

Testing and Surveillance

Testing and surveillance is not yet at the level needed to provide policymakers and the public with a full and real-time picture of the number of cases in the United States. To change this, lab-based PCR tests should assess infections for not only SARS-CoV-2 virus, but all known viral respiratory pathogens. At-home tests also need to test for more than SARS-CoV-2, and they need to be ubiquitous, accessible, and either very cheap (under \$3 per test) or free. Importantly, the results of reliable Covid and other viral tests need to be systematically collected and directly linked to appropriate treatment, clinical trial enrollment, and isolation guidance. An approach should also be developed to collect population-level data on immunity to SARS-CoV-2 and how this immunity is changing over time.

The United States should invest in four comprehensive, real-time surveillance systems. These systems should assess pathogens in the environment (wastewater and air) and animals (deer, rats, and other species). They should look for genetic variants of SARS-CoV-2 and other respiratory viruses. They should assess population immunity against respiratory viruses. And they need to track the numbers of hospitalizations, intensive care admissions, and fatalities. All of this information needs to be available to government and non-government researchers in real time for analysis and to anticipate potential infectious disease outbreaks.

Long Covid

The world knows too little about long Covid, and this must change. The first step should be the creation of a coordinated national research program that uses existing patient cohort studies to form a new cohort that includes individuals with various health and vaccination statuses, and from diverse socio-demographic backgrounds. Fundamental questions that urgently need answers within the next year include determining the frequency of long Covid, whether asymptomatic or mild Covid infections are less liable to evolve into long Covid, how well vaccinations protect Americans against long Covid, and what factors, medications, or other interventions mitigate long Covid. The government should also accelerate ongoing long Covid research, including the NIH's RECOVER initiative, the CDC's INSPIRE study, and other meritorious research projects and programs. Additionally, research into the

specific causes and effects of long Covid amongst children and racial minorities is necessary, to support America's future and better address health disparities. A research program should determine what immunological factors predispose people to or protect them from long Covid so that targeted therapies can be developed and rapidly tested. Finally a comprehensive assessment is needed to ensure that the health, social, and disability services necessary for sufferers of long Covid are provided.

**Staffing shortages
are the main limit on
the system's ability to
provide quality care.**

Workforce

Health care workers have been on the front lines of the Covid pandemic. They have worked valiantly to serve the infected and uninfected alike, sometimes with inadequate supplies of PPE, ventilators, beds, and most critically, other colleagues. There are a record number of health care jobs still unfilled, burnout among those working is dangerously high, and thousands of health care workers have died of Covid. Staffing shortages are the main limit on the system's ability to provide quality care. The limitation on beds is driven less by physical space constraints than by the lack of physicians, nurses, respiratory technologists, perfusionists, and other personnel needed to staff them.

To get to the next normal, the United States must have a fully functioning health care system in which routine visits, tests, and treatments can be provided to people across the full range of illnesses, including but not limited to viral respiratory illnesses. Regulatory flexibility will be needed to facilitate care provision in both normal and emergency circumstances. Protecting the workforce from physical and mental health threats during crises is vital, and support for everyday wellbeing is important, too. Additionally, it is important to create a pool of flexible health care workers to deploy in emergencies. The U.S. government should

also invest in partnerships with faith-based groups and other organizations that supported vaccination and testing efforts throughout the pandemic, to identify opportunities for these organizations to provide ongoing health screenings and education.

Equity

The Covid pandemic has disproportionately impacted people of color, rural communities, tribal lands, and other underserved groups and locations, exacerbating existing health disparities. Solutions and strategies must prioritize health equity and the reduction of health disparities, with the end goal of building a public health system capable of reaching vulnerable and historically neglected populations. In the near term, public health leaders must recognize variations in need across different communities, and tailor investments, outreach, and public health programming to individual communities. Specifically, research into Covid-related health disparities and potential solutions is necessary to keep these disparities from persisting in the future. Government actors should acknowledge historic and current factors leading to distrust of the government and healthcare system and design and launch interventions to restore minority communities’ trust in these institutions. Additionally, government actors should establish innovative payment models that reward community actors and faith-based organizations’ efforts to support community health. The former should involve meaningful investment

in the recruitment and training of minority health care workers. Finally, the U.S. must make a renewed and sincere commitment to address diseases endemic in minority communities, such as diabetes, which can both bolster minority communities’ trust in government and reduce long-term government health expenditures.

Global Investment

Although this report will focus primarily on opportunities for domestic actions and investments, lowering global Covid cases will slow the mutation of the virus and reduce the likelihood that a more virulent or transmissible variant emerges. Ultimately, if Covid continues to circulate widely in the Global South, realization of the next normal will be difficult to impossible in the United States, so the U.S. has both a moral imperative and economic and health incentives to support other countries’ public health efforts.

Financing the Process of Getting to the Next Normal

The next normal with Covid can be an improvement over life before the virus emerged. There is likely to be a better work-life balance with more teleworking and less commuting, a reimagining of the education system, a platform for rapid development of highly effective vaccines and therapeutics, better indoor air quality, fewer respiratory infections of all kinds, and more effective surveillance to anticipate and respond to new viral threats.

Getting to this better place by creating some of the tools outlined in this report will require Congressional and state legislation, as well as significant resources. Funding is especially critical. Unfunded mandates and requirements may make some difference, but most of the needed changes are challenging or impossible to implement without funding. Financing both the response to Covid and preparation for future biosecurity threats will be a wise investment with high returns to the nation.



The economic costs of the Covid pandemic have been significant. By the end of April 2020, nearly half of all businesses closed at least temporarily. Indeed, the first two quarters of the pandemic were disastrous for the economy, with GDP contracting nearly 10% and unemployment nearing 15%. The country has recovered to some degree, but employment is still 2.3% below pre-pandemic levels, with service industries including travel and hospitality hit particularly hard. Additionally, there was and continues to be substantial cost to individual families, with 20 million Americans living in households without enough to eat in the fall of 2021 and 12 million American adults reporting they were unable to pay rent.

This economic hardship occurred despite substantial government assistance. The government thus far has provided about \$6 trillion in stimulus and support for individual American households, while the Federal Reserve kept interest rates historically low to further stimulate the economy.

It will take years to fully quantify the economic costs of the pandemic, but they are enormous. Early estimates suggest that lockdowns cost the United States between \$20 and \$35 billion per day^{1,2}. Preliminary estimates of the pandemic’s total economic impact—separate from the health costs—will be over \$7.5 trillion in losses.

Given such enormous costs, “policies that can materially reduce the spread of SARS-CoV-2 have enormous social value.”³ Investing billions per year now to

reduce the risks of a pandemic and its economic and health impacts—even if one occurs only every century— would return about \$4 for every \$1 invested, placing it among the best investment decisions in American history.

What will the various policies and programs proposed in this Roadmap cost the United States government? While this report’s authors are not budget analysts, it is possible to provide reasonable estimates. Overall, estimate annual costs at around \$100 billion in the first year, around \$30 billion in each of years 2 and 3 of implementation, with annual costs thereafter ranging from \$10 to \$15 billion.

The costs would be front loaded. Larger expenditures would be necessary to initiate projects, such as establishing a series of surveillance platforms, upgrading the country’s health data infrastructure, improving indoor air quality in schools and public buildings, and developing a multi-drug antiviral therapeutic. For example, there are just under 100,000 school buildings in the U.S. The GAO estimates that about 36,000 need upgraded or new HVAC systems, which would cost approximately \$72 billion.^{4,5}

After these start-up costs, annual expenditures would be much lower. For instance, estimates suggest maintaining a comprehensive infectious pathogen surveillance system and accompanying data infrastructure would cost approximately \$2 billion per year.⁶ A system of 20,000 permanent community health workers to provide public health services for approximately 20 million vulnerable Americans would cost about \$2 billion per year. Expanding long Covid cohorts to arrive at definitive answers and assess potential therapeutics would cost about \$1.5 billion. Next, DARPA (created to catalyze the development of technologies supporting the technical superiority of the U.S. military) has a \$3 billion annual budget. Investing \$3 billion per year in ARPA-H or a similar organization to catalyze the development of biosecurity and pandemic preparedness technologies—vaccines, diagnostics, and therapeutics—seems prudent.

The next normal with Covid can be an improvement over life before the virus emerged.

1 Mulligan C, Murphy K, Topel R. Some basic economics of Covid-19 policy. Chicago Booth Review. Published April 27, 2020. Accessed February 28, 2022. <https://www.chicagobooth.edu/review/some-basic-economics-covid-19-policy>
2 Michel N, Burton D. The cost of coronavirus shutdown orders. The Heritage Foundation. Published April 20, 2020. Accessed February 28, 2022. <https://www.heritage.org/economic-and-property-rights/report/the-cost-coronavirus-shutdown-orders>
3 Cutler D, Summers L. The Covid-19 pandemic and the \$16 trillion virus. JAMA. 2020; 324(15):1495-1496. doi:10.1001/jama.2020.19759




4 U.S. Government Accountability Office. K-12 education: School districts frequently identified multiple building systems needing updates or replacements. Published June 2020. Accessed February 27, 2022. <https://www.gao.gov/assets/gao-20-494.pdf>
5 Griffith M, Pearce A. The air we breathe: Why good HVAC systems are an essential resource for our students and school staff. Learning Policy Institute. Published December 8, 2020. Accessed February 27, 2022.
6 McKinsey. Surveillance systems cost estimate. Published May 11, 2021. Accessed February 27, 2022.

Conclusion

Unfortunately, health crises in the United States are often followed by collective amnesia. Few obelisks or markers are erected to commemorate those lost. The sense of helplessness in the face of an unrelenting and implacable adversary leads many to try to forget the appalling deaths and terrible disruptions. Americans often want to move on rather than remember and build better.

But, after the Covid pandemic, this American predilection for moving on would be a mistake. Covid is not going to be the last pandemic, biosecurity threat, or public health emergency. Ensuring that the country is prepared the next time requires remembrance and concerted work. This report lays out a Roadmap for 2022 to rapidly get the United States to the next normal and to begin building the infrastructure and systems the country needs to reduce both the risk of another pandemic and the consequences if one occurs.

This report specifically addresses how the United States might:

-  **Achieve, define, and characterize the next normal**
([Chapter 1: Next Normal](#) and [Chapter 2: Possible Scenarios](#))
-  **Reduce Covid transmission**
([Chapter 3: Testing and Surveillance](#), [Chapter 4: Cleaner, Safer Indoor Air](#), and [Chapter 5: Personal Protective Equipment](#))
-  **Reduce the severity of Covid**
([Chapter 6: Vaccines](#), [Chapter 7: Therapeutics](#), and [Chapter 8: Long Covid](#))
-  **Build the infrastructure necessary to address Covid and future biosecurity threats**
([Chapter 9: Health Data Infrastructure](#), [Chapter 10: Public Health Infrastructure](#), [Chapter 11: Healthcare Workforce](#), and [Chapter 12: Communication and Education](#))
-  **Tailor these strategies to specific high-risk settings**
([Chapter 13: Schools and Childcare](#) and [Chapter 14: Worker Safety](#))

01

Next Normal



Summary

The pandemic and its restrictive measures will likely end when Covid death rates decline to those of influenza. This is not to suggest that any deaths are acceptable. It is an interim period as approaches to addressing Covid change and the country transitions into the next normal. By enacting the new policies delineated in this report, society can mostly move on to the next normal, which will feel much like the old normal. However, in the next normal, the country can realize important improvements over pre-Covid.

The Next Normal

The SARS-CoV-2 virus is here to stay. The virus appears to be on a path towards becoming endemic. The world will likely be living with the SARS-CoV-2 virus for a long time. Omicron will not be the last variant. Indeed, it is possible there will be another variant of concern within the next 12 months.

But the world will not return to a pre-Covid normal. Normal will be different. For one thing, the SARS-CoV-2 virus will continue to evolve. Covid may recede in importance and no longer threaten the American economy, politics, schools, or daily life as it has for the last two years. Instead, the SARS-CoV-2 virus may join the ranks of other endemic respiratory viral illnesses like seasonal influenza, respiratory syncytial virus (RSV), adenovirus, parainfluenza, and others that routinely sicken and threaten lives but do not throw the country into crisis. “Endemic Covid” does not mean without potential to cause disease and health care burden. A shift toward endemicity does signal a need to establish ongoing approaches to monitor and react appropriately to changes in SARS-CoV-2 infections and spread.

Notably, the next normal is likely to be an improvement over what came before because some of the glaring problems revealed and exacerbated by Covid can be remedied or at least mitigated, reducing the impact of future variants or surges.

Parents and employees are unlikely to forget that good airflow is essential for keeping everyone healthy and safe.

For instance, Covid made apparent the poor state of indoor ventilation and air filtration in many public and commercial structures, particularly schools and workplaces. Parents and employees are unlikely to forget that good airflow is essential for keeping everyone healthy and safe. Indoor air quality improvements can reduce transmission of SARS-CoV-2, as well as other respiratory viruses and airborne particulate matter that can exacerbate non-infectious conditions such as asthma. In the next normal, indoor air quality is likely to be much improved.

Similarly, employers are likely to implement improved sick leave policies and encourage employees with flu-like illnesses to use them, since sneezing and coughing throughout a workday will likely no longer be seen as laudatory or perhaps even acceptable.

What Will the Next Normal Be Like?

The next normal must look and feel a lot like the old normal, which means certain things must be the same. In the next normal, Americans should feel that they have adequate access to a full range of healthcare services at hospitals and physician offices with resilient healthcare providers and sufficient staff, and that precautions and environmental monitoring are in place to reduce exposure if a new variant or virus appears. With this and other reassurances, including societal acceptance of voluntary continued mask-wearing for immunocompromised individuals and others, they can feel confident enough to work, attend school, shop, worship, socialize, and take public transportation without the imposition of emergency measures or restrictions. For instance, grocery shopping or going to school should no longer require masking or distancing or be subject to periodic lockdowns.

Some of the key attributes of the next normal are:

Healthcare and Long-Term Care Providers

Hospitals, nursing homes, physician offices, and other healthcare and long-term care facilities will have sufficient staff, supplies, and the legal and regulatory flexibility to safely provide a full range of services, including virtual and home-care options and Covid vaccines and therapies, while keeping healthcare workers protected from infection and with care for their wellbeing. Surges will not overwhelm the health care system.

Schools and Childcare

Schools and childcare facilities will be safe and open to provide in-person instruction and care that ensures optimal education of America's children.

Economy

The U.S. economy can operate normally, ending supply chain snarls and filling store shelves. Workers will have additional protections to keep them healthy and safe. There will be better worker sick leave policies to reduce

transmission of viruses, as well as more flexibility in where people do their work to enhance work-life balance.

Religious Worship

Places of worship can operate with full congregation services, without the need for masking, distancing, or other public health restrictions.

Social Activities

Indoor activities and services, from sports games, concerts, and theatrical performances to bars and restaurants, can operate normally without the need for masking, distancing, or other public health restrictions.

Travel

Domestic plane, rail, bus, and other transportation can operate normally, without the need for masking, distancing, or other public health restrictions.

How will Americans know that the next normal has arrived?

Influenza has been a scourge for centuries. Its severity waxes and wanes depending upon minute genetic changes in each strain and how those changes interact with the immune system. Bad flu seasons can fill hospitals, cause temporary worker shortages, and kill more than 50,000 Americans

Bad flu seasons can fill hospitals, cause temporary worker shortages, and kill more than 50,000 Americans in a year.

in a year. Nevertheless, this is not viewed as a crisis, and the nation does not respond by imposing lockdowns, mask mandates, or other emergency public health measures.

The lethality of the SARS-CoV-2 virus and the absence of population immunity led to a two-year death toll of nearly 1 million Americans. A different response was necessary. Fortunately, the virus’s lethality among the vaccinated has dropped substantially.

The United States has long tolerated certain levels of community prevalence, hospitalization, and death from circulating respiratory viruses. From a risk perspective, the next normal should strive for a lower or equal amount of risk compared to pre-pandemic life, with a cumulative viral respiratory illness risk at about the level associated with a bad influenza and RSV season. Practically this means average mortality from major viral respiratory illnesses (as measured by the National Center for Health Statistics) should be less than 0.5 deaths per one million Americans per day, or 165 deaths per day. This could be measured directly from death certificates or based on excess population mortality, assuming this excess is likely from viral respiratory illnesses.

Americans want to know when the country and their community will be in this next phase so normal activities can resume without—or with minimal—precautions. There is no single metric that dictates being in the next normal or when emergency measures should be imposed or retained. Economists determine the health of the economy using multiple indicators, primarily unemployment, inflation, and GDP growth. Similarly, a dashboard for respiratory viral illnesses will be composed of several critical metrics. Each metric could be assessed both for their daily

levels and how they have changed over the previous seven days. And like the economic indicators, the thresholds of concern vary, and different indicators necessitate different interventions. Slow economic growth for two quarters portends a recession and requires stimulative policies such as deficit spending, while inflation is usually addressed with higher interest rates. Finally, it bears noting that even when critical metrics provide positive indications, some precautions may still be warranted—America does not, for example, take zero precautions with respect to influenza.

The dashboard for viral respiratory illnesses includes several metrics: vaccination rates, seroprevalence, wastewater virus loads, health system stress, and death rates.

Vaccination rates are critical because they impact the burden of disease in a community.

Vaccination rates are important for assessing population immunity, especially among the elderly. They are also critical because they impact the burden of disease in a community. Immunity from previous infections or seroprevalence is also important to assess how well the community can withstand viral infection. Wastewater virus levels are a way of determining the amount of circulating virus. Since people do not have to report personal tests and results, it serves as a passive but accurate early indicator of viral spread that often precedes confirmed cases and can demonstrate whether respiratory virus incidence is increasing or declining.

Stressors of the health care system, including staff shortages and excessive hospital occupancy, are also important since deaths increase when hospitals cannot provide optimal care. Deaths from respiratory viruses are obviously an important metric for policy decisions.

Figure 1 provides a mock-up of a respiratory virus dashboard for policymakers, while Figure 2 provides a mock-up of the dashboard components that might be useful for the public.



Figure 1

Illustrative Respiratory Virus Dashboard For Policy Makers

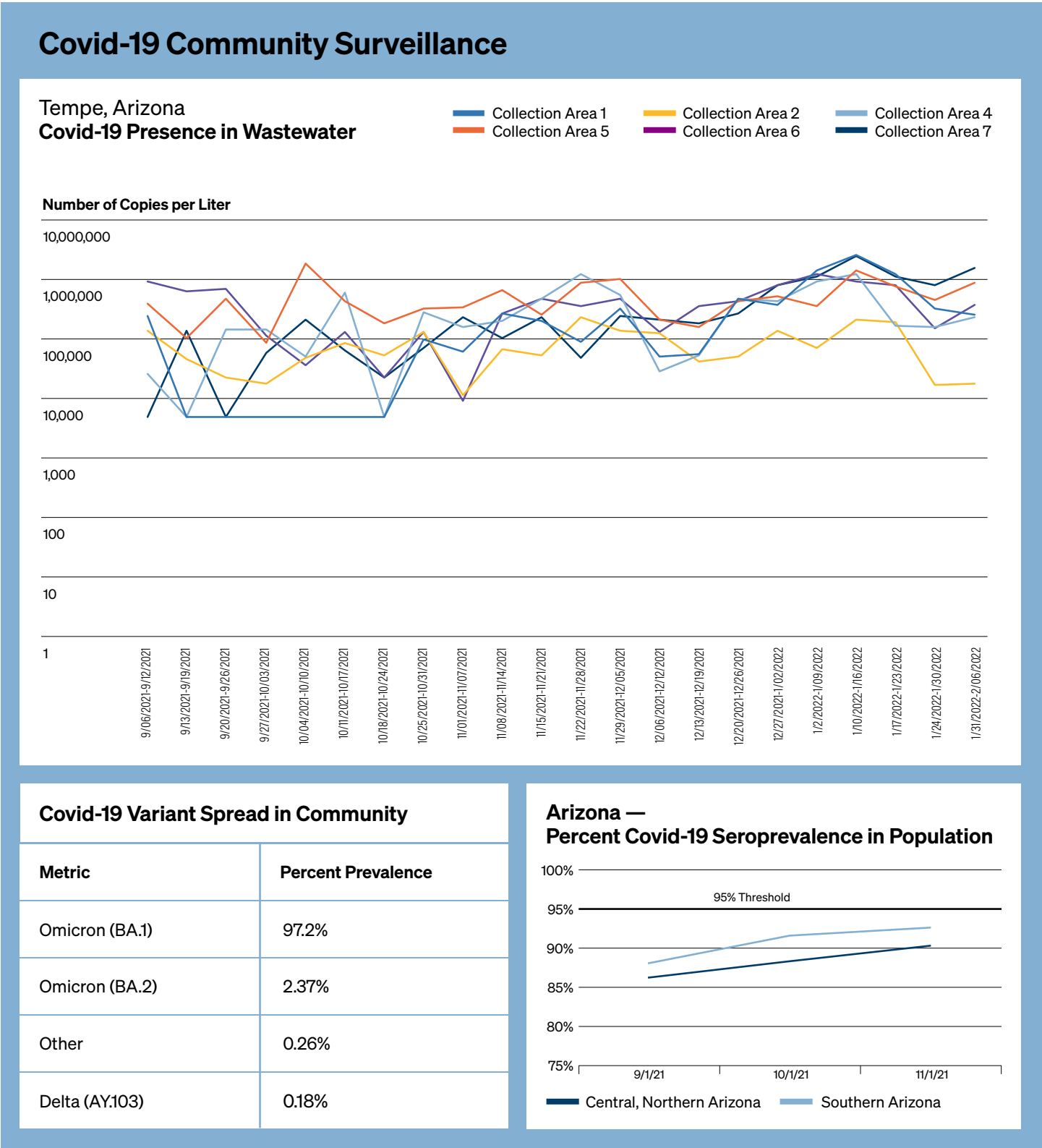
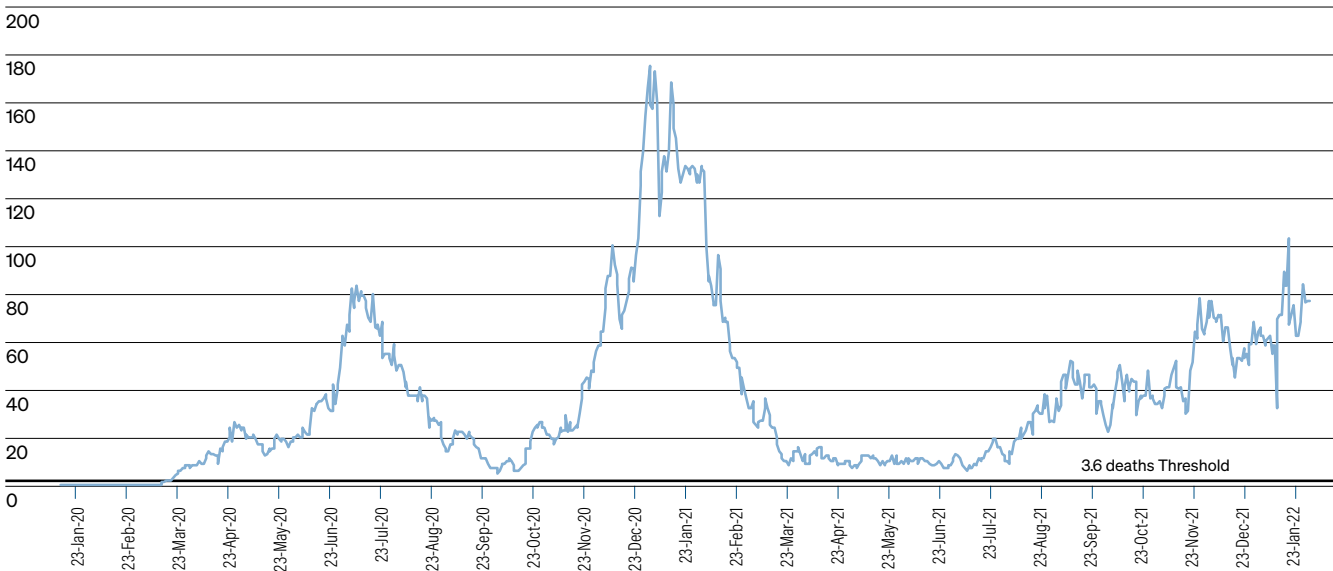


Figure 1

Illustrative Respiratory Virus Dashboard For Policy Makers

Covid-19 Deaths

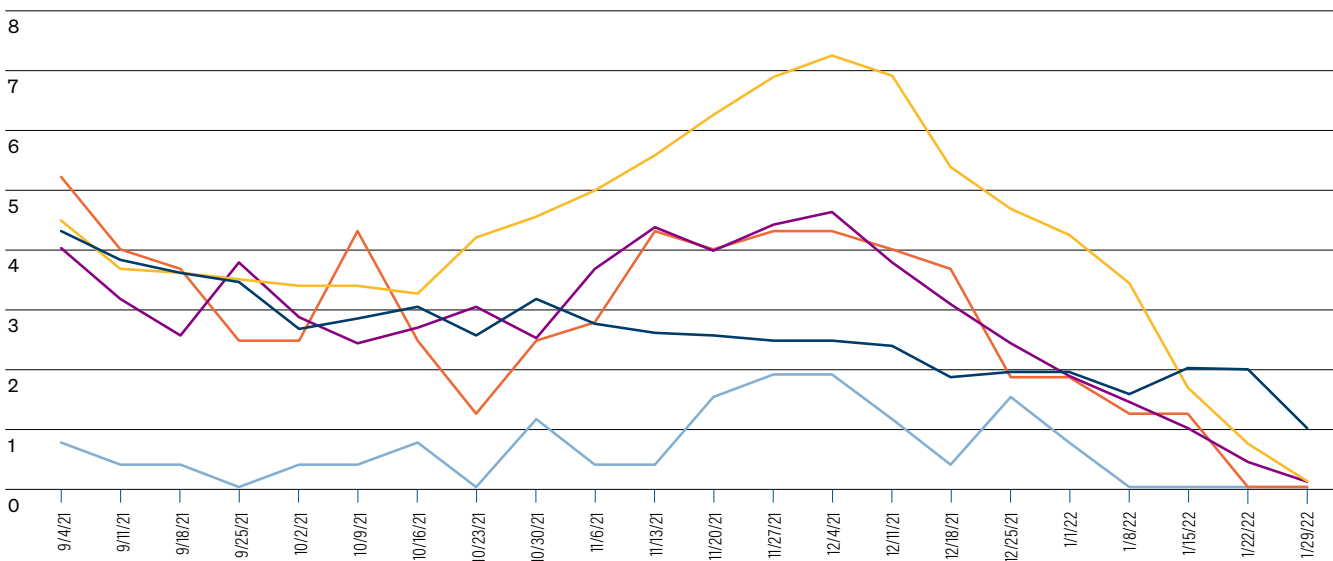
Arizona
7-Day Average COVID-19 Deaths



Source: CDC

COVID-19 Deaths By Race, per 100,000 People

Asian Black Hispanic
White American Indian/Alaska Native



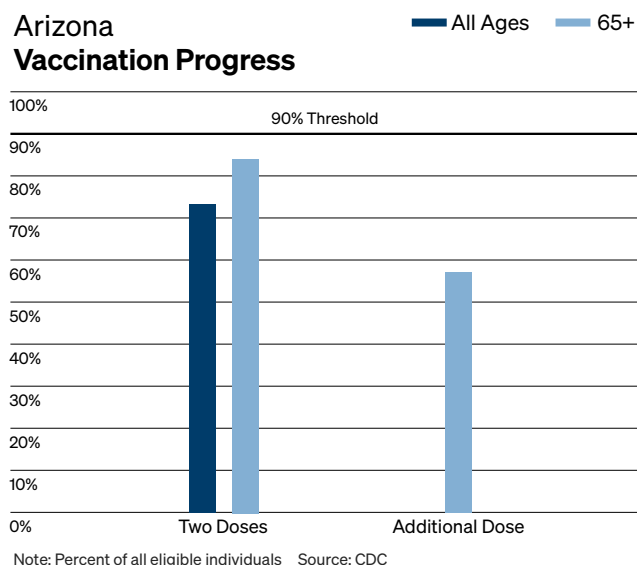
Source: CDC

Figure 1

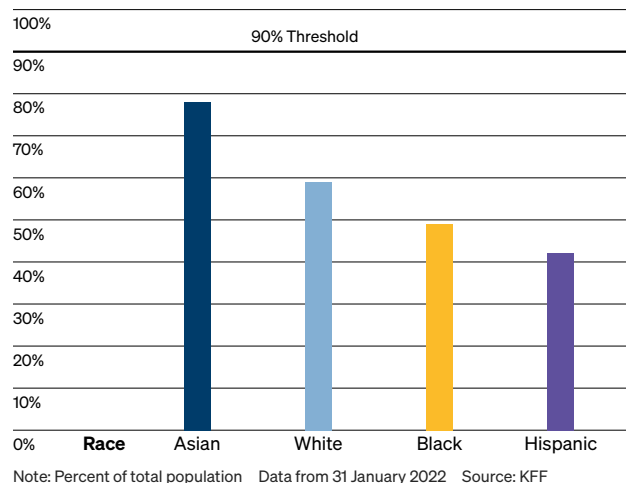
Illustrative Respiratory Virus Dashboard For Policy Makers

Vaccines

Arizona Vaccination Progress

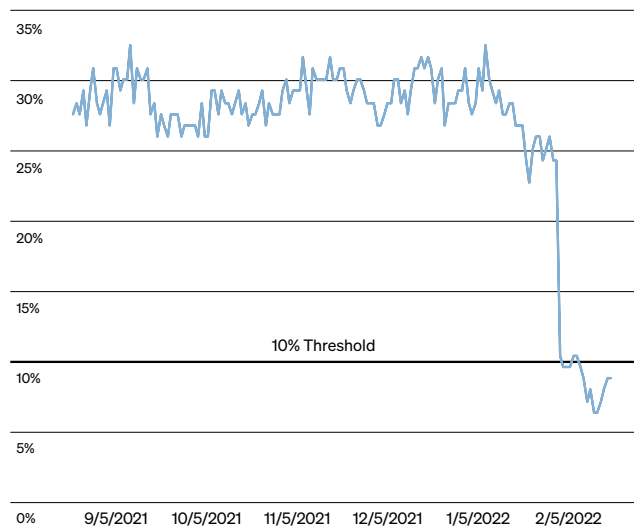


Arizona Vaccination, At Least One Dose by Race



Healthcare Strain Metrics

Arizona Percent Hospitals Reporting Staffing Shortage



Arizona Percent of Inpatient Beds Occupied by Circuit Breaker Status

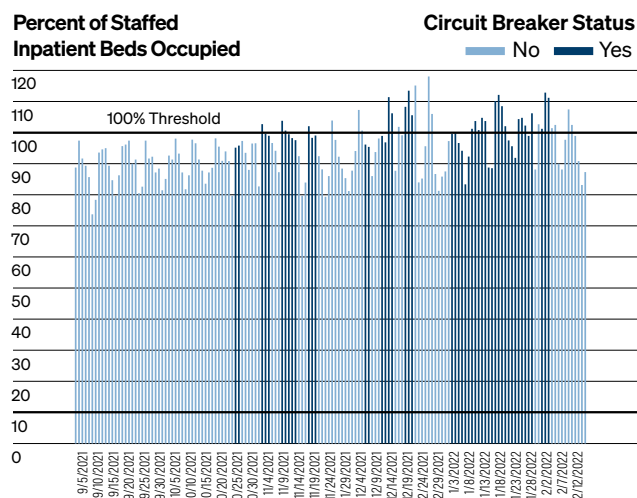


Chart by Dr. Jeremy Faust, Benjamin Renton, Dr. Kristen Panthagani, Alexander Chen, and Dr. William Hanage. View the Hospital Capacity Circuit Breaker Dashboard at covidcircuitbreaker.org

The U.S. Hospital Capacity Circuit Breaker dashboard (by Faust and colleagues) leverages public health data to determine when any jurisdiction is at high risk of exceeding hospital capacity in the following 1-14 days. On the included graph, dark blue bars indicate when hospital capacity is forecast to soon be exceeded (note: any capacity threshold can be chosen; 100% capacity is shown). With this warning, hospital systems can act to increase capacity by limiting or cancelling elective procedures, increasing staffing and physical care space, and carefully triaging admissions and discharge decisions; local governments can act by encouraging or requiring indoor mask use (and providing high-quality masks to the public), temporarily limiting capacity in crowded indoor environments, requiring proof of vaccination, and taking any other actions that slow the spread of Covid during surges, including delivering free rapid tests to all places of residence and businesses.

Each metric has a threshold to indicate when the country is sustainably at a tolerable respiratory viral illness level without the need for significant public health interventions like closing businesses or requiring masks in schools.

Importantly, each metric in this dashboard can be measured and utilized to inform policy at the national, state, and local levels.

Two important caveats: The United States does not presently have real time data for each of these metrics, and appropriate thresholds for some metrics have not been set at the national level, which hinders regional comparisons. For instance, wastewater surveillance is not yet standardized or timely enough to provide a comprehensive country-level snapshot across the whole United States. Given the lack of standardized data and differences in sampling technologies in local sewersheds, thresholds today must be set at the local level. Comparisons will only be possible if differences in data formats and reporting at local centers are standardized and accounted for using a consistent methodology for determining pathogen thresholds. Similarly, data on hospital bed occupancy is not reliably reported daily by all hospitals. To ensure accuracy and utility of such a dashboard, the data inputs for these critical metrics need rapid upgrading (see *Chapter 9: Health Data Infrastructure*).



Unfortunately, the United States has yet to arrive at the next normal.

Unfortunately, the United States has yet to arrive at the next normal. Going into March 2022, the country is currently experiencing about 5 deaths per million people per day from Covid. That is about 10-fold higher than was normal for major respiratory diseases prior to the Covid pandemic. And while wastewater surveillance testing indicates declining Covid infections, hospital bed occupancy still appears strained in several parts of the country.

Figure 2

Illustrative Respiratory Virus Dashboard For The Public

Arizona Covid-19 Dashboard February 2022

Covid-19 Indicators	Metric	Threshold	Current Status	Trending
Vaccine Metrics	Vaccination — All Ages Primary Series Completed	90%	73.9%	↑
	65+ Primary Series Completed	90%	84.7%	↑
	65+ Additional Dose(s)	90%	58.1%	↑
Community Surveillance	Covid-19 Seroprevalence in Population	95%	-91.4%	↑
	Covid-19 Prevalence in Wastewater	TBD	3.24M (Tempe, AZ)	↑
Healthcare Strain	Percent Hospitals Reporting Staff Shortage	10%	8%	↓
Deaths	7-Day Average Total Covid-19 Deaths	3.6	52	↓

Current Status

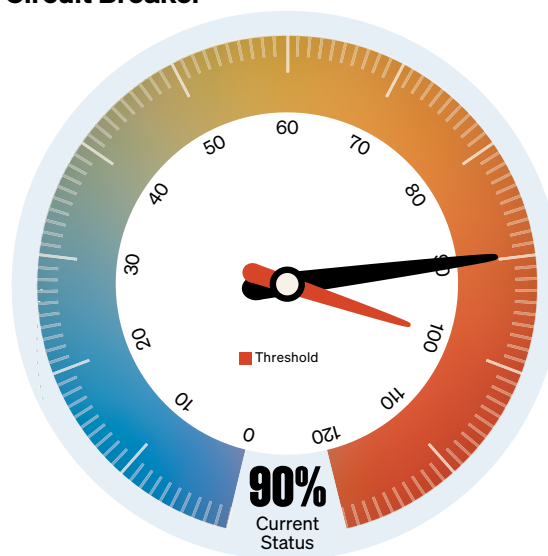
- Current Status
- Unfavorable Status

Trending

- ↑ Trending Up — Positive
- ↑ Trending Up — Negative
- ↓ Trending Down — Positive
- ↓ Trending Down — Negative
- ↔ Trending Stable

Covid-19 Demographics	Metric	Threshold
Vaccination	Asian	78%
	Black	49%
	Hispanic	42%
	White	59%
Deaths	Weekly Deaths per 100K People — Asian	0.63
	Weekly Deaths per 100K People — American Indian/Alaska Native	0.99
	Weekly Deaths per 100K People — Black	1.03
	Weekly Deaths per 100K People — Hispanic	0.60
	Weekly Deaths per 100K People — White	1.33

Circuit Breaker



The objective of this Roadmap is to describe the strategic goals and operational steps needed to get to and sustain the next normal during and after 2022.

Among the most important of these is the creation of a resilient infrastructure to manage new variants without imposing severe mitigation measures or inviting the divisiveness, disparities, and deaths that accompany them. Some of the groundwork must be laid by legislation to provide the authorities and funding necessary. Other important changes are regulatory or require enforcement of existing policies.

If the country takes the appropriate steps outlined in the subsequent chapters, many elements of the next normal can be quickly realized —and will likely look just like the pre-pandemic.

- Among the most important immediate steps are:
- Assess the combined impact of major viral respiratory illnesses**
Shift the approach from focusing solely on Covid-induced harms, including hospitalizations and deaths, to monitoring outcomes related to major endemic respiratory viral illnesses.
 - Recognize preexisting risk tolerance**
Pre-Covid, Americans tolerated risks from respiratory viral illnesses like influenza and RSV, and they need to be ready to continue to tolerate similar levels of risk in the next normal. Efforts to find, improve, and increase uptake of vaccines and treatments for these earlier illnesses should be accelerated.
 - Improve on prior measures to combat major viral respiratory illnesses**
Many of the measures implemented to combat Covid, such as improvements in indoor air, will help mitigate major respiratory viral illnesses.
 - Establish thresholds to monitor the status of viral respiratory illnesses**
A straightforward characterization of normal —with a clear dashboard of metrics, as outlined in Figure 1 —clarifies tolerable and emergency risk levels, which inform public health activities and the imposition of mitigation measures.
 - Disseminate a respiratory illness prevention approach**
The nation should revise the CDC’s well-accepted approach to combating influenza and disseminate a comprehensive Respiratory Disease Prevention approach. This would include improving indoor air quality, using high quality N95 filtering facepiece respirators (especially among vulnerable populations and when there is high local respiratory viral transmission), using rapid at-home testing, and staying at home when ill with flu-like symptoms. This will require investments in HVAC systems and HEPA filters, along with paid sick leave for all workers and ubiquitous and free or low-cost at-home tests for respiratory viruses.

Invest in future capabilities

Significant public and private investments and partnerships are required to get to and sustain the next normal, returning substantial economic, health, social, educational, and security benefits. Specifically, this report’s authors estimate that \$100 billion is necessary in year 1, \$30 billion in each of years 2 and 3, and \$10 - \$15 billion annually on a permanent basis.

Design health interventions with equity in mind

The Covid pandemic has hit communities of color and rural populations particularly hard, exacerbating existing health and economic disparities. Public health and healthcare supports must be tailored to reduce and ultimately eliminate these disparities experienced by underserved communities, and community leaders must be included in this design process to ensure interventions are effective. Investments targeted to low-income, rural, and minority communities are necessary to support those most in need.

To get to and sustain a next normal for the long term that improves upon the pre-Covid world, the country must:

Invest in biosecurity

Improved surveillance of viral threats in the United States and around the world can provide an early-warning system accelerating the deployment of treatments and vaccines.

Buttress equitable health delivery

Pre-Covid, the health care system has had persistent and widely acknowledged problems, including low provision of mental health services, poor use of telemedicine, and racial, socio-economic, and geographic disparities in healthcare access, affordability, and outcomes. These deficiencies have contributed substantially to the adverse impacts of Covid. Investments in the next normal must proactively institute policies to enhance virtual medicine and mental health care, as well as eliminate unfairness in access to and provision of services. There must also be investment in the health care workforce to ensure adequate staffing at all facilities and reduce burnout.



Instill trust

Countries with high levels of societal trust fared comparatively well over the past two years. Political divisiveness cost hundreds of thousands of American lives. A national effort must be launched to implement fixes that go well beyond health to target misinformation and enhance social and political inclusiveness. Indeed, misinformation about Covid vaccines is a major factor in the low rate of vaccine uptake in the United States compared to peer nations. In the next few years, misinformation is likely to suppress the uptake of standard childhood vaccines, leading to more avoidable deaths. Covid misinformation is part of a larger problem of media-driven falsehoods and factual inaccuracies that must be addressed to achieve as high a vaccination rate as possible. Additionally, the U.S. government should acknowledge prior mistakes, as well as existing disparities in care and outcomes, to lend credence to its trust-building efforts.

Rebuild public health and preparedness for future pandemics

Before the pandemic, the nation’s public health infrastructure and workforce were starved for resources. A new system must be built on sustained and adequate funding to overcome the mistakes of the past. As reflected in the draft PREVENT Pandemics Act, the federal government should invest in more rigorous and regular assessments of the country’s readiness for future viral

disease outbreaks and broader public health crises. Key public health agencies should stand up regional hubs, in addition to central headquarters, to better coordinate with state and local governments.

Improve public health communication and messaging

The nation’s public health professionals are being demonized because their tools are blunt, invasive, and not always fully effective. Their messages are valuable and important but have been shifting, unclear, and anxiety-producing. New tools such as secure, real-time data platforms and better surveillance would improve messaging and offer reassurance rather than alarm. Additionally, consideration should be given to the messengers selected to deliver these messages. For example, in minority communities, trusted community leaders and local clinicians can be better leveraged as public health advocates.

Achieving these measures will require spending money. But these allocations must be viewed as investments with lasting societal benefits. Two years of Covid cost the country trillions of dollars. Investing billions to ensure better surveillance, vaccine and therapeutic development, air quality, and other measures will provide a handsome return.

To get to and sustain the next normal necessitates a wide array of interventions. The subsequent chapters provide the outline of some of the strategic goals and a few of the initial operational steps to get there. But more research and experience will invariably reveal other actions that will be needed or show that some of the recommendations listed here are wrong. The authors of this report disagreed on some of the nuances of its many recommendations but agreed that actions taken now can substantially shape the path to, and the actual state of, the next normal.





02

Possible Scenarios

Summary

Although the forecast remains uncertain, there will likely be fewer deaths from Covid in 2022 than in each of the two previous years. If new variants are not significantly more transmissible or lethal, infection fatality rates continue their steady decline, and key tasks are completed, influenza will soon overtake Covid to again become the nation's most deadly viral respiratory illness.

Possible Future Scenarios

Preparing for the future requires a basic understanding of how Covid will behave over the next 12 to 24 months. Just as important is an awareness of the changes already wrought by the pandemic: Hundreds of millions of Americans are vaccinated, tens of millions more have been infected, and information about how to mitigate and treat the virus has grown substantially.

Of course, the trajectory of the pandemic over the next 12 months (March 2022 - March 2023) remains uncertain.

Omicron only reemphasizes the importance of humility in anticipating likely scenarios and steering between ill-advised optimism and paralyzing pessimism.



The SARS-CoV-2 virus has mutated and surprised scientists many times over the past two years. Omicron was an unanticipated strain. It did not arise from the variants prevalent at the time but had been evolving undetected for many months before spreading widely. Omicron only reemphasizes the importance of humility in anticipating likely scenarios and steering between ill-advised optimism and paralyzing pessimism. Nonetheless, defining possible scenarios for infections and disease is central to rapidly getting to the next normal.

The course of the pandemic is usually measured by the total number of SARS-CoV-2 infections. But as the virus becomes endemic, more infections will likely be asymptomatic or at most cause mild illness, and as more at-home tests are used, the data on cases will be less reliable.

Better metrics for monitoring optimistic, intermediate, and pessimistic scenarios for the next year may therefore include wastewater samples, coupled with the number of Covid-related hospitalizations and deaths. Another important benchmark is the strain that the overall burden of respiratory infections of any severity places on the healthcare system because of permanent or temporary loss of workforce. These metrics are driven in large part by population immunity, viral evolution, and health system resilience (see *Chapter 1: Next Normal*).

In the optimistic scenario, Covid would be similar to seasonal flu. Although this scenario would still result in 15,000 to 30,000 Covid deaths each year, this outcome would mean SARS-CoV-2 has a similar impact to other seasonal respiratory viruses. Conversely, the pessimistic scenario envisions mortality levels of 100,000 to 300,000 Covid deaths a year (Figure 1). Notably, even the pessimistic forecast projects significantly fewer annual deaths than the approximately 475,000 that the nation experienced in 2021.⁷

Defining possible scenarios for infections and disease is central to moving forward.



Two Drivers of the Covid Scenarios

There are three scenarios to arrive at estimates of Covid-associated deaths: optimistic, intermediate, and pessimistic. And there are two parameters that inform these estimates as well as the ranges around them: the virus’s attack rate (incidence) and infection fatality rate (IFR).

The yearly attack rate is the total number of infections over the course of a year (including repeat infections), divided by the total population. Using data from household transmission studies, seroprevalence studies, and epidemic dynamics, the projected yearly attack rate for March 2022 to March 2023 ranges between 20% to 80% for SARS-CoV-2. This attack rate varies depending on two primary factors: the virus itself and the level of immunity in the population. The Omicron variant was able to spread widely in a population that had abundant immunity to ancestral Covid viruses. How much future variants increase transmissibility and escape from existing immunity will largely define the effective attack rate. Even so, a complete escape from immunity is unlikely. Vaccinations are very likely to continue reducing infections and transmissions, at least to some degree. Indeed, recipients of booster doses were significantly less likely to have symptomatic illness.⁸

⁷ Ritchie H, Mathieu E, Rod  s-Guirao L, et al. Coronavirus (COVID-19) deaths. Our World in Data. Published March 5, 2020. Accessed February 18, 2022. <https://ourworldindata.org/Covid-deaths>

⁸ Covid-19 incidence and death rates among unvaccinated and fully vaccinated adults with and without booster doses during periods of Delta and Omicron variant emergence - 25 U.S. jurisdictions, April 4–December 25, 2021. Centers for Disease Control and Prevention. Published January 27, 2022. Accessed February 18, 2022. <https://www.cdc.gov/mmwr/volumes/71/wr/mm7104c2.htm>

Figure 1

Possible Scenarios And Implied Covid-Related Annual Deaths

	Optimistic scenario	Intermediate scenario	Pessimistic Scenario
Attack rate Infectiousness—the proportion of the population infected	20% 66 million Americans	40% 132 million Americans	80% 264 million Americans
Infection fatality rate (IFR) Virulence—the proportion of people infected who die	0.03% 3 deaths per 10,000 infections	0.05% 5 deaths per 10,000 infections	0.1% 10 deaths per 10,000 infections
Annual deaths	15,000–30,000	30,000–100,000	100,000–300,000
Deaths per million people per day	0.08–0.25	0.25–0.83	0.83–3.32

The infection fatality rate (IFR) is the percentage of infected individuals who die because of their infection. For Covid, current data suggest an IFR of approximately 0.075% during the January 2022 Omicron wave, down from an approximate IFR of 0.5% during the winter 2020-2021 Alpha-dominated wave.

Continued reductions in the IFR may occur as population immunity increases. Conversely, viral evolution and waning immunity could see the IFR increase. The IFR from March 2022 to March 2023 will likely lie between

0.03 - 0.10%. In other words, between three and ten people in 10,000 who are infected will die. Seasonal influenza varies somewhat in its IFR from year-to-year, but commonly used estimates range from 0.05% to 0.1%.

By themselves, these numbers place per-infection severity for SARS-CoV-2 at a level similar to seasonal influenza. But because of SARS-CoV-2's greater circulation, Covid will likely cause more deaths than influenza.

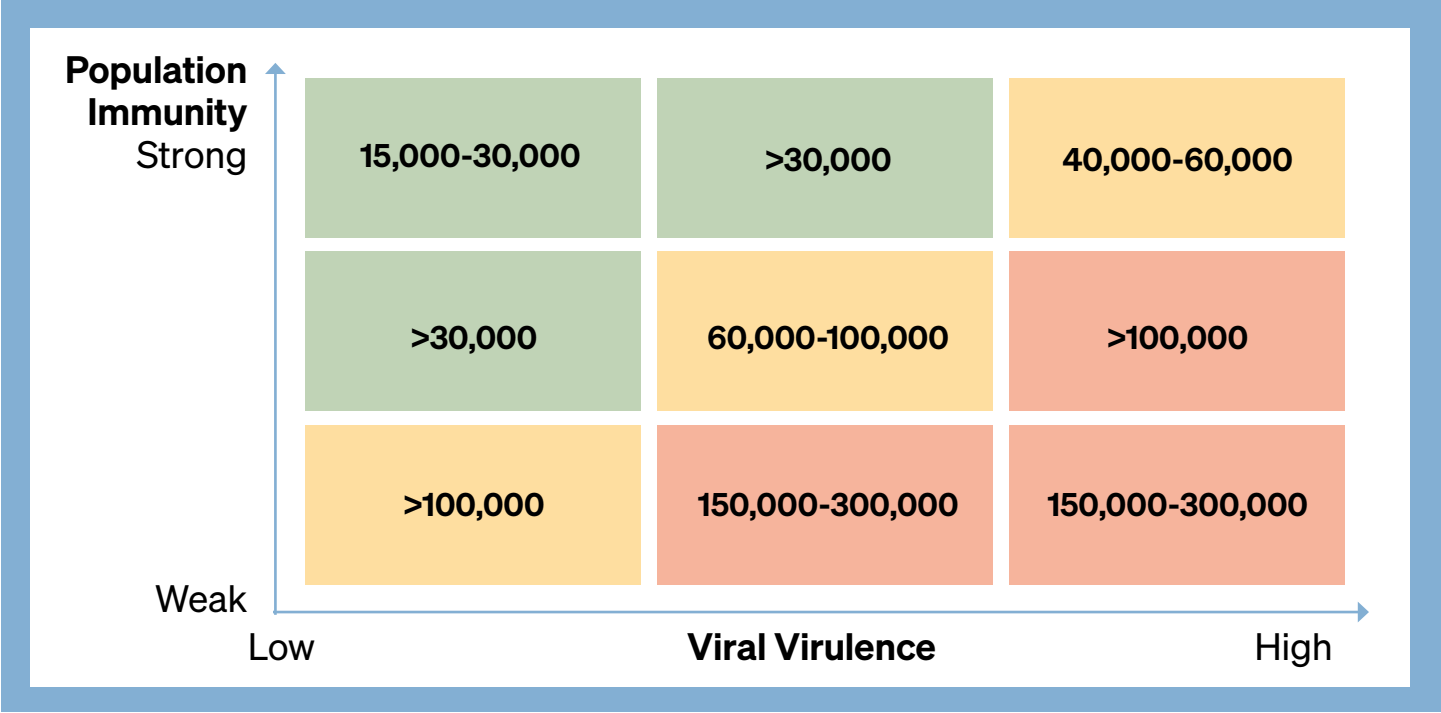
Attack rate and IFR have changed over time not only because of the virus and variants, but because population immunity has increased. Assessing possible scenarios for the next 12 months depends on future changes in population immunity, including the percentage of the population that is immune as a result of vaccination or infection, as well as the durability of this immunity and resistance to escape from immunity by future viral variants. Population immunity can also be altered by future vaccination efforts.

By estimating those two key variables —attack rate and IFR — and incorporating population immunity, it is possible to project optimistic and pessimistic scenarios over a range of population immunity over the next 12 months (Figure 2).

By themselves, these numbers place per-infection severity for SARS-CoV-2 at a level similar to seasonal influenza.

Figure 2

Potential Annual Deaths Across Virological And Immunological Possibilities



There are three additional factors that influence the impact of these possible scenarios. First, mortality and infections are unlikely to be spread uniformly over time and geographies. There is likely to be seasonality, such that the deaths and hospitalizations will be concentrated around the Thanksgiving and Christmas holidays, as well as the summer (especially in southern states where heat drives indoor congregation). Similarly, some states and geographies are likely to be harder hit than others. Variables such as the percentage of the population fully vaccinated or with immunity from infection, as well as the quality of local health care, could continue to be critical determinants of local outcomes. Thus, even in the optimistic scenario, health care use and mortality could sometimes strain healthcare infrastructure in some places while not doing so in others. New York City was hit hard by Covid early in the pandemic, stressing the healthcare system significantly at a time when other parts of the nation experienced relatively few Covid infections and saw normal hospital operations.

Second, even if the IFR and overall deaths are low, the number of people sickened could still be high in some scenarios. Such a disease burden could disproportionately impact critical sectors of the workforce including healthcare workers, first responders, and teachers, as well as vulnerable populations, such as the elderly, immunocompromised, and communities of color.

Finally, as emphasized in *Chapter 1*, the impacts of hospitalization and deaths are not solely a function of Covid, since SARS-CoV-2 infections do not occur in isolation. Influenza, RSV, parainfluenza, adenovirus, other respiratory viruses, other diseases, and co-morbidities impact hospitalizations and deaths. Co-infections with other respiratory viruses and SARS-CoV-2 can occur that may complicate outcomes in the future. Consequently, the focus must shift away from looking at Covid in isolation and towards assessing the impacts of major viral respiratory illnesses both singly and in combination (see dashboard in *Chapter 1*).

The focus must shift away from looking at Covid in isolation and towards assessing the impacts of major viral respiratory illnesses.

Holistically, the strains on local health systems impede healthcare providers' ability to effectively treat and respond to both viral respiratory illnesses and other population health needs. Although no formal definition of health system strain exists, health providers and communities should consider the overall bed occupancy rates, how health workforce shortages are exacerbated by required Covid isolation and quarantine periods, and equipment shortages that include personal protective equipment, therapeutic drugs, and ventilators. If a local Covid or other viral respiratory illness outbreak strains one or more of these components, there will likely be downstream care and quality impacts. Health systems should have plans in place to requisition supplies and staff or transport patients. Health systems' resilience to strain is dependent upon their respective abilities to absorb high patient caseloads and shortages of equipment and staff. Investments and partnerships with other local providers can bolster this resilience. Ultimately, if scenario variation at the local level contributes to high system strain, local outcomes will likely suffer.

Optimistic scenario

In this scenario, SARS-CoV-2 evolution beyond Omicron does not result in variants of concern with substantial impact on hospitalizations and death. Any newly emerging variants are less deadly, less transmissible, or both. Also, population immunity is high and durable. In this optimistic scenario, the number of annual Covid-related deaths would likely be in the range of 15,000 - 30,000 from March 2022 to March 2023, a lower toll than from influenza in moderate seasons. The burden on the healthcare system would therefore be reduced to a level

similar to that caused by influenza-like illnesses in most years prior to 2020. Even in this scenario, SARS-CoV-2 infections will arise, likely with some seasonality and in some geographies. Surges that occur in winter will likely occur simultaneously with influenza or seasonal respiratory viruses, potentially causing strain and disruption for healthcare and other industries.

Intermediate scenario

The Omicron wave subsides by the early spring, but other variants of concern emerge or resurface that have characteristics similar to the viruses seen in 2020 and 2021. The outcome would be substantial virus circulation but, because of greater population immunity, a lower disease burden than in previous years. In this scenario, the virus will likely cause between 30,000 and 100,000 deaths from March 2022 to March 2023.

The most important factor in the intermediate scenario is likely to be the ability of policymakers to have accurate real-time information about new variants, relevant population immunity, and other pandemic-related variables. Policymakers will need to rapidly and appropriately react to changes in these variables with strategies and measures outlined in subsequent chapters. Efforts to quickly and regularly gather information about viral mutations, population immunity, characteristics of viral spread, and geographies with high transmission rates can facilitate appropriate and focused mitigation strategies. In the intermediate scenario, population immunity is a critical factor. The higher the vaccination rate and population immunity, the lower the number of hospitalizations and deaths. Public health mitigation efforts will be extremely important in influencing the severity of the scenario.

The higher the vaccination rate and population immunity, the lower the number of hospitalizations and deaths.

Pessimistic scenario

This scenario arises with an Omicron-like emergence event involving a highly mutated virus that is more transmissible, more deadly, and/or evades population immunity. A virus with these characteristics would spread widely and cause more severe illness than Omicron, including in vaccinated people. This type of virus (and the concern it elicits amongst the general populace) may also contribute to additional downstream health complications, if individuals forgo other important medical care or experience increased stress and anxiety. Finally, a pessimistic scenario becomes more likely if population immunity wanes dramatically or is ineffective against new variants. This could result in between 100,000 and 300,000 deaths over the next year and even more strain on the healthcare and public health infrastructures.

Likelihood of each scenario

It is very challenging to predict with any certainty how probable each scenario is. However, rough estimates are possible. These estimates are influenced by the growing sustained cellular and broadening antibody immunity on a population level, due to vaccination, boosting, and infection, which at minimum significantly reduce severe outcomes and deaths. Additionally, estimates must consider the evolution of the virus. Potential evolutionary outcomes include continued drift within the Omicron variant without increase in virulence, Omicron drift leading to an increase in virulence to Delta-like levels, and new highly-diverged variants with Omicron-like infectivity. It is unclear how rare Omicron-like variants will be, but the observation of one event in just over two years of viral evolution suggests that it may be encountered in the next year but is far from certain.

Considering these possibilities, it seems the optimistic scenarios are the least likely, with a likelihood of only approximately 10%. Conversely, there is about a 40% likelihood of a pessimistic scenario with more than 100,000 deaths, but a reasonably low chance of any variants’ virulence and infectivity being sufficiently high to drive mortality above 200,000 in the next year. Scenarios with greater than 200,000 deaths almost certainly require evolution of a novel variant that both infects a large fraction of the population (attack rate >60%) and is more severe than Omicron (IFR >0.1%). The most likely scenario is some

intermediate situation in which COVID-related mortality over the next year is in the 30,000 —100,000 range. These are estimates, with wide confidence intervals. There is known high population immunity, but how the virus will evolve is entirely unknown. Additionally, there is greater uncertainty at the upper end of the mortality range, as there are a greater number of variables at play. These projections are made in the spirit of humility, with a pragmatic eye. The virus may surprise scientists again, and characterizations of possible scenarios are important for planning.

Combined deaths from major respiratory viruses

The prior chapter outlined that public health leaders must strive for an interim goal of less than 0.5 deaths per million people per day in the next normal from major respiratory viruses. To stay below this threshold, the country must keep combined deaths from Covid, RSV, and flu equal to or below 60,000. This is possible. The lower end of the intermediate Covid scenario, combined with average annual flu and RSV-related deaths, would yield approximately 60,000 deaths —but it is far from guaranteed.

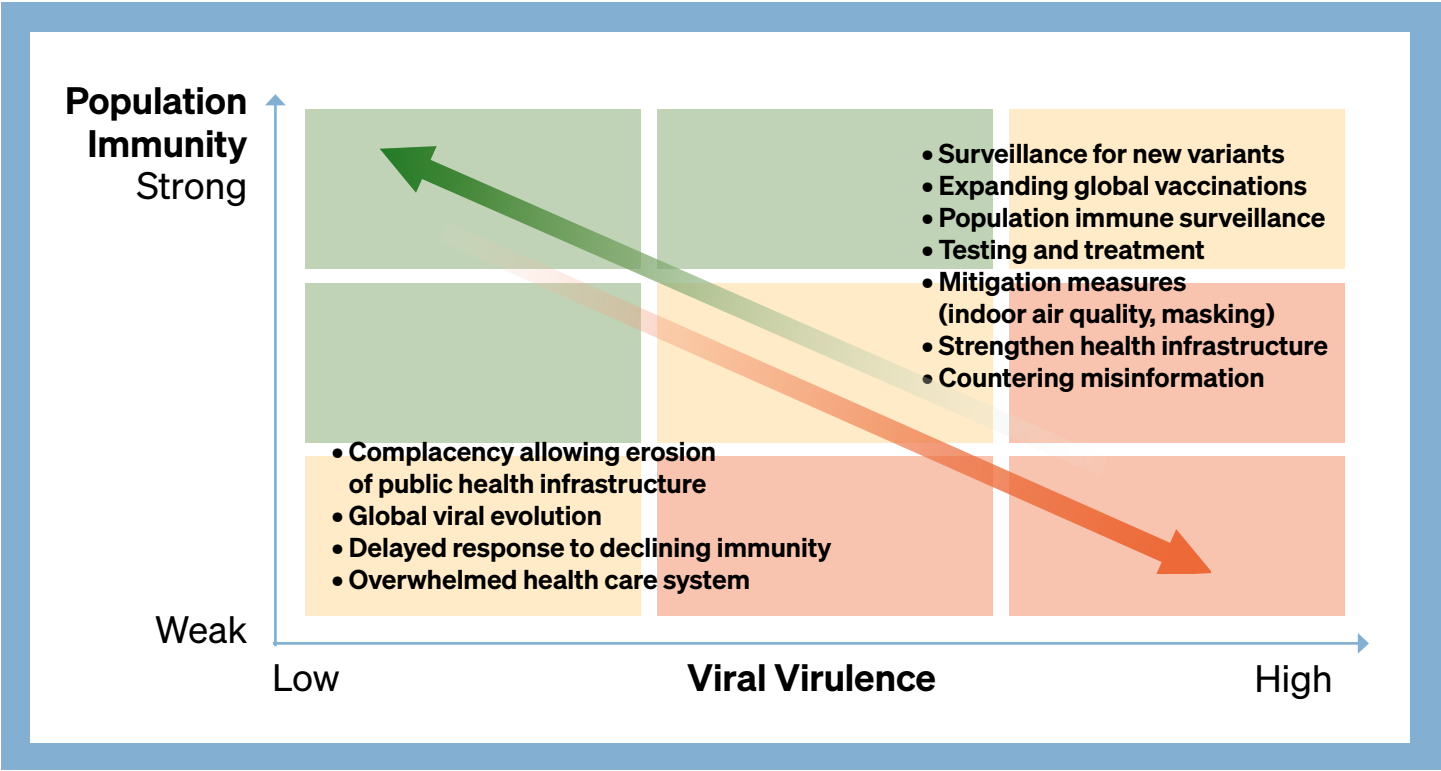
Mitigating Adverse Scenarios

There are specific actions policymakers, businesses, institutions, and the public can take now to influence the toll each of the three scenarios might take over the next 12 months. To ensure deaths and hospitalizations stay at the lowest end of each range requires ongoing and active disease surveillance, management, planning, and investment (Figure 3). The remaining chapters have recommendations on how to increase this likelihood and how to deploy key resources most effectively. Failing to take such actions increases the chances of seeing the worst tolls that are projected within each scenario, with overwhelmed health care systems and more deaths and strife.

Taking comprehensive action across four key areas can help shift the nation from the highest to lowest range in each scenario: virus surveillance, population immunity and resistance, health infrastructure, and public health measures.

Figure 3

Interventions that Impact which Scenario is More Likely



First, the nation must invest in proactive virus surveillance at the local, national, and international levels, which likely involves surveying, consolidating, and strengthening existing systems and establishing new ones to fill gaps as needed. Effective, real-time viral surveillance will accelerate effective responses if problematic variants emerge. These efforts should be coupled with support for global vaccination efforts to reduce the development of variants.

If new variants of concern emerge, early detection and analysis will enable public health responses and better equip policy decision-makers. A strong viral surveillance, virological, and epidemiological scientific infrastructure will be needed for these efforts. The U.S. government can also bolster access to affordable testing and invest in domestic surveillance to identify outbreaks and reduce disease transmission (*Ch 3: Testing and Surveillance*).

Next, the federal government should prioritize bolstering population immunity and disease resistance. This can be achieved by increasing vaccination rates, including boosters, especially among vulnerable populations,

Taking comprehensive action across four key areas can help shift the nation from the highest to lowest range in each scenario.

and investing in technologies to accelerate vaccine development, improve vaccination efficacy, counter vaccine disinformation, and mitigate adverse outcomes (*Ch 6: Vaccines*). A key factor will be developing approaches to accurately measure and track the durability and effectiveness of population immunity at a national level through immune surveillance (also discussed in *Ch 3: Testing and Surveillance*). Additionally, streamlining development and deployment of effective therapeutics will play a critical role in mitigating disease spread, health system overload, and deaths when variants evade population immunity or populations are not vaccinated (*Ch 7: Therapeutics*). Finally, efforts to prevent and mitigate the effects of long Covid can improve recovery processes and protect against long-term consequences of infection (*Ch 8: Long Covid*).

The federal government can also reduce the impact of viral respiratory illnesses by strengthening the country’s public health and data infrastructures (*Ch 10: Public Health Infrastructure; Ch 9: Health Data Infrastructure*), as well as augmenting the healthcare workforce (*Ch 11: Healthcare Workforce*).

Finally, effective and evidence-based public health measures will play a critical role in reducing virus transmission, hospitalizations, and deaths. These actions will be particularly important if and when new variants emerge and new transmission waves occur. These measures should be instituted in schools, childcare settings (*Ch 13: Schools and Childcare*), and workplaces (*Ch 14: Worker Safety*). Key actions to protect against catastrophic outcomes should include the effective deployment of personal protective equipment (*Ch 5: Personal Protective Equipment*) and air filtration and ventilation system improvements (*Ch 4: Cleaner, Safer Indoor Air*). To increase trust in government and promote adherence, these countermeasures and the country’s overall health status should be regularly and effectively communicated to the public (*Ch 12: Communication and Education*).

Several examples of how actions can mitigate adverse consequences are delineated in Table 1.

Table 1

Risk-Based Triggers And Recommended Actions

Risk-based Trigger	Infrastructure	Policy Maker Action
New high-risk variant of concern	Surveillance for variants of concern	Assess need for initiation of variant vaccine
Surge transmission in a country	Bolstered global vaccine/booster manufacturing capacity Mask/test supply chain and production	Deploy more vaccines and increase administration capacity Local/regional mitigation methods and test availability
Drop in population immunity	Immune surveillance	Deploy additional vaccine boosters

Conclusion

The uncertainties in this forecast are considerable. The SARS-CoV-2 virus continues to evolve in unpredictable ways. Nonetheless, this year’s death toll is expected to be below those of each of the past two years.

The scenario that evolves over the next year is not predetermined, however, and will be influenced by actions taken in response to changes in the virus and population immunity. Effective and rapid reaction to new information can change a potentially pessimistic scenario towards an intermediate outcome or an intermediate scenario to an optimistic outcome. However, the reverse is also true. Inaction or complacency in the setting of an optimistic or intermediate set of variables could lead to more pessimistic outcomes. Thus, the following chapters are intended to provide a framework of information and actions that can be taken to ensure a consistent shift towards lower death and hospitalization numbers through well-coordinated policy implementation. And if civil society makes some crucial changes, the pandemic is likely to recede.



03

Testing and Surveillance



Summary

To prepare for Covid variants and other infectious agents, national testing and surveillance systems are needed. Lab and at-home tests should check not only for Covid but influenza and RSV. Excess manufacturing capacity should be secured, prices reduced, and reimbursement assured. Those with positive results should be quickly and equitably connected with treatments, trials, and care.

Better But Needs to Improve

Two years into the pandemic, the United States has made dramatic strides in improving access to Covid testing. From January 2021 to January 2022, the number of tests being performed increased nearly 7-fold. The government is mailing 500 million at-home tests to Americans.

Nevertheless, access and affordability remain problematic.

The United States has not built the comprehensive testing and surveillance systems for Covid and other respiratory viruses needed to achieve the next normal.

During surges, the system becomes clogged.



These gaps in infrastructure limits the nation's ability to monitor the overall state of the pandemic necessary to inform public policies and resource allocation, and limits individuals' abilities to make the best decisions for their own healthcare and behavior. These gaps include:

- Testing to identify people infected with SARS-CoV-2 for isolation and treatment has relied on a patchwork testing infrastructure. During surges, the system becomes clogged, slowing results and interfering with efforts to limit transmission.
- Rapid tests have not been linked to medical and public health interventions such as treatment interventions or

up to date advice on isolation recommendations. Since treatments must be deployed shortly after the start of symptoms for them to be effective, this lack of direct linkage ensures that the wealthy and well-resourced are more likely to get treatment than others.

- Systematic surveillance for variants or animal reservoirs has been limited.
- There has been no systematic surveillance for population immunity.

Achieving the next normal will require significant advances in testing access and affordability, higher sensitivity and specificity, better surveillance, and sophisticated efforts to link highly sensitive and specific tests to reporting systems and treatments.

National Testing Infrastructure

A national medical and public health testing infrastructure should do three things.

First, it must expand beyond identifying Covid-positive patients to monitoring for multiple important respiratory viruses. Second, it should make rapid tests both ubiquitous and affordable, which means less than \$3 per test. Finally, it should link sickened individuals who test positive — whether through a PCR or rapid test — to a rapid healthcare consultation and suggested treatment options. In addition, to accelerate research into new treatments or items of public health urgency (such as virus transmission patterns) testing should also link to clinical research trials evaluating different potential treatments and public health questions.

National Surveillance System

A national surveillance system needs three parts.

First, it must monitor wastewater, air, and animals for respiratory viruses and other pathogens of public health consequence like multi-drug resistant bacteria to anticipate surges and spread. Genetic surveillance for viral variants should be routine and can be efficiently performed from wastewater as well as clinical samples. And third, population immunity should be tested to assess underlying immune protection and should link to infection and disease data. To inform public policy decisions, these surveillance systems require representative samples with standardized

reporting structures as well as secure and de-identified data that are publicly accessible in real time.

The country is far from this ideal.

The country is far from this ideal. While wastewater surveillance has the potential to offer relatively inexpensive snapshots of infectious pathogen spread at the population level, the nation's present system has several important limitations: it is not nationally representative, it focuses on SARS-CoV-2 and not other key respiratory viruses, and it lacks coordination, standardization and timeliness in sampling and data dissemination. Zoonotic surveillance is in even worse shape since there is no systematic effort to test animal reservoirs that pose threats in the form of new variants and animal-human transmission. In addition, there are no systematic efforts to check the national immune status, which can similarly be multiplexed to check the immune status against multiple pathogens, offering multiple avenues of pathogen surveillance in the form of immune-surveillance.

All of these deficiencies compromise effective policymaking, including surge preparation and identification of viral variants. Instead, the CDC and other decision-makers have had to rely on epidemiology and other data from foreign countries, such as Israel and the United Kingdom.



Augment PCR Testing and Ensure Broad Access to Rapid Tests

Existing SARS-CoV-2 PCR test kits should be replaced with low-cost multiplexed molecular PCR test kits for multiple pathogenic respiratory viruses, at minimum influenza and RSV. This expansion will help in capacity planning for surges, limit spread and speed treatments when warranted.

Long delays in receiving the results of PCR tests and barriers to obtaining PCR or clinic-based point-of-care tests made them ineffective for initiating treatment and limiting spread of Covid. A sensitive and specific home-based rapid test that accurately detects people who are infectious is preferable for both tasks, which is why the federal government should prioritize the manufacture and distribution of highly sensitive and specific tests and do more to instruct people in their uses and link positive individuals to immediate treatment.

With current and expected future needs, and given that rapid tests can be quickly adapted to new variants and pathogens, a production surge capacity of 1 billion rapid tests per month should be the goal. This amount should be adequate for rapid output expansion in the event of new variants and new pandemic viruses.

To ensure tests are affordable and accessible, manufacturers should reduce manufacturing and shipping costs. For instance, instead of selling boxes with just one or

two tests, they could follow the Costco model and offer 10 or 20 tests in each box. Changes in materials or the design of strips and swabs could reduce costs.

Government distribution models can build on the recent USPS per-household distribution model, with greater attention to equity and household size. Alternatively, programs such as Project Act, sponsored by the Rockefeller Foundation, or the ‘Say Yes! Covid test’ partnership distribution model sponsored by the National Institutes of Health, Centers for Disease Control, and local public health officials could be scaled and maintained beyond existing communities.

Private insurers should simplify test reimbursement. Regulations mandating private insurance and Medicare coverage of at-home tests should be extended to Medicaid and should include services that enable the tests to link to healthcare and public health reporting. Finally, the U.S. government could identify a centralized purchaser for sub-scale entities to negotiate prices for aggregated testing kit demand to lower test costs.

Improve Links Between Tests and Treatments

To maximize the benefits of the mass distribution of rapid antigen tests, there must be a new approach to rapidly connecting Covid-positive individuals to life-saving antiviral treatments and isolation procedures.

Current efforts to encourage voluntary ad-hoc self-reporting through test manufacturer apps haven’t worked well, particularly since there is little or negative incentive to report positive results. Since treatment must be given soon after symptom onset to achieve greatest benefit, results from at-home rapid antigen tests should be linked directly to telemedicine and treatment options. Additionally, reliable reports from highly sensitive and specific PCR and at-home tests that link to treatment could also improve public decision-making. The federal government should support a robust “test-to-treat” platform that links all testing with

Long delays in receiving the results of PCR made them all but useless.

high sensitivity and specificity to treatment. Such a program might provide individuals with accurate tests that link either through a QR code or phone call to a telehealth proctor for guidance and authentication of test results..

The federal government should support a robust “test-to-treat” platform.

The federal government should support a robust “test-to-treat” platform that links home-based rapid antigen testing results to treatment. Such a program might provide individuals with rapid at-home tests that link either through a QR code or phone call to a telehealth proctor for guidance and authentication of test results. With consent and at no cost, eligible positive individuals can be provided oral antiviral medications via home delivery or pick-up at a pharmacy. The initial effort might focus on Americans who are at greatest risk for hospitalization, including Medicare beneficiaries and high-risk Veteran Affairs patients.

Fortunately, as demonstrated by the bipartisan PREVENT Pandemic Act recently introduced in the U.S. Senate, political leaders support many of these suggestions. For instance, the PREVENT Pandemic Act would allow the HHS Secretary to contract with private entities to manufacture rapid tests, enable the FDA to consult with external parties to accelerate the development and evaluation of in-vitro diagnostic tests, and clarify the CDC Director’s authority to provide grants to states to establish or operate public health surveillance and reporting systems. This proposal presents a critical and timely opportunity to initiate meaningful reforms and improvements across America’s testing and surveillance systems.



Establish a National Surveillance Network

The federal government should launch a real-time national surveillance network for major respiratory viruses. This network must have the infrastructure to collect, analyze, and publicly report on viral, environmental, zoonotic, genetic, and immunological testing results to inform public health decision-making and identify potential outbreaks. This infrastructure, established to track respiratory viruses, would serve as an expandable platform to broaden surveillance for other pathogens of public health consequence, including drug-resistant tuberculosis and antibiotic-resistant bacteria.

Building a national wastewater surveillance program in the next few months is achievable. The federal government could partner with an organization to coordinate and standardize existing technologies and participating organizations. This system would coordinate data from various jurisdictions, including states, cities, counties, and tribal territories, with the goal of obtaining representative specimens from each locale possessing centralized

wastewater facilities. Wastewater surveillance assessments should include representative genetic variant sequencing in addition to viral prevalence data. Normalized thresholds should be developed to allow comparisons across systems and jurisdictions. Standardized reporting should flow automatically into a publicly accessible national database.

Immunological surveillance programs should be developed using passively collected blood specimens like aliquots from plasma or blood donors. Another source might be the discards at commercial labs and hospitals. Immunological surveillance should also include the general populace and individuals working in high-risk occupations, such as health care workers, teachers, and poultry plant employees.

The data must be accessible to researchers and the public.

To supplement this population-level surveillance data, hospitals, laboratories, point-of-care testing sites, and other health facilities should be required to report major respiratory viral test results. Viral genome sequences should be conducted on a statistically and representative sample, from patients who are asymptomatic or present with mild or severe illness. Testing and reporting for respiratory viruses should prioritize access to near real-time data.

To maximize the utility of these surveillance programs, the government must establish a secure, standardized, and timely national platform to host surveillance data. The data must be accessible to researchers and the public (see *Chapter 9: Health Data Infrastructure*). Reporting from healthcare facilities should be streamlined, in a standardized format, and use new national reporting software, such as that being developed by NIH RADx.

Accelerate Development of New Testing and Surveillance Technologies

Using regulatory and financial incentives, the federal government should accelerate the development of new testing and surveillance technologies.

One big change should be new standards at the FDA that prioritize testing speed and production in addition to sensitivity and specificity, particularly for tests that have a strong public health purpose to quickly identify the most infectious people and limit onward spread, such as rapid tests. The FDA should also allow the use of reliable data from other countries in order to expedite review of EUAs for tests. An advisory group modeled on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) could define recommended evaluation metrics and use cases for diagnostic tests for respiratory viruses.

The FDA’s Office of In Vitro Diagnostics’ technical and clinical evaluation committee’s capacity can be expanded by leveraging external teams to more rapidly evaluate innovative technologies, and the Independent Test Assessment Program could be further scaled to fast-track FDA approvals. Finally, the federal government can refocus the Rapid Acceleration of Diagnostics (RADx) initiative on development of low-cost and scalable tests that can be ready for evaluation in the near-term.

From a financial perspective, advance purchasing agreements can be used to spur innovation and could be used for new at-home tests and alternative platforms that test for multiple respiratory viruses simultaneously.

Testing and Surveillance Strategic Goals

1. Direct HHS to re-evaluate and re-design national approach to testing and scale at-home rapid test manufacturing and distribution.

- Supplement existing SARS-CoV-2 PCR tests with multiplexed molecular testing for multiple respiratory viruses.
- Prioritize low-cost rapid tests usage for screenings and shift away from PCR tests for low-risk screenings.
- Revamp the current distribution model by building on the recent USPS and/or ‘Say Yes! Covid Test’ distribution models to expand access and affordability, considering equity and household size.
- Scale distribution programs in community locations including pharmacies, grocery stores, corner stores, and schools to better reach underserved populations and those who move frequently.
- Expand the testing manufacturing base by investing and developing a U.S. government-owned or partnered production facility for rapid diagnostic tests, raw materials (including reagents), and specimen collection devices to enable a surge capacity of 1 billion tests per month.
- Hold industry accountable for monitoring, reporting on, and acting to resolve supply chain issues.
- Link rapid tests to reliable public health reporting, as well as rapid healthcare consultation and treatment.

2. Direct HHS to develop long-term purchasing and reimbursement strategies that promote affordability and supply chain stability while increasing testing and surveillance.

- Centrally negotiate prices through an agreed-upon purchaser for testing kits to ensure access to low-cost tests.
- Take a “design-to-value” approach to reduce the ‘per test’ cost, considering a larger number of kits per box, packaging redesigns, and changes to test strips and swabs.
- Use financial incentives, such as contingency contracts and guaranteed purchases to create predictable demand



- for manufacturers and low-cost supply for the public.
- Require Medicaid to cover the cost of at-home tests, as is now required for private insurers and Medicare.
 - Encourage private insurers to create billing codes for rapid tests to avoid the current long and unwieldy reimbursement process that relies on retail receipts.
 - Require private insurers to share clear, step-by-step information for navigating their health plans’ reimbursement rules to get their tests covered.

3. Direct and fund HHS to establish a test-to-treat system all testing with high sensitivity and specificity to treatment (see [Chapter 7: Therapeutics](#) and [Chapter 9: Health Data Infrastructure](#) for additional detail).

- Fund or incentivize private development of a test-to-treat model for reliable Covid and other viral tests, linking SARS-CoV-2-positive individuals to treatment (including therapeutics, medical consultations and clinical and public health studies).
- Establish and provide clear treatment and isolation guidance to SARS-CoV-2 positive individuals via test-to-treat system.

4. Direct the FDA and CDC to accelerate the development, assessment, and regulatory review of new respiratory viral testing technologies, using financial and regulatory incentives.

- a. Redefine the authorization process for new tests to optimize for speed, in addition to quality and accuracy.
- b. Expand regulatory pathways for rapid antigen tests by enabling the use of reliable data from other nations and creating an alternative regulatory pathway for authorization and approval of rapid tests for public health purposes.
- c. Create an advisory group modeled on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to define clear evaluation metrics for tests in the development pipeline and use cases by test type.
- d. Expand the capacity of FDA's Office of In Vitro Diagnostics technical and clinical evaluation committee by using external teams (e.g., leading researchers) to evaluate innovative technologies with no or limited predicates.
- e. Refocus the Rapid Acceleration of Diagnostics (RADx) initiative to target low-cost, highly scalable SARS-CoV-2 tests and different sampling platforms that can be ready for evaluation in the near-term
- f. Continue to scale the Independent Test Assessment Program (ITAP) and enable greater fast-track FDA approval for tests that are addressing public health emergencies (e.g., able to identify infectious individuals).
- g. Use advance purchasing agreements to accelerate development of new at-home tests, new testing technologies (e.g., wearables), and other platforms that test for multiple respiratory viruses (e.g., multiplex molecular tests)

5. Fund the establishment of a real-time national surveillance network that leverages viral, environmental, genetic, immunological, and zoonotic testing to anticipate and identify respiratory viral outbreaks.

- a. Fund the establishment, expansion, and operations of environmental, genetic, and immunological surveillance to collect real-time, representative data on respiratory viruses, viral variants, and immunological defenses.

- b. Launch and scale immune surveillance programs for the general populace, key reservoir species, and individuals working in associated at-risk occupations (e.g., health care workers, teachers, poultry plant workers).
- c. Establish a publicly available, secure, and standardized national platform for surveillance results and develop analytical tools that translate this data into insights that inform public health decision-making (see [*Chapter 9: Health Data Infrastructure*](#)).
- d. Require hospitals, laboratories, and other health facilities to report all respiratory viral test results and viral genome sequencing in a standard format and cadence to the central platform, linked anonymously to outcomes, vaccination status, and other socio-demographic information (see [*Chapter 9: Health Data Infrastructure*](#)).



04

**Cleaner, Safer
Indoor Air**

Summary

SARS-CoV-2 is primarily spread through indoor air. Ventilation and air filtration lower virus concentrations and reduce the likelihood of transmission. Fans and filters should be used far more to protect children, workers, and others from Covid and other viral infections.

It's in the Indoor Air

Aerosols are the main vehicle for spreading Covid.^{9,10} Infected individuals expel particles containing SARS-CoV-2 when they speak, sing, cough or breathe.^{11,12} When non-infected individuals inhale these particles, they may become infected. Aerosols are concentrated in close proximity to the infected person, and many infections are traced to such encounters. But aerosols also move with air, can travel far, and remain airborne for long periods. When inhaled, aerosol particles with viruses can deposit anywhere from the nose to the deep lung.¹³ Indoor aerosol transmission in shared-room air, especially from people with few symptoms and who often don't know they are infected, is a key reason Covid transmission has been so difficult to control. Super-spreading is an important contributor to the spread of the pandemic¹⁴ and is only explained by inhalation of aerosols in shared-room air in poorly ventilated locations.¹⁵ Multiple cases of long-range

transmission (when people were not present in the same room at the same time) have been documented but are thought to be less common.¹⁶ Outdoors there is substantially less risk of virus exposure because wind and air currents efficiently disperse virus particles and environmental stressors like ultraviolet light are more likely to be present.¹⁷

Indoor aerosol transmission in shared-room air, especially from people with few symptoms and who often don't know they are infected, is a key reason Covid transmission has been so difficult to control.

9 Greenhalgh T, Jimenez JL, Prather KA, Tufekci Z, Fisman D, Schooley R. Ten scientific reasons in support of airborne transmission of SARS-CoV-2. *Lancet*. 2021 May 1;397(10285):1603-1605. doi: 10.1016/S0140-6736(21)00869-2

10 Klompas M, Milton DK, Rhee C, Baker MA, Leekha S. Current insights into respiratory virus transmission and potential implications for infection control programs. *Annals of Internal Medicine*. 2021. doi:10.7326/M21-2780.

11 Coleman KK, Tay DJW, Sen Tan K, et al. Viral load of SARS-CoV-2 in respiratory aerosols emitted by Covid patients while breathing, talking, and singing. *Clinical Infectious Diseases*. 2021. doi:10.1093/cid/ciab691

12 Adenaiye OO, Lai J, Bueno de Mesquita PJ, et al. Infectious SARS-CoV-2 in exhaled aerosols and efficacy of masks during early mild infection. *Clinical Infectious Diseases*. 2021. doi:10.1093/cid/ciab797

13 Milton DK. A rosetta stone for understanding infectious drops and aerosols. *Journal of the Pediatric Infectious Diseases Society*. 2020;9(4):413-415. doi:10.1093/jpids/piaa079

14 Lewis D. Superspreading drives the Covid pandemic — and could help to tame it. *Nature*. 2021;590:544-546. doi: <https://doi.org/10.1038/d41586-021-00460-x>

15 Peng Z, et al. Practical indicators for risk of airborne transmission in shared indoor environments and their application to Covid outbreaks. *Environmental Science and Technology*. 2022;56:1125–1137. <https://doi.org/10.1021/acs.est.1c06531>

16 Fox-Lewis A. et al. Airborne transmission of SARS-CoV-2 delta variant within tightly monitored isolation facility, New Zealand (Aotearoa). *Emerging Infectious Diseases*. 2021;28(3). 10.3201/eid2803.212318

17 Bulfone T. et al. Outdoor transmission of SARS-CoV-2 and other respiratory viruses: A systematic review. *Journal of Infectious Diseases*. 2021;223:550-561. doi: 10.1093/infdis/jiaa742

Covid and Attention to Indoor Air Quality

Huge progress has been made in reducing pollution levels in outdoor air, but comparatively little attention has been devoted to indoor air. Schools, homes, bars, and workplaces often have limited supply of clean air and allow viruses to spread in aerosols. Unfortunately, improving indoor air quality has not been a consistent societal objective for more than half a century.¹⁸ Indeed, the quality of indoor air has not only failed to improve in recent decades, but by some measures has worsened.

Throughout much of the pandemic, the importance of improved ventilation and filtration was unrecognized or unacknowledged in guidance issued by the CDC, WHO, and other governmental bodies. This reflects a fundamental misunderstanding of the ways in which SARS-CoV-2 is transmitted, and as a result there has been almost no systematic effort to improve indoor air quality to reduce viral transmission. Additionally, when airborne infection transmission is acknowledged, building owners and operators often refuse to measure indoor air quality and remediate it because doing so could be seen as an admission of past failures and open them to liability.

Indeed, the quality of indoor air has not only failed to improve in recent decades, but by some measures has worsened.

Better Air Brings Benefits Beyond Covid

Increasing access to clean indoor air will have many benefits. First, it reduces transmission of Covid. Second, it reduces transmission of other respiratory viruses such as influenza, rhinovirus, or a possible future respiratory pandemic.¹⁹ Third, it can reduce indoor particulate matter²⁰ and allergens that can exacerbate other respiratory illnesses such as asthma.²¹ Improving indoor air quality — especially in schools and workplaces — will reduce health care costs²² and absenteeism, and it will improve productivity, academic performance, and cognitive function.^{23,24,25,26} Improving indoor air quality also addresses equity concerns because

18 Morawska et al. Sanitary ventilation by radiant disinfection. *The Scientific Monthly*. 1945;60:325–334. <http://www.jstor.org/stable/18316>

19 Wang CC et al. Airborne transmission of respiratory viruses. *Science*. 2021;373. DOI: 10.1126/science.abd9149

20 Jones ER, Laurent JGC, Young AS, MacNaughton P, Coull BA, Spengler JD, Allen JG. The effects of ventilation and filtration on indoor PM2.5 in office buildings in four countries. *Building and Environment*. 2021;200. doi: 10.1016/j.buildenv.2021.107975

21 Institute of Medicine. *Clearing the air: Asthma and indoor air exposures*. Washington, DC: National Academies Press. Published 2000. Accessed February 18, 2022. <https://pubmed.ncbi.nlm.nih.gov/25077220/>

22 Putri WCWS, Muscatello DJ, Stockwell MS, Newall AT. Economic burden of seasonal influenza in the United States. *Vaccine*. 2018;36(27):3960–3966. doi: 10.1016/j.vaccine.2018.05.057

23 The Lancet Covid Commission Task Force on Safe Work, Safe School, and Safe Travel. Designing infectious disease resilience into school buildings through improvements to ventilation and air cleaning. Published April 2021. Accessed February 18, 2022.

<https://static1.squarespace.com/static/5ef3652ab722df11fcb2ba5d/t/60a3d1251fccc67243e91119/1621348646314/Safe+Work+TF+Designing+infectious+disease+resilience+April+2021.pdf>

24 Allen JG, MacNaughton P, Satish U, Santanam S, Vallarino J, Spengler JD. Associations of cognitive function scores with carbon dioxide, ventilation, and volatile organic compound exposures in office workers: A controlled exposure study of green and conventional office environments. *Environmental Health Perspectives*. 2016;124:805–812. <http://dx.doi.org/10.1289/ehp.1510037>

25 United States Environmental Protection Agency. Evidence from scientific literature about improved academic performance. Accessed February 18, 2022. <https://www.epa.gov/iaq-schools/evidence-scientific-literature-about-improved-academic-performance>

26 Stafford T. Indoor air quality and academic performance. *Journal of Environmental Economics and Management*. 2015;70:34–50. <https://doi.org/10.1016/j.jeem.2014.11.002>

the negative effects of poor indoor air disproportionately impact low-income communities, minority communities, and rural populations.²⁷

Improving indoor air quality will have significant benefits in indoor workplaces where employees spend 8 to 12 hours every day in environments where they have little control over how closely they stand to their coworkers or customers, particularly since personal respiratory protection may be difficult or ineffective for the full workday.

Effectively limiting exposure to respiratory pathogens requires following traditional industrial hygiene principles and applying a hierarchical and layered approach. The emphasis must be on providing clean air generally instead of personal protective equipment such as respirators and face masks (see *Chapter 5: Personal Protective Equipment*).

To prevent viral transmission through indoor aerosols, three methods can be applied to the air to reduce the chance of infection:

Ventilation

Expel air with aerosols outside and introduce virus-free air from the outdoors. This can be achieved by opening doors and windows or adjusting HVAC systems to introduce more outdoor air. But moving air around with a recirculating forced air system, window air conditioner, mini-split air conditioner unit, or fan doesn't work because these simply mix contaminated air and are not ventilation.²⁸

Filtration

Keep the air indoors but remove the floating aerosols. In environments where air is recirculated or there is inadequate flow of outside air, stationary HVAC systems or portable HEPA filters can remove the virus and other contaminants from the air.^{29,30,31}

Disinfection

Keep the air and floating aerosols indoors, but “kill” (inactivate) the virus.³²

Finally, necessary investments in ventilation, filtration, and disinfection are expensive and often cost-prohibitive for low-income communities. Specific funds must be allocated to low-income communities to enable these investments for small businesses, schools, and other public buildings. Additionally, income-linked subsidies should be provided to households, to promote residential upgrades to filtration and ventilation systems.

Improving indoor air quality, especially in schools and workplaces, will reduce health care costs and absenteeism, and it will improve productivity, academic performance, and cognitive function.

27 Ferguson L, Taylor J, Davies M, Shrubsole C, Symonds P, Dimitroulopoulou S. Exposure to indoor air pollution across socio-economic groups in high-income countries: A scoping review of the literature and a modelling methodology. *Environment International*. 2020;143:105748. doi: 10.1016/j.envint.2020.105748

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30 Morris AC. The removal of airborne SARS-CoV-2 and other microbial bioaerosols by air filtration on coronavirus disease 2019 Covid surge units. *Clinical Infectious Diseases*. 2021. <https://doi.org/10.1093/cid/ciab933>

31 Lindsley WG. Efficacy of portable air cleaners and masking for reducing indoor exposure to simulated exhaled SARS-CoV-2 aerosols. *Morbidity and Mortality Weekly Report*. 2021;70(27):972-976. https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e1.htm?s_cid=mm7027e1_w

32 Nardell EA, Nathavitharana RR. Airborne spread of SARS-CoV-2 and a potential role for air disinfection. *JAMA*. 2020;324(2):141-142. doi:10.1001/jama.2020.760

Clean Air Strategic Goals

1. Empower the EPA Office of Radiation and Indoor Air to better regulate indoor air quality.

- a. Educate building owners and operators, employers, and the public generally on the importance of indoor air quality and ways to improve it.
- b. Require regular monitoring, reporting, and posting of indoor air quality by building owners and operators.
- c. Create a standard indoor air labeling system, similar to a restaurant hygiene assessment, that communicates results of building air quality assessment to the public and occupants.
- d. Develop and disseminate risk assessment tools to guide installation of controls for high-, medium- and low-risk settings.
- e. Establish a product rating and certification system that evaluates products' abilities to improve indoor air quality.
- f. Establish a certification program for manufacturers and installers of germicidal UV light technology.
- g. Establish incentives and a ratings system to advance energy-efficient portable filtration technology, prioritizing Clean Air Delivery Rate per kilowatt hour, as HEPA filtration systems may not be the most optimally energy efficient solutions.

2. Direct the EPA to fund and/or mandate improvements in indoor air quality.

- a. Immediately fund school systems to make needed improvements in ventilation and air filtration or direct them to do so with currently available funds. The objective should be to have clean air in every classroom.
- b. Require federal buildings, airports, train stations, schools, and other public buildings to improve air quality by maximizing existing HVAC systems, increasing the flow of outside air, or installing higher efficiency filters to clean air that is recirculated.
- c. Incentivize revision of local building codes to meet updated indoor air quality standards.

- d. Establish ventilation requirements for indoor work environments, including HVAC system maintenance and minimum performance requirements.
- e. Provide funding to reconfigure ventilation systems in high-risk settings with inadequate ventilation and filtration systems.
- f. Provide income-linked subsidies for households to purchase portable air filtration to improve air quality in homes.
- g. Provide income-linked subsidies for households to purchase low-cost CO2 infrared meters to monitor quality of ventilation.
- h. Provide funding to low-income zip codes to support investments in filtration and ventilation systems in small businesses, schools, and other public buildings.

3. Create a National Resource for Airborne Infection Research, Education, and Training.

- a. Create a lead agency to fund basic and clinical research on airborne infection and indoor air quality and to coordinate research, education, and training between EPA, HHS (CDC, NIOSH, NIH, and BARDA), Labor, Homeland Security, and Defense.
- b. Create a new national research office, including a dedicated research facility, to conduct intramural and fund extramural airborne infection clinical research, educate the public about the importance of indoor air quality, and support training.
- c. Focus research on controlling aerosol transmission of respiratory viruses, particularly in occupational settings and commercial buildings.



05

**Personal Protective
Equipment (PPE)**

Summary

Cloth masks are ineffective at preventing person-to-person transmission of viral respiratory disease. The United States must have stockpiles and production capacity of N95 filtering facepiece or similar respirators to ensure adequate supplies for the public and workers during future surges and pandemics.

Aerosols, Not Droplets

Early in the pandemic, the CDC stated that Covid spread person-to-person by droplets from coughs and sneezes propelled into the nose or mouth of someone nearby, although they admitted the possibility of inhalation as well. Droplets are large ($> 5 \mu\text{m}$) and fall to the ground within seconds or a few minutes. Aerosols are smaller, remain suspended in air for many minutes or hours, and are easily dispersed throughout a room. Despite numerous studies and substantial expert consensus, the CDC waited until late October 2020 —11 months into the pandemic —before finally acknowledging the possibility of airborne spread of SARS-CoV-2.^{33,34,35,36,37}

Route of transmission has important implications for the efficacy of masks or respirators as a means of minimizing person-to-person spread of Covid. Only

Only certified respirators can fulfill the three criteria of effective masks or respirators: high filter efficiency, low breathing resistance, and the potential for minimal leakage around the facepiece.

certified respirators can fulfill the three criteria of effective masks or respirators: high filter efficiency, low breathing resistance, and the potential for minimal leakage around the facepiece.

33 Morawska L, Milton D. It is time to address airborne transmission of coronavirus disease 2019 (COVID-19). *Clinical Infectious Diseases*. 2020; 71(9): 2311-2313. <https://doi.org/10.1093/cid/ciaa939>

34 Morawska L, Cao J. Airborne transmission of SARS-CoV-2: The world should face the reality. *Environment International*. 2020; 139: 105730. <https://doi.org/10.1016/j.envint.2020.105730>

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Figure 1

Time to infectious dose for an uninfected person (receiver)*

		Receiver Is Wearing (% inward leakage)				
		Nothing	Typical cloth mask	Typical surgical mask	Non-fit-tested N95 FFR [†]	Fit-tested N95 FFR
Source Is Wearing (% outward leakage)		100%	75%	50%	20%	10%
Nothing	100%	15 min.	20 min.	30 min.	1.25 hours	2.5 hours
Typical cloth mask	75%	20 min.	26 min.	40 min.	1.7 hours	3.3 hours
Typical surgical mask	50%	30 min.	40 min.	1 hour	2.5 hours	5 hours
Non-fit-tested N95 FFR [†]	20%	1.25 hours	1.7 hours	2.5 hours	6.25 hours	12.5 hours
Fit-tested N95 FFR	10%	2.5 hours	3.3 hours	5 hours	12.5 hours	25 hours

[†] FFR = filtering facepiece respirator; N95 = not oil-proof, 95% efficient at NIOSH filter test conditions

A simple comparison based on the CDC definition of close contact (less than 6 feet away from an infected person for a cumulative total of 15 min or more over a 24-hour period) shows that cloth and medical masks provide only minutes of additional protection. Only with a respirator will this time extend beyond an hour.⁴⁰

In January 2022, two years into the pandemic, the CDC finally recommended that the public use high quality N95 filtering facepiece respirators (FFRs) or something similar but did not withdraw its advice about wearing

cloth masks. Unfortunately, there are many important deficiencies — in study design and data analysis — that diminish the usefulness of most of the mask studies conducted during the pandemic, which may have led to delays in government action.⁴¹

N95 FFRs were in short supply throughout 2020 because most were manufactured offshore, and stockpiled respirators were inadequate to healthcare needs. Retooling by legacy manufacturers, entry of new manufacturers, use of different designs, and around-

38 Lindsley, William G., et al. "A comparison of performance metrics for cloth masks as source control devices for simulated cough and exhalation aerosols." *Aerosol Science and Technology* 55.10 (2021): 1125-1142.

39 Brosseau, Lisa M. "Fit testing respirators for public health medical emergencies." *Journal of occupational and environmental hygiene* 7.11 (2010): 628-632.

40 Brosseau L, Ulrich A, Escandon K, Anderson C, Osterholm M. Commentary: What can masks do? Part 1: The science behind Covid-19 protection. Center for Infectious Disease Research and Policy. Published October 14, 2021. Accessed February 20, 2022. <https://www.cidrap.umn.edu/news-perspective/2021/10/commentary-what-can-masks-do-part-1-science-behind-covid-19-protection>

41 Brosseau L, Ulrich A, Escandon K, Anderson C, Osterholm M. Commentary: What can masks do? Part 2: What makes for a good mask study — and why most fail. Published October 15, 2021. Accessed February 20, 2022. <https://www.cidrap.umn.edu/news-perspective/2021/10/commentary-what-can-masks-do-part-2-what-makes-good-mask-study-and-why-most>

Respirators cannot be the only intervention.

the-clock NIOSH testing eventually resolved the supply chain issues by early 2021.

In situations where interventions like ventilation fail to eliminate person-to-person transmission, respiratory protection can play an important role. In addition to protecting the wearer, a well-fitting respirator can prevent outward emission of infectious virus from the wearer. This is important for a virus that easily transmits pre- and asymptotically. Respirators cannot be the only intervention, however, because people must wear them correctly and continuously during all contacts (including at home), which is difficult to achieve. Respirators are the last line of defense and should be combined with source and pathway interventions like ventilation.

The Fixes Needed

When Covid transmission rates are high or suddenly surge, respiratory protection indoors will be necessary in many situations. Workers in higher-risk settings need access to reusable respirators, and all workers should have access to N95 FFRs. The public should have access to inexpensive or free N95 FFRs or similar respirators, and the government should prioritize distribution to low-income, minority, and rural communities that may have increased difficulties acquiring them and have been especially hard-hit by the pandemic. There should be a robust domestic respirator manufacturing industry to ensure sufficient supply for healthcare and other high-risk settings, with capacity to ramp up production during respiratory emergencies such

as another pandemic or surge. In addition, there needs to be a testing and certification process for respirators for the public, including children. The federal government needs to ensure there are sufficient respirator supplies for workers and the public in the Strategic National Stockpile and should establish a national registry of approved respirators for the public. These recommendations are all supported by the National Academies' 2022 Consensus Study Report.⁴²

The January 25, 2022 discussion draft of the bipartisan PREVENT Pandemics Act recognizes these needs.⁴³ Among other items, it authorizes the HHS Secretary to contract with private companies to enhance PPE surge capacity and supply chain flexibility, provides the FDA with additional enforcement authority to crack down on counterfeit PPE and other fake medical devices, and establishes a pilot program to fund states' development of their own stockpiles.

Aerosol Transmission

The default assumption must be that transmission for all respiratory viruses occurs through small particle aerosol inhalation. Assuming droplet transmission as the default puts too many people at risk and does not reflect current knowledge of transmission by inhalation of human-generated aerosols.



⁴² The National Academies of Sciences, Engineering, and Medicine. Consensus Study Report: Frameworks for Protecting Workers and the Public from Inhalation Hazards. Published 2022. Accessed February 20, 2022. <https://www.nap.edu/catalog/26372/frameworks-for-protecting-workers-and-the-public-from-inhalation-hazards>

⁴³ PREVENT Pandemics Discussion Draft. Accessed February 18, 2022. <https://www.help.senate.gov/imo/media/doc/PREVENT%20Pandemics%20discussion%20draft%20sxs%20final.pdf>

Public Areas

The federal government (CDC or another agency) should develop a public communication program to inform communities when transmission is elevated and individuals should wear well-fitting N95 FFRs or similar respirators when spending time in indoor locations with other people during shopping, entertainment, worship, dining, or similar activities.

The supply chain of respirator manufacturing must be considered a national and economic security priority.

Supply and Supply Chain Issues

The national stockpile should be replenished with elastomeric and powered air purifying respirators for healthcare workers, which must be deployed immediately as future surges or pandemics occur. A regular inspection and replacement process must be initiated to ensure the integrity of stockpiled respirators.

The national stockpile should also have adequate supplies of N95 FFRs for all essential workers as well as the public, to be deployed as needed during future surges or pandemics. FFRs must be regularly inspected and replaced well ahead of expiration, with regular deployment to states and FEMA for use during wildfire, flooding and similar emergencies.

The supply chain of respirator manufacturing must be considered a national and economic security priority. Where necessary, domestic manufacturing capacity for respirators must be assured⁴⁴. Enough respirators must be available to the public and easily purchased online and in department stores.

The Department of Health and Human Services or an appropriate federal agency must be directed to conduct a thorough assessment of domestic respirator manufacturing supply and needs for the immediate and long-term future.

Regulatory Oversight

The CDC/NIOSH National Personal Protective Technology Laboratory (NPPTL) has all of the necessary expertise for managing the oversight and approval of respirators in workplaces. Its mandate should be expanded to include the oversight and approval of respirators worn by the public, and additional resources should be provided to meet these new responsibilities. NPPTL should be provided the level of funding needed to ensure the ongoing development of up-to-date standards and testing methods for respirators and other PPE relevant to preventing transmission of viral respiratory pathogens.

Workplaces

A science-driven, objective, systematic, risk-based framework for selecting respirators for infectious respiratory pathogens is needed and should be incorporated into OSHA standards and guidance. Risk must be defined in terms of the nature of exposure, which should take into consideration a host of factors. These include: the number of contacts, length of exposure, nature of human respiratory activities (talking, singing and shouting generate more particles than silent breathing), ventilation quantity and quality, and room size. Distance from the infection source should not be considered an important feature of exposure nor a method for preventing transmission. Small infectious respiratory particles spread easily throughout an indoor space especially where ventilation is sub-optimal. While risk for serious health outcomes may be related to sex, age, co-morbidities and other demographic factors, these should not be the primary variables for determining workplace risk.

⁴⁴ Radcliff B, Brailo A. Beware: Our N95 Supply Chain Is Fragile. MedPage Today. Published February 18, 2022. Accessed February 23, 2022. <https://www.medpagetoday.com/opinion/second-opinions/97272>

The level of respiratory protection must be matched with the level of risk.

Demography should only be used to adjust the level of risk after first determining the likelihood and degree of exposure.

The level of respiratory protection must be matched with the level of risk. Respirators with higher assigned protection factors must be used for higher exposure jobs, workplaces, and work activities. Employers must be required to deploy source and pathway controls like ventilation before implementing respiratory protection since respirators cannot be the only method for preventing person-to-person infection from an aerosol-transmissible infectious respiratory disease.

Healthcare workers with direct patient care responsibilities should top the priority list for personal protective equipment. They must be provided reusable respirators such as elastomeric half-mask respirators for the remainder of the pandemic.⁴⁵ These respirators must be fit-tested and workers trained as part of a comprehensive respiratory protection program complying with OSHA's respiratory protection standard. Where the risks are elevated, workers should be provided more protective powered air purifying or similar respirators.

Next on the priority list are people who work in non-healthcare high-risk settings like emergency services, meat packing, poultry, food processing, corrections, grocers, and warehousing. These are followed by workers in moderate-risk settings such as restaurants, retail, and transportation. Both sets of workers should be provided respirators by employers and fit-tested in the context of comprehensive respiratory programs.

Workers in lower-risk jobs in which interactions with co-workers or the public are few and brief should be encouraged and permitted to wear N95 FFRs, preferably provided and paid for by their employer.

OSHA should update its Workplace Covid Guidelines to outline these updated requirements and recommendations for respirator use.

The CDC should update and strengthen the Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (Covid) Pandemic to require respiratory protection for all healthcare workers exposed to SARS-CoV-2 on the job, rather than only healthcare workers involved with the care of or who have direct contact with patients with confirmed or suspected Covid infection.

OSHA should update its Workplace Covid Guidelines.

Most of the focus has been on filtering facepiece style respirators. Innovative designs of elastomeric respirators are available, many without exhalation valves. These should be made available to more workers and required in healthcare settings. NIOSH and OSHA should undertake the research and regulatory changes needed to encourage the development and deployment of reusable respirators for both source control and personal protection.

⁴⁵ The National Academies of Sciences, Engineering, and Medicine. Consensus Study Report: Study on the Use of Elastomeric Respirators in Health Care. Published 2018. Accessed February 20, 2022. <https://www.nationalacademies.org/our-work/study-on-the-use-of-elastomeric-respirators-in-health-care>

PPE Strategic Goals

1. The CDC NIOSH National Personal Protective Technology Laboratory (NPPTL) should define, assess, and approve performance standards for respirators for public use.

- a. Fund NPPTL to expand its scope of operations as the primary assessor and approver of respirators for public use.
- b. Direct NPPTL to develop and implement a ratings and certification process for evaluating public-use respirators.
- c. Direct NPPTL to develop specifications and performance tests that evaluate respirators for outward and inward leakage.
- d. Direct NPPTL to develop specifications and performance tests that evaluate respirators for use by children.
- e. Direct NPPTL to develop and implement comfort assessments that will encourage use of respirators by the public.
- f. Launch a CDC-led public education program on how to select, fit, and use a N95 FFR or similar respirator, and provide ongoing guidance on recommended respirator use in indoor settings.
- g. Direct the FDA to recognize all NPPTL standards, testing, and approval processes for public-use respirators without requiring further testing or approval.

2. An appropriate federal agency should use regulatory and financial incentives to increase onshore production and equitable distribution of N95 FFRs or similar respirators.

- a. Use advanced purchasing agreements to incentivize long-term domestic production of affordable respirators and smooth demand.
- b. Promote respirator production at geographically dispersed domestic facilities to protect against supply chain disruptions and increase access.
- c. Diversify sources of respirator production to include SME respirator manufacturers, which can bolster product innovation and supply.

- d. Utilize the Defense Production Act to ramp up production if necessary.
- e. Direct NPPTL to develop simple, standardized respirator designs that can be quickly manufactured when supplies are low or supply chains are disrupted.
- f. Restock the Strategic National Stockpile with reusable and disposable respirators for distribution to employers and the public during future surges and re-evaluate and replace supply on a regular cadence.
- g. Establish and fund a national free or low-cost distribution program that prioritizes equitable respirator distribution, with a focus on low-income and minority Americans.
- h. Require, support, and incentivize hospitals and other healthcare facilities to stockpile reusable respirators for use in surge situations.

3. NIOSH and OSHA should require or recommend N95 FFRs or similar respirators for workers in medium- and high-risk settings.

- a. Direct OSHA to update regulations to apply the respiratory protection standard to all moderate- and high-risk work environments.
- b. Require or recommend all employers to provide workers in healthcare, long-term care, correctional facilities, homeless shelters, and other settings with direct patient care or customer, co-worker, or visitor contacts with fit-tested, reusable N95-equivalent or more protective respirators.



06

Vaccines

Summary

The rapid arrival of Covid vaccines saved millions of lives. The country needs research on optimal dosing and combination of already-approved vaccines. The search for new vaccines that offer better, broader, and longer-lasting protection should be an even bigger priority. Worldwide manufacturing capacity should be strengthened and global vaccination efforts further supported. The FDA should offer clear guidance on when boosters are needed and how new vaccines prove efficacy. A media ecosystem spreading misinformation on vaccines must be confronted in innovative ways.

A Miraculous Effort

The United States developed, manufactured, and tested Covid vaccines in record time. Within 10 months of the declaration of a pandemic, this national effort created the first highly effective Covid vaccines. By February 2022, the United States had two FDA-approved mRNA vaccines (Pfizer and Moderna) and a third adenovirus-based vaccine (Johnson & Johnson) available under an Emergency Use Authorization (EUA). A fourth, protein-based vaccine (Novavax) is under review by the FDA.

These vaccines have been remarkably effective. Too often this goes unappreciated. Vaccinated people have a 1 in 34,000 chance of dying from Covid and a low hospitalization rate. According to data from Los Angeles, the unvaccinated are 23 times more likely to be hospitalized than vaccinated and boosted individuals.⁴⁶ While vaccines may not eliminate transmission, they are doing the most important things: reducing severe Covid and saving lives.

These vaccines have been remarkably effective. Too often this goes unappreciated.

Uncertainties about future viral variants and waning immunity necessitate sustaining and strengthening research and development of vaccines. Variant-specific mRNA vaccines are being tested. Research to develop better or more broadly neutralizing vaccines is proceeding. Development of effective mRNA vaccines for other respiratory viruses, including influenza and respiratory syncytial virus, should be an urgent priority, with the ultimate goal of creating a single vaccine against multiple respiratory viruses. Fortunately, dozens of next-generation vaccine candidates are in preclinical or clinical development in the U.S. and hundreds globally.

⁴⁶ Muoio D. Unvaccinated 23 times more likely than boosted to be hospitalized during omicron wave. Fierce Healthcare. Published February 2, 2022. Accessed February 21, 2022. <https://www.fiercehealthcare.com/providers/unvaccinated-23-times-more-likely-boosted-be-hospitalized-during-omicron-wave>

Supply chain, manufacturing capacity, and approval processes must remain robust, flexible, and efficient.

The federal government successfully relied on the Defense Production Act to maximize the output of domestic vaccine manufacturing. However, the supply chain for raw vaccine ingredients and consumables remains fragile and needs bolstering. Manufacturing plants subsidized by the federal government for vaccine production have been unable to deliver quality vaccines but are critical to national biosecurity, highlighting the importance of strengthening the industrial base for domestic and near-shore vaccine manufacturing.

Despite the ample vaccine supply and a monumental effort by the Biden administration to establish broad distribution programs, about 20 percent of Americans have yet to receive a single vaccine dose and another 33% have received only one.⁴⁷ Among Americans over 65, 66% have received a booster.⁴⁸ Low vaccination rates are the main reason the United States has suffered unusually high Covid death and hospitalization rates.

Public messaging about vaccines has sometimes been confusing. This has been compounded by widespread vaccine misinformation. Although surveys indicate that a substantial percentage of the unvaccinated population will remain difficult to convince, any increase in vaccine uptake will help reduce overall incidence of Covid and accelerate the transition to the next normal. Programs to improve public health messaging, counter misinformation, and improve vaccine uptake at the local level must remain a priority. Consistency and transparency regarding recommendations and rationale are key to building trust. Establishing clear lanes in which policy experts provide policy guidance and scientists provide technical guidance can reinforce that trust.

The variants that partially eroded the efficacy of both vaccines and medical therapies may have emerged from areas of the world with large numbers of people living with immunosuppressive conditions and limited access to quality vaccines. Fully 92 nations missed the WHO's global

target of vaccinating 40% of their populations by the end of 2021.⁴⁹ Even more nations will miss the summertime goal of 70%. The United States has supplied 400 million doses of vaccines to low- and middle-income countries that lack their own vaccine production capacity.⁵⁰ But more needs to be done. Enhancing global vaccine distribution and administration will reduce the risks of new viral variants emerging. Global vaccination efforts should largely focus on health workers and vulnerable individuals in those nations since the Omicron variant has ended the global goal of stopping infections through vaccination coverage alone.

Vaccine Research and Development Should be Sustained and Enhanced

The amazing success of the first vaccines cannot make the United States complacent on Covid vaccines. Federal funding of research on vaccines for respiratory viruses, as well as immunology and virology must be sustained. There are five main research priorities. First, optimizing scheduling and vaccine combinations. Second, identifying novel technologies to improve vaccine immunogenicity, durability, and tolerability. Researching mucosal delivery mechanisms is the third, while the fourth is developing strategies on adjuvants usage and dose-sparing. The last is improving thermostability, storage, and transport.

⁴⁷ Centers for Disease Control. Covid-19 Vaccinations in the United States. Accessed February 21, 2022. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

⁴⁸ Centers for Disease Control. Covid-19 Vaccinations in the United States. Accessed February 21, 2022. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

⁴⁹ National Public Radio. The goal: At least 40% vaxxed in all nations by year-end. This map shows how we stand. Published December 30, 2021. Accessed February 21, 2022.

<https://www.npr.org/sections/goatsandsoda/2021/12/30/1068920127/the-goal-at-least-40-vaxxed-in-all-nations-by-year-end-this-map-shows-how-we-sta>

⁵⁰ Southeray S. US donates 400 million COVID-19 vaccine doses to COVAX. Center for Infectious Disease Research and Policy. Published January 26, 2022. Accessed February 2021, 2022. <https://www.cidrap.umn.edu/news-perspective/2022/01/us-donates-400-million-covid-19-vaccine-doses-covax>

Two major funding priorities must be to develop vaccines that protect against multiple variants and to create universal pan-sarbecovirus vaccines to protect against all coronaviruses.

To help the FDA, more work must be done to define surrogate markers for vaccine efficacy and the potential role for human challenge studies. The federal government should make “at risk” investments in variant-specific vaccines as an insurance policy against Omicron or other variants becoming more deadly. Informed by immune surveillance and vaccine effectiveness, the CDC and the FDA should together establish a framework for deciding if and when to recommend additional vaccine doses or revaccination, as well as when to produce and use new variant-specific, pan-variant, or other vaccines.

Strengthen and Enhance Domestic Vaccine Manufacturing Capacity

New or modified vaccines will not help if they cannot be produced quickly at mass scale. Using advance purchasing agreements and other financial incentives, the federal government must incentivize vaccine manufacturing infrastructure. Maintaining manufacturing capacity to meet uncertain needs will require public-private partnerships at every stage of the supply chain. The FDA should pre-inspect multiple plants to ensure that surge capacity remains ready on an ongoing basis. If done properly, the additional capacity can be used to manufacture other biologics unrelated to pandemics. Training centers and online courses should be created and their completion incentivized so the country has an adequately trained workforce for vaccine production.

Increasing Vaccine Uptake via Targeting Programs and by Countering Disinformation

The underlying causes for poor vaccine uptake vary, but misinformation and distrust are major factors. Five approaches need to be implemented. Early indications are that localized approaches and grassroots campaigns work best.

First, the federal government should recreate and sustainably fund the teams that vaccinated highly vulnerable residents of long-term facilities, those in congregate settings, the homeless, and other underserved groups. These teams will be useful in delivering public health interventions to these populations, especially vaccines such as influenza and pneumococcal pneumonia vaccines. The government should also expand funding for community health worker programs, to provide sustained support to these populations.

Next, CMS should reimburse clinicians for discussing vaccinations with patients insured by Medicare and Medicaid, as well as institute similar requirements for Medicare Advantage plans and plans sold on the exchanges. These reimbursement policies should also be extended into nursing homes and skilled nursing facilities.

New or modified vaccines will not help if they cannot be produced quickly at mass scale.

Additionally, misinformation on vaccines has seeped into the American discourse through cable channels, as well as social and fringe media, convincing millions to forgo vaccination. Confronting vaccine misinformation will probably require changing media laws and regulations to eliminate algorithms that preserve misinformation bubbles and making platforms responsible for the misinformation they house.

The Administration should also consider stark public service advertisements that graphically illustrate the worst outcomes of SARS-CoV-2 infections in unvaccinated people modeled on successful anti-smoking efforts and campaigns to encourage varicella and human papillomavirus vaccinations.

Fourth, both federal and local policymakers should establish partnerships with trusted community leaders and faith-based organizations to provide educational supports and address vaccine hesitancy within minority communities.

Finally, the Vaccine Adverse Event Reporting System is unreliable as an adverse event reporting system. Simultaneously, anti-vaccine groups have co-opted the data and propagated misinformation. It should be replaced with a reliable and representative system of active monitoring for vaccine adverse events.

The Administration should also consider stark public service advertisements that graphically illustrate the worst outcomes of SARS-CoV-2 infections in unvaccinated people.



Vaccine Dosing and Booster Policies, and Infection-Mediated Immunity

The federal government needs to do a better job providing clear, evidence-based advice about when and for whom additional vaccine “booster” doses are needed. The NIH has not conducted studies to define an optimal dosing schedule or combination of vaccines. More insight is needed into whether prior SARS-CoV-2 infections offer protection similar to two doses of vaccine.

The time period for which proof of prior vaccination or infection should be considered protective needs to be determined based on real-world data on the decline

in protection. Similarly, combinations of infection and vaccination, especially in the wake of variants such as Omicron, should be continually evaluated to determine their impact on durable immunity. Research by NIH into these issues should be an urgent priority, with results needed before the end of 2022.

The Administration should develop a national program for serological and, if possible, cellular immunology surveillance to complement viral surveillance programs (see *Chapters 3: Testing and Surveillance* and *9: Health Data Infrastructure*). To enable this work, the federal government should establish an interoperable, electronic, national verification system to capture vaccination data, positive SARS-CoV-2 test data (including from high sensitivity and specificity rapid at-home tests with QR codes that can be uploaded), and serology information (see *Chapter 3: Testing and Surveillance*).



Leading the Global Vaccine Rollout Effort

Helping vaccinate the world is not only a moral imperative but is integral to protecting Americans from the emergence of variants such as Delta and Omicron. This goal cannot be met if millions of donated vaccine doses go unused and expire because shipments arrive in poor nations late or with little notice and inadequate resources are available to support their administration.

The White House should seek sufficient funding from Congress to support vaccine delivery and adult immunization efforts in low- and middle-income countries. The administration must improve the predictability of American vaccine donations, and work with local health officials to develop the logistics and community engagement strategies necessary to reach the vulnerable people most in need of vaccination.

The United States should continue to support regional manufacturing hubs in low- and middle-income nations to ensure earlier and more equitable global vaccine access in future pandemics. This might best be accomplished by having the World Bank create new mechanisms to mobilize surge financing for manufacturing in future pandemics and work with regional entities to bolster pooled procurement mechanisms, such as the African Vaccine Acquisition Trust and the Asia-Pacific Vaccine Access Facility. The United States should also support efforts at the World Trade Organization to restrict or eliminate the use of export restrictions on vaccines and other essential medical supplies during pandemics, including the present one. The U.S. government can leverage its research and licensing agreements to encourage more technology transfer to production facilities in developing countries in order to accelerate global vaccine manufacturing.

Vaccines Strategic Goals

1. Direct and fund HHS—including the NIH and FDA—to accelerate vaccine-related research and development.

- a. Dedicate additional federal funding to research on respiratory virus vaccines, immunology, and virology.
- b. Dedicate additional federal funding to correlates of protection to facilitate development of next-generation Covid and respiratory viral vaccines.
- c. Enter ‘at risk’ agreements with manufacturers to develop vaccines targeting SARS-CoV-2 variants, multiple respiratory viruses, and all coronaviruses.
- d. Incentivize manufacturers to develop innovative vaccines, including those that are easier to administer, thermostable, and mucosal vaccines.
- e. Incentivize manufacturers to evaluate the use of adjuvants to augment vaccine efficacy and durability, as well as potentially expand supply.
- f. Direct the FDA to clarify best practices for next-generation Covid vaccine clinical trials, the incorporation of biomarkers when clinical efficacy studies aren’t feasible, and the potential role for human challenge studies.

2. Direct HHS to expand domestic vaccine production capacity.

- a. Partner with commercial facilities to expand the industrial base for domestic vaccine manufacturing and establish surge capacity.
- b. Identify and contract with multiple sources for critical reagents and raw materials to ensure supply chain security.
- c. Promote resilience and flexibility in manufacturing capacity, including support of off-site construction of modular manufacturing facilities.
- d. Fund the expansion and training of the vaccine production workforce.

3. Direct and provide sufficient funds for HHS to achieve at least an 85% vaccination rate by the end of 2022.

- a. Conduct a detailed zip code-level analysis of vaccination rates, identify subgroups of unvaccinated populations, and launch tailored grass-roots efforts in partnership with community leaders and faith-based organizations to provide education on and promote vaccination.
- b. Stand up teams and utilize community health workers to vaccinate hard-to-reach populations, such as those experiencing homelessness, in long-term care facilities, or in underserved or remote areas.
- c. Fund CMS to improve vaccination rate disparities in poor-performing long-term care facilities and nursing homes with predominantly minority populations.
- d. Direct CMS to reimburse clinicians for discussing vaccinations with patients insured by Medicaid and Medicare, and institute similar requirements for Medicare Advantage plans and plans sold on the exchanges, across care settings.
- e. Delineate two separate codes (and payments) for vaccine delivery and vaccine counseling, enable counseling code to be billed on the same day as a vaccine delivery, and mandate coverage across Medicaid, Medicare, Medicare Advantage, and the exchanges.
- f. Combat misinformation via consistent and clear public health messaging, including altering VAERS so it is not a source of misinformation. Partner with social media outlets to reduce misinformation and spread factual information.
- g. Fund initiatives through CMS that expand FQHC authority to partner with community and faith-based organizations in establishing and maintaining immunization sites.

4. Direct HHS agencies to develop and publish clear, evidence-based guidelines for future vaccine doses.

- a. Direct the NIH to initiate research into the impacts of previous infection and heterologous prime boost regimens (e.g., mRNA vaccine followed by J&J booster) on immune protection.
- b. Direct the NIH to collaborate with vaccine manufacturers to establish optimal primary and booster vaccine schedules for the different vaccinations based on updated clinical studies and real-world data.
- c. Direct the CDC to establish vaccination guidelines for different populations, depending on risk, including the need for additional “booster” dose(s).
- d. Launch a national immune surveillance infrastructure to monitor longitudinal population immunity and adverse reactions, as well as identify changes that may warrant revaccination or use of different vaccines (see *Chapter 9: Health Data and Infrastructure*).

5. Direct USAID to continue to lead global vaccine efforts.

- a. Direct the CDC and USAID to collaborate to determine total U.S. vaccine donations over 2022 and align on a process and timeline to allocate supply to countries in need.
- b. Direct USAID to work with vaccine manufacturers to expand global vaccine manufacturing hubs.
- c. Direct USAID to fund global vaccine storage capacity and vaccine administration efforts.
- d. Streamline technology transfer to and intellectual property agreements with developing countries, to accelerate global vaccine manufacturing.
- e. Direct USAID to engage the WHO and development banks to mobilize financing and procure supplies to support vaccinations and diminish inequalities.



A female pharmacist with dark curly hair, wearing a white lab coat over a light blue button-down shirt, is working in a pharmacy. She is holding a tablet computer in her left hand and a white pen in her right hand. She is reaching up with her right hand to a shelf filled with various pharmaceutical boxes and bottles. The background shows more shelves stocked with medications. The overall scene is brightly lit, typical of a modern pharmacy.

07

Therapeutics

Summary

Newly developed and repurposed therapeutics to treat Covid have saved lives. Despite their expedited development, identification of safe and effective therapies relied on a patchwork of trials and the urgent reconfiguration of existing trial networks to focus on Covid drug development. Many of the drugs are in short supply, cumbersome to administer, or difficult for patients to get. The federal government must sustain and expand its capabilities to conduct large-scale, coordinated clinical trials in a crisis, and intensify efforts to develop more treatments, especially ones that are easier to administer. It must improve access to treatments, especially among patients with underlying risk factors, children, and minority communities. Finally, it should devise a framework to hedge against the emergence of variants that will inevitably become resistant to existing antiviral therapies.

A Quiet Success Story

Efforts to develop effective treatments for Covid have notched some extraordinary successes, a story sometimes overshadowed by controversies surrounding unproven therapies. Among the major advances were the expedited development and December authorizations of Pfizer's Paxlovid and Merck's molnupiravir. Both are antiviral pills that patients can take by mouth. If given early, both reduce the risk of progression to severe Covid. Separately, the rapid creation of monoclonal antibodies by numerous other pharmaceutical companies including Roche, Regeneron, Eli Lilly, GlaxoSmithKline, and Vir Biotechnology has been critical in treating people with high risk of severe outcomes from SARS-CoV-2 infection, and these development platforms are designed to enable rapid updates to combat virus evolution.

Efforts to develop effective treatments for Covid have notched some extraordinary successes.

In February, the FDA authorized the use of bebtelovimab, a monoclonal antibody developed by Eli Lilly meant to replace two earlier intravenous treatments that were not effective against the Omicron variant. Physicians have also gotten better at using traditional treatments like baricitinib and steroids to treat severely ill patients.

But much more is needed.

Accelerating Therapeutic Development, Availability, and Access

Early in the pandemic, efficient therapeutic development was hindered by a multitude of small and competing trials that had little prospect of generating reliable information. The early authorization of convalescent plasma based on unreliable data delayed the development of more promising therapies. The clinical trials infrastructure in the United States, arguably the best in the world, was not designed to execute trials in an expedited and coordinated manner under the pressures of a pandemic. Unlike the United Kingdom, the United States was not able to leverage a coordinated health care system where every patient had the opportunity to volunteer to participate in a clinical trial as a care option.

There were high hopes for monoclonal antibody treatments to rescue sick, hospitalized patients. But clinical trials showed these drugs work best in the outpatient setting even though their intravenous administration make them awkward to give outside of hospitals. While monoclonal antibodies have certainly saved lives and redefined treatment options for SARS-CoV-2-positive individuals, they are cumbersome to manufacture, available in limited supply, and are prone to losing their activity when confronted with a new variant. Omicron rendered all but two of the authorized antibody treatments ineffective. On February 23, the FDA limited the use of one of those final options, the GSK/Vir monoclonal antibody sotrovimab, citing reduced effectiveness against the Omicron BA.2 variant. This rapid evolution of the SARS-CoV-2 virus has shown the need to continually redesign monoclonal antibodies to match evolving variants.

Remdesivir, the first drug authorized by the FDA to treat Covid in hospitalized patients, was recently found to reduce hospitalization if given early in the disease course. But the drug requires multiple days of intravenous administration, a significant barrier to its use in outpatient settings.

Omicron rendered all but two of the authorized antibody treatments ineffective.

Indeed, major limitations exist with all of the treatments that have either been approved or authorized for use against Covid. For example, only three of the drugs are formulated for oral administration, and only two have been authorized for use in children under 12. None are formulated into an easily administered oral, multi-drug antiviral cocktail that can reduce the risk of drug resistance while effectively reducing the risk of hospitalization and death. And none are yet authorized to address host-targeted inflammatory cascades that can exacerbate illness and lead to death.

Moreover, many challenges have limited the utility of these therapeutics, including viral mutations, in-patient administration, and supply shortages. Poor coordination between Covid testing efforts and the broader health care system has often delayed their deployment. There are significant racial and ethnic disparities with respect to treatment utilization, with Black, Asian, and Hispanic-identifying patients all less likely than Whites to receive monoclonal antibodies.⁵¹

⁵¹ Wiltz J, Feehan A, Molinari N, et al. Racial and Ethnic Disparities in Receipt of Medications for Treatment of COVID-19 — United States, March 2020–August 2021. Centers for Disease Control: Morbidity and Mortality Weekly Report. Published January 14, 2022. Accessed February 21, 2022. <https://www.cdc.gov/mmwr/volumes/71/wr/mm7103e1.html>

Accelerating the Development of High-Value Treatments



There are five primary purposes of Covid therapeutics. First, preventing infection after known exposure. Second, keeping the sickened out of the hospitalized. Third, reducing hospital stays. Fourth, preventing or ameliorating long Covid. And finally, saving lives.

Beyond the present stable of monoclonal antibodies, oral antiviral drugs, and repurposed treatments, there are significant opportunities to accelerate the development of therapies supporting these objectives. The discussion draft of the bipartisan PREVENT Pandemics Act introduced in the U.S. Senate identifies several potential means of incentivizing and accelerating the development of innovative therapeutics, including the establishment of new priority designations for specific biologics and treatments using new platforms.⁵²

This report's authors believe the federal government should prioritize the development of therapeutics that are easy to manufacture and administer. These include orally administered antiviral drugs, especially those that can be combined into a multi-drug cocktail, and prophylactic

monoclonal antibodies that can be administered outside the clinic, potentially via a subcutaneous or intramuscular delivery mechanism. The Milken Institute is currently tracking 332 Covid treatment candidates at various stages of development.⁵³ Of these, 237 are in clinical trials and 95 are in pre-clinical development. Some will be easier to scale than others.

Next, the U.S. government should strengthen the ACTIV public-private partnership and ACTT multinational platform to further accelerate the development of the most promising therapeutics. Building on the ACTIV platform, the NIH should further expand the number of adequately powered trials using private sector contract research organizations and clinical sites to provide strong evidence for or against effectiveness across meaningful outcome measures in participants who are diverse in age, ethnic background, and known co-morbidities.

Such an accelerated effort will require more efficient use of existing resources, as well as rapid increases in total clinical research capacity and throughput. This would require partnering with clinical research organizations and persuading or using funding authorities to mandate academic medical centers that receive federal research funds to prioritize large collaborative projects, rather than undertake small bespoke therapy studies or industry-funded studies outside of the ACTIV portfolio.

Development should focus on four main types of therapeutics: oral multi-drug antiviral cocktails, long-acting monoclonal antibodies, intravenous antiviral treatments, and immune modulators.

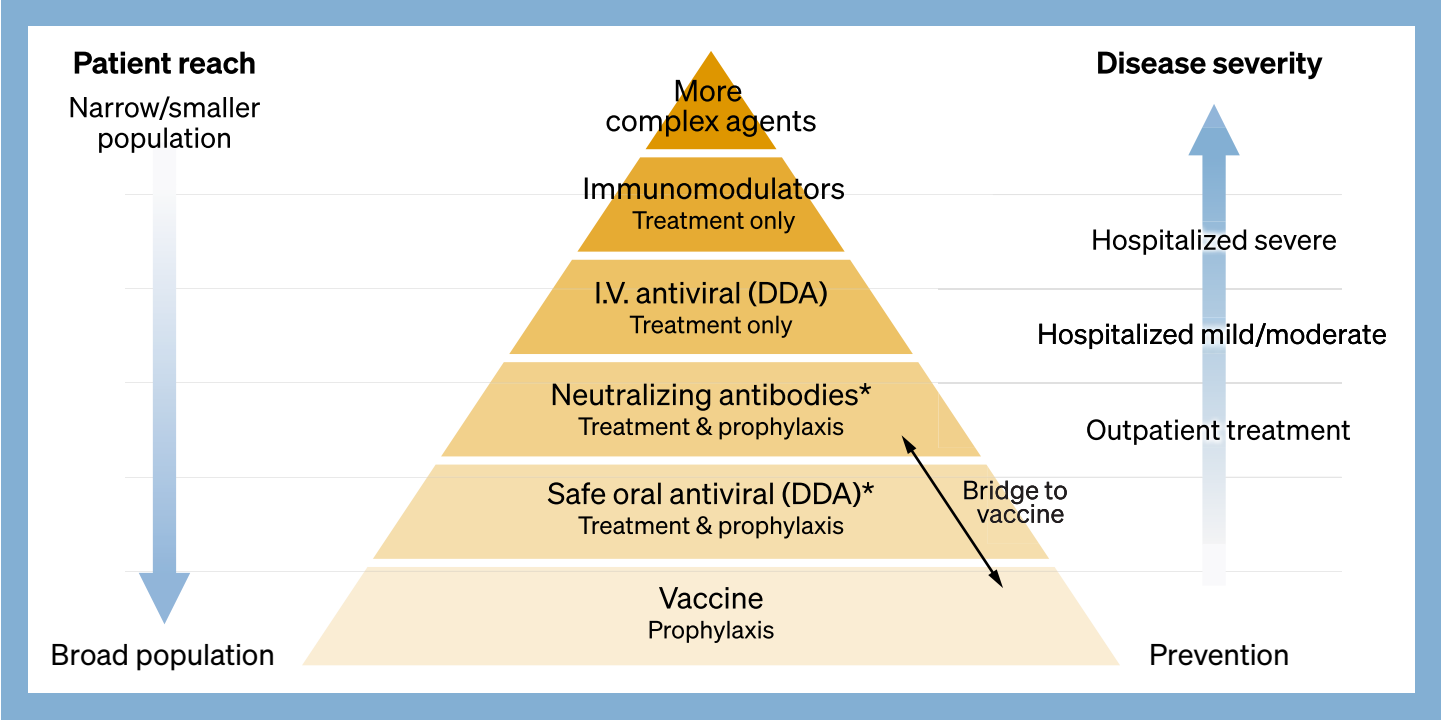
The federal government should prioritize the development of therapeutics that are easy to manufacture and administer.

⁵² PREVENT Pandemics Discussion Draft. Accessed February 18, 2022. <https://www.help.senate.gov/imo/media/doc/PREVENT%20Pandemics%20discussion%20draft%20sxs%20final.pdf>

⁵³ Milken Institute. Covid-19 Treatment and Vaccine Tracker. Last updated February 17, 2022. Accessed February 18, 2022. <https://covid-19tracker.milkeninstitute.org/>

Figure 1

Vaccination and Treatment Options, by Disease Severity and Patient Reach



Most of the attention should focus on oral, multi-drug antiviral cocktails, which are easy to administer and are the least likely to encounter viral resistance.

Next on the priority list should be monoclonal antibodies. These medicines tend to have long durations, can be useful in prophylaxis, are often helpful in particularly vulnerable patients, and can reduce the risks of viral resistance or escape when given in combinations.

Finally, immune modulators could be effective in preventing or ameliorating severe outcomes like long Covid and Acute Respiratory Distress Syndrome. Among the targets for these drugs are inflammatory pathways (e.g., complement cascade and pro-and anti-inflammatory cytokines), coagulation cascade regulators, and autoantibodies. For the subset of patients who fail to activate the immune system properly, immune stimulators should also be considered.

Given the lack of pediatric authorizations and studies, the federal government should accelerate clinical trials to establish safety, efficacy, and optimal dosing of therapeutics for children.

Most of the attention should focus on oral multi-drug antiviral cocktails.

Finally, the federal government should do more to promote research into the potential repurposing of existing medications for new Covid-related indications. To be sure, ACTIV led by the Foundation for the National Institutes

of Health is doing this, but these efforts need more urgency, greater resources, and better alignment with drug development efforts across HHS, including BARDA. If any drugs are demonstrated to be safe and effective Covid treatments, the benefits of skipping expensive and time-consuming drug discovery and possibly human safety trials would clearly be welcome.

Anticipating and Combating Emerging Drug Resistance

The introduction of mono-therapy approaches for new antivirals increases the risk of antiviral resistance and potential to further drive viral evolution towards new variants. To monitor for and mitigate this risk, the federal government should require each manufacturer to share all data on antiviral resistance collected during clinical evaluation, including genomic sequences of the viruses and metadata associated with observed genetic changes in viruses collected from people undergoing treatment. Manufacturers should support an independent network for ongoing genomic surveillance for known markers associated with reduced therapeutic efficacy, sharing data publicly in real time.

Finally, the NIH should accelerate clinical studies evaluating combination therapies of available oral treatment options, which is the best approach to reduce the risks of antiviral resistance to any single drug. Such combinations are now the standard of care in treating HIV/AIDS.



Deploying Effective Treatments Quickly

To meet the demand for currently approved treatments, the administration should use every mechanism and incentive possible to rapidly scale up supplies of Paxlovid, Evusheld, bebtelovimab, and sotrovimab. To scale vaccine production, the Biden administration utilized the Defense Production Act. Similar approaches should be used to turbocharge supplies of these effective but scarce medicines.

Notably, the discussion draft of the PREVENT Pandemics Act would launch a new pilot designation to accelerate the development of new drug manufacturing technologies, as well as establish manufacturing surge capabilities within BARDA, both of which are likely to mitigate supply shortages over the long-term.⁵⁴

⁵⁴ PREVENT Pandemics Discussion Draft. Accessed February 18, 2022. <https://www.help.senate.gov/imo/media/doc/PREVENT%20Pandemics%20discussion%20draft%20sxs%20final.pdf>

Collaborating Proactively with the Private Sector

The federal government should not tackle these challenges alone. The NIH and BARDA should work collaboratively with the private sector to prioritize promising, scalable treatments and move them quickly through the research pipeline.

Several companies have developed rapid monoclonal antibody discovery and production platforms. Given that the Omicron variant has escaped the targeted epitopes for most currently authorized antibodies, companies should be incentivized to rapidly update their antibodies to match circulating virus variants. Antigenic cartography and other approaches should be used to create libraries of monoclonal antibodies with potential activity against future variants. Some of these antibodies with desirable characteristics such as predicted resilience to mutations should be moved to advanced preclinical (and possibly clinical) development at risk.

If companies are unable to update their antibodies, they should make their manufacturing facilities and supplies available to enable the scale-up and production of other antibody treatments that remain effective against circulating virus variants.

There must be an effective test-to-treat platform for all Americans so that everyone who tests positive for Covid is offered appropriate and rapid treatment.

The federal government should not tackle these challenges alone.

Establishing an Affordable and Effective Test-to-Treat Pathway

Finally, there must be an effective test-to-treat platform for all Americans so that everyone who tests positive for Covid is offered appropriate and rapid treatment, whether that test occurs at home, a pharmacy, a hospital, or elsewhere.

Rapid antigen tests have great specificity at detecting active Covid infections and thus can serve as reliable and affordable triggers to initiate health consultations and rapid delivery of prescription medications. The federal government should establish a data tracking system that, for those who participate, will proactively initiate an immediate healthcare consultation and suggest appropriate treatment options or clinical trial enrollment after positive tests.

Outpatient Covid treatments should be widely available at no cost — no deductible, no co-pay, and free for the uninsured—for anyone testing positive for Covid and meeting FDA indications. The federal government should prioritize equitable distribution by investing in outreach to underserved populations, as well as supplying safety net facilities and pharmacies in low-income areas with appropriate supplies of therapeutics. Certain Covid treatments should also be made more readily available for preexposure prophylaxis in high-risk groups, especially those who do not respond to vaccination.

Therapeutics Strategic Goals

1. Direct HHS (inclusive of CDC, BARDA, the NIH, and the FDA) to prioritize clinical research and development of Covid therapies, using both regulatory and financial incentives.

- a. Expand the ACTIV and ACTT platforms to rapidly evaluate existing and novel treatments more quickly in a coordinated manner.
- b. Fund acceleration of clinical trials and review processes for oral antiviral therapies and multi-drug antiviral cocktails.
- c. Fund acceleration of clinical trials and review processes for Covid therapeutics targeted to children.
- d. Strengthen requirements regarding recruitment and inclusion of diverse participants in Covid clinical trials to ensure safety and efficacy for all groups.
- e. Fund accelerated development of host-targeted therapies and immune modulators that can reverse or block cytokine-induced inflammation and treat acute respiratory distress syndrome (ARDS).
- f. Incentivize evaluation of existing therapies that might be repurposed for Covid.
- g. Reward the rapid development of monoclonal antibodies to match currently circulating virus variant(s).
- h. Incentivize additional research into the basis of long Covid, identify new therapeutic targets, and extend efforts in host targeting.

2. The federal government should accelerate the production and distribution of Covid therapies, using both regulatory and financial incentives.

- a. Rapidly scale up supplies of currently approved treatments (Paxlovid, Evusheld, bebtelovimab, and sotrovimab) with every mechanism and incentive possible. This should include using the Defense Production Act to expand, prioritize, and expedite supply of raw materials and production facilities to meet the urgent demand.

- b. Invest in additional on-shoring or near-shoring manufacturing capacity and raw material, ancillary, and other supply chain items required for therapeutics.

3. Direct the CDC to launch a comprehensive, publicly accessible, proactive genotypic and phenotypic surveillance system to monitor development of treatment resistance among viruses in the general population and resulting from patients treated with SARS-CoV-2 targeted treatments.

- a. Require manufacturers to share antiviral resistance and related genomic sequencing data acquired during clinical evaluations.
- b. Require manufacturers to fund for a period of 5 years and report data to a new independent body conducting ongoing genomic surveillance to detect reduced drug efficacy.
- c. Leverage infrastructure built to combat treatment resistance for SARS-Cov-2 to address broader antimicrobial resistance challenges, potentially in a coordinated effort with BARDA.

4. Direct HHS to establish a test-to-treat system that proactively offers clear guidance on self-isolation, therapeutic treatment, and/or clinical trial enrollment to Covid-positive individuals.

- a. Fund development of a system linking home- or rapid-test results with immediate clinical consultation and rapid distribution and provision of appropriate antivirals in high-risk individuals.
- b. Prioritize equitable distribution by investing in outreach to underserved populations, as well as supplying safety net facilities and pharmacies in low-income areas with appropriate therapeutics.



8

Long Covid

Summary

Long Covid is a serious and sometimes disabling condition affecting millions. Despite a \$1 billion Congressional allocation, research into its incidence, causes and treatments has been achingly slow. The Biden Administration must appoint a long Covid point person who can corral agencies to accelerate studies already begun, launch new ones and address gaps in the health and social service support system for current and future patients.

Fatigue, Brain Fog, and Curtailed Work Schedules

Long Covid has been linked to over 200 symptoms.

Over the past two years, vaccines, treatments, and increased immunity have blunted the short-term risk of hospitalization and death from Covid. But as the pandemic transitions to endemic, the nation remains unequipped to address Covid's long-term health impacts, which are formally known as Post-Acute Covid Syndrome and informally as long Covid.

The CDC defines long Covid as “a wide range of new, returning, or ongoing health problems people can experience four or more weeks after first being infected” by SARS-CoV-2.⁵⁵ Long Covid has been linked to over 200 symptoms⁵⁶, from fatigue, brain fog to shortness of breath. It seems to manifest in organ systems ranging from the heart to the lungs and gastrointestinal tract.⁵⁷

Although the reported frequency of long Covid in early studies of Covid patients varied from 5% to 60%, working estimates suggest the syndrome affects 1 in 3 infected patients.⁵⁸ Even if this is an over-estimate, the numbers are daunting. For example, if only 1 in 20 progresses to long Covid the US is facing the prospect of more than 4 million people with long Covid. Importantly, patients who have asymptomatic or mild infections can still be affected by long Covid. Evidence to date clearly illustrates that long Covid's distribution reflects the same health inequities characterizing Covid infections and deaths, with studies indicating that people of color and low socioeconomic status are at greater risk of developing long Covid.⁵⁹ While estimates have primarily relied on data from adult patients,

55 Centers for Disease Control. Post-Covid Conditions. Accessed February 20, 2022.

<https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html>

56 Davis H, Assaf G, McCorkell L, et al. Characterizing long Covid in an international cohort: 7 months of symptoms and their impact. *EClinical Medicine*. 2021; 38. <https://doi.org/10.1016/j.eclinm.2021.101019>

57 Al-Aly Z, Xie Y, Bowe B. High-dimensional characterization of post-acute sequelae of COVID-19. *Nature*. 2021; 594: 259-264. <https://doi.org/10.1038/s41586-021-03553-9>

58 Taquet M, Dercon Q, Luciano S, et al. Incidence, co-occurrence, and evolution of long-COVID features: A 6-month retrospective cohort study of 273,618 survivors of COVID-19. *Plos Medicine*. 2021. <https://doi.org/10.1371/journal.pmed.1003773>

59 Lambert N. Long Covid Health Disparities Impacting Survivors' Health Outcomes. Published June 9, 2021. Accessed February 21, 2022. https://static1.squarespace.com/static/5e8b5f63562c031c16e36a93/t/60cc20f784df6c45410096e2/1623990521374/Health+Equity+Task+Force+Presentation_Dr_Lambert.pdf

infected children are also at risk of developing long Covid. Estimates in early studies of children have found incidence rates of 1% to 27%.^{60,61} At the moment, there is no specific treatment for long Covid. But preliminary data suggests that vaccination can reduce the risk of long-term health effects after infection.⁶²

The symptoms of long Covid can persist for months with major impacts on people's lives, social interactions, and the larger economy. Nearly half of long Covid patients have cut back on their work schedules⁶³ and nearly a quarter have stopped working entirely.⁶⁴ Long Covid within the US military creates new national defense risks.⁶⁵ If Covid becomes endemic, then there is a risk that many more Americans will experience long Covid, creating huge and lasting health impacts that may rival the pandemic itself.

Long Covid was first identified as a problem in May 2020⁶⁶, with the National Institutes of Health (NIH) launching its first study on long Covid in June 2020.⁶⁷ As the pandemic progressed, reports of the disease's frequency and severity mounted, and in December 2020, Congress allocated over \$1 billion to long Covid research.⁶⁸

Despite the large numbers of infected patients and generous government funding, much of the progress so far can be attributed to patient advocacy and non-NIH funded research.^{69,70} The return on federal investments has been poor, and knowledge about long Covid remains limited.

Long Covid's causes, incidence, risk factors and most effective prophylactics and treatments are still mysteries.

Long Covid's causes, incidence, risk factors and most effective prophylactics and treatments are still mysteries.

Multiple challenges have contributed to the failure to understand this important disease. Research done so far has been siloed, with barriers to sharing resources and data. Initiation of critical cohort studies has been slow, inhibiting the generation of longitudinal, population-level data. Current long Covid research lacks a long-term focus, which risks creating further delays for therapy development. Most importantly, there is no urgency to get rapid answers to basic questions to guide public health and patient care decisions.

There were over 200 long Covid studies registered on ClinicalTrials.gov as of February 2022, but only 8 are

60 Buonsenso D, Munblit D, De Rose C, et al. Preliminary evidence on long Covid in children. *Acta Paediatrica*. 2021; 110(7): 2208-2211. <https://doi.org/10.1111/apa.15870>

61 Say D, Crawford N, McNab S, et al. Post-acute COVID-19 outcomes in children with mild and asymptomatic disease. *The Lancet: Child and Adolescent Health*. 2021; 5(6). [https://doi.org/10.1016/S2352-4642\(21\)00124-3](https://doi.org/10.1016/S2352-4642(21)00124-3)

62 U.K. Health Security Agency. The effectiveness of vaccination against long Covid. Published February 2022. Accessed February 21, 2022. <https://ukhsa.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=fe4f10cd3cd509fe045ad4f72ae0dfff>

63 Davis H, Assaf G, McCorkell L, et al. Characterizing long Covid in an international cohort: 7 months of symptoms and their impact. *EClinical Medicine*. 2021; 38. <https://doi.org/10.1016/j.eclinm.2021.101019>

64 TUC. Workers' Experiences of Long Covid. Published June 20, 2021. Accessed February 20, 2022. <https://www.tuc.org.uk/research-analysis/reports/workers-experiences-long-covid>

65 Prater S. Covid-19 Can Lead to Long Term Health Concerns. Fort Carson Public Affairs Office. Published September 20, 2021. Accessed February 20, 2022. https://www.army.mil/article/250425/covid_19_can_lead_to_long_term_health_concerns

66 National Institute of Allergy and Infectious Diseases. A Longitudinal Study of Covid-19 Sequelae and Immunity. Published June 2, 2020. Accessed February 20, 2022. <https://clinicaltrials.gov/ct2/show/NCT04411147>

67 National Institute of Allergy and Infectious Diseases. A Longitudinal Study of Covid-19 Sequelae and Immunity. Published June 2, 2020. Accessed February 20, 2022. <https://clinicaltrials.gov/ct2/show/NCT04411147>

68 National Institutes of Health. NIH Launches New Initiative to Study Long Covid. Published February 23, 2021. Accessed February 20, 2022. <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-launches-new-initiative-study-long-covid>

69 Callard F, Perego E. How and why patients made long Covid. *Social Science and Medicine*. 2021; 268. 10.1016/j.socscimed.2020.113426

70 National Institutes of Health. Citizen Scientists Take on the Challenge of Long-Haul Covid-19. Published September 3, 2020. Accessed February 20, 2022. <https://www.nih.gov/citizen-scientists-take-challenge-long-haul-covid-19>

funded by the NIH.⁷¹ Even though millions if not tens of millions of Americans suffer from long Covid, 74% of all studies — including 7 of the 8 NIH-funded studies — are either in the “recruiting” or “not yet recruiting” stage. Worse, the proposed completion date for many studies is at least 2 years away. The NIH is in the process of developing a national long Covid study platform: Researching Covid to Enhance Recovery (RECOVER).⁷² Despite a nearly \$500 million dollar allocation to the study, recruitment for RECOVER is only just beginning, and no information about the more than 200 proposed clinical sites was available. Finally, people suffering from long Covid are having a hard time navigating the system to get the health and supportive services they need. To be sure, some progress has been made. An ICD-10 code has been established permitting medical billing for treating patients with long Covid. In addition, guidance has been issued clarifying non-discrimination protections for long Covid patients under the Americans with Disabilities Act. But thousands if not millions are still having difficulty navigating the health care and disability systems. Consequently, long Covid needs to be elevated to a national priority on par with vaccines and antiviral therapeutics.

Long Covid needs to be elevated to a national priority on par with vaccines and antiviral therapeutics.

A Long Covid Lead

A point person is needed. President Biden should designate a senior health official, such as the HHS Secretary or the US Surgeon General, to chair a long Covid task force, drive interagency coordination, and lead external engagement and public health messaging related to long Covid. The long Covid task force should be separate from the White House Covid task force, as the latter is focused on the acute public health responses to Covid while the former is focused on a chronic, long-term problem facing American society.

This task force needs the authority to coordinate a whole-of-government response, from research activities at the NIH to disability guidance from the Social Security Administration (SSA).

This group must issue clear priorities, with performance metrics and timelines. It must hold agencies accountable. The task force should hold its first convening within 30 days of its creation, and it should commit to providing monthly progress updates until the major issues related to long Covid are addressed.

The task force’s top two priorities should first be conducting a review of all long Covid policies, projects, and programs, and second to accelerate ongoing research initiatives. The task force must ensure that research is focused on characterizing long Covid’s incidence, causes, risk and mitigating factors, and potential therapeutic targets.

There are several research short cuts that should be quickly taken to get rapid answers to crucial questions. First, the CDC already has a long COVID study in the field at sites across the country, and this could rapidly be expanded and used as a key surveillance and research system — and a biorepository could be added. In addition, existing general population research cohorts including the All of Us Research Program⁷³, employment-based population cohorts such as the military’s Millennium Cohort Study⁷⁴,

71 U.S. National Library of Medicine. Clinical Trials. Accessed February 20, 2022. https://clinicaltrials.gov/ct2/results?cond=long+covid&age_v=&gndr=&type=&rslt=&Search=Apply
72 RECOVER: Researching Covid to Enhance Recovery. Accessed February 20, 2022. <https://recovercovid.org/>

73 National Institutes of Health. All of Us Research Program. Accessed February 20, 2022. <https://allofus.nih.gov/>

74 U.S. Department of Defense. Millennium Cohort Study. Accessed February 20, 2022. <https://www.millenniumcohort.org/>

condition-specific cohorts such as the Jackson Heart Study⁷⁵, and subgroup specific cohorts such as the Black Women’s Health Study should be used.⁷⁶ Research is especially needed to quantify the risk factors and impact of long Covid on children, communities of color and those with low socioeconomic status. Drawing from existing cohort studies such as Environmental Influences on Child Health Outcomes (ECHO), in addition to prospective enrollment of children will be critical.⁷⁷

The extensive health data from these studies, combined with targeted collection of Covid information, should facilitate rapid answers to urgent questions about long Covid’s prevalence and incidence, risk factors, patient experience, and the impact of vaccination status. In addition to these efforts, new prospective cohort studies like RECOVER will be needed to improve characterization of the disease. These prospective studies should also collect data on relevant sociodemographic information to help identify and mitigate long Covid disparities.

The Longer Needs of Long Covid

To coordinate this work, the long Covid task force should immediately direct the NIH to stand up a team for long Covid population health science that is responsible for reviewing and partnering with all existing cohort studies for long Covid in the United States. Within 90 days, it should launch a unified, open-access platform that integrates data from these diverse studies. This platform should be updated continuously as data from additional studies are incorporated, and it would be used by scientists to generate new insights about long Covid.

Second, the government should rapidly accelerate long Covid research, including driving progress on the NIH’s RECOVER initiative, expanding and strengthening the CDC’s INSPIRE study, and supporting other meritorious research projects and programs. INSPIRE, a CDC-funded

long Covid study being conducted in partnership with 8 leading academic health centers, is already using a cloud-based technology platform for these purposes and could offer best practices to other government-funded studies.

To enroll participants in these studies and others, the long Covid task force should work to engender trust in research. Within 90 days, the government should launch a

Within 90 days, it should launch a unified, open-access platform that integrates data from all existing long Covid cohort studies.

national messaging campaign to meet the RECOVER and INSPIRE enrollment targets and ensure study participants are representative across age, sex, race, ethnicity, disability, and socioeconomic strata. There is also an opportunity to engage partners from previous pandemic-related clinical research endeavors, such as the studies for convalescent plasma and Covid vaccines. ACTIV, the NIH’s platform study for Covid therapeutics development, is an example of an existing clinical trial network that could be used to recruit for long Covid. At least quarterly updates should be published on a public-facing website for accountability and public transparency. Moreover, these studies should be producing data reports at regular intervals leveraging preprint servers, not just using traditional peer-review channels for results communication. When research is published through the peer-review process, these publications should be required to be open access as opposed to held behind firewalls; a policy many journals have adopted for Covid and should be the norm for scientific research beyond the pandemic.

75 Jackson Heart Study. Accessed February 20, 2022. <https://www.jacksonheartstudy.org/>
76 Boston University Slone Epidemiology Center. Black Women’s Health Study. Accessed February 20, 2022. <https://www.bu.edu/bwhs/>

77 National Institutes of Health. Environmental Influences on Child Health Outcomes (ECHO) Program. Accessed February 20, 2022. <https://www.nih.gov/research-training/environmental-influences-child-health-outcomes-echo-program>

Third, to maximize the impact of RECOVER and other related initiatives, the task force should take steps to ground all long Covid-related research in open science principles. Building on the strong open science precedent set by the \$1 billion Cancer Moonshot initiative launched in 2016 by then-Vice President Biden, the long Covid research agenda should emphasize open data to rapidly improve clinical and biospecimen data sharing, foster collaboration and accelerate scientific discovery. For example, the purpose-built data and biospecimen repository cores for the RECOVER study should be opened to integrate data from other efforts to study long Covid, from patient-led initiatives such as Body Politic and Survivor Corps to cohort studies such as the CDC’s INSPIRE and the National Covid Cohort Collaborative. Consolidating all



data reporting into a single, publicly accessible platform would not only amplify the impact of research but also improve the ease of rapid-cycle analyses by external scientists. The goal of every federally funded research project should be to produce strong science and to generate data for others to leverage. Moreover, there should be no grace period —as soon as data are available to be shared, they should be shared —not after a period where some investigators get preferential access. The government can support the infrastructure for sharing. In addition, the data and biospecimen resources, which would be fully deidentified, should also link with socioeconomic data to address long Covid health equity issues.

To promote accountability for research investments, in the next 90 days, the task force should direct HHS to

launch a public database of federally funded long Covid projects modeled off of the TAGGS platform for general Covid initiatives, and it should issue a set of milestones and key performance indicators for which progress reports are posted at regular intervals. As the Biden Administration helps jumpstart the long Covid research enterprise, it has a rare opportunity to initiate long-term shifts in the culture and practice of biomedical R&D.

Fourth, to streamline the development of medical products for long Covid, the task force should work with the FDA to issue guidance about expectations for authorization and approval of long Covid diagnostics and treatments. Just as the FDA issued prospective guidance about clinical trials for Covid therapies and vaccines, so too should it release guidance addressing evidence standards for long Covid. Key questions include clarifying the applicability of surrogate markers versus clinical endpoints and the use of patient-reported outcome measures. Long Covid cohorts and registries should align data collection and analysis with this guidance to ensure the evidence generated from those studies is optimized to inform therapeutic development. Furthermore, the FDA will need to issue guidance as to whether long Covid products will still be eligible for Emergency Use Authorization even if the formal public health emergency declaration has expired. In parallel, CMS should be tasked with initiating a process to streamline decisions about coverage, coding, and payment processes for long Covid.

Fifth, the long Covid task force should ensure that evaluating care delivery interventions for long Covid receives as much financial support as potential pharmacological interventions. The task force should direct the NIH to begin identifying potential study sites for multi-center care delivery trials and draw from investigators’ experience conducting randomized controlled trials for related conditions, such as Post-ICU Syndrome.

66 hospitals have launched long Covid-specific clinics.

Ensuring Good Care for Survivors

In addition to supporting research for the future, the task force will need to improve clinical care for long Covid patients in the present. As of February 2022, 66 hospitals have launched long Covid-specific clinics.⁷⁸ Nevertheless, many patients still struggle to access resources, have their symptoms acknowledged and validated, or receive timely and responsive care. To improve care for these patients, the long Covid task force should in the next 90 days designate an independent entity, such as the National Academy of Medicine, to develop standardized, consensus-based guidelines for managing long Covid. These guidelines should identify best practices for clinicians at each level of the health system, from primary care practices and mental health providers to hospitals and multidisciplinary centers. The review process could be informed by existing resources from the American Academy of Physical Medicine and Rehabilitation⁷⁹, Long Covid Physio⁸⁰, and the burgeoning network of Post-Covid Care Centers.⁸¹

Beyond clinical management, the task force should ensure policies for disability status and insurance coverage to ensure parity between benefits and services for long Covid and other disabilities. For example, the Social Security Administration could issue guidance to establish long Covid as a medically determinable impairment. The federal government needs to ensure there is capacity and infrastructure to manage the need, including home and community-based services.

With long Covid affecting nearly a third of all infected patients, disability programs are likely to experience unprecedented demand, and processes need to be set up to streamline the application and adjudication process. To this

end, the long Covid task force should in the next 90 days commit to setting up a hotline and website that provides easy-to-understand information to the lay public about how to assess whether they are eligible for disability status due to long Covid, and if so, identify the necessary process and requisite documentation for applications.

Lastly, as long Covid becomes part of the next normal, patients and caregivers will need to be supported. Modeled on the Ryan White HIV/AIDS Program, local programs need to be established to provide patient-centered, community-level outreach, support, and care coordination. Mental health should be a particular focal point given both the prevalence of neurological sequelae and the effects of long Covid on the ability to work or conduct the activities of daily life. Disability infrastructure including Centers for Independent Living, Aging and Disability Resource Centers, Parent Training and Information Centers, should all be bolstered and prepared to meet long-Covid survivors across the lifespan and prepared to support them in advocacy and systems navigation. Every part of the health care system — hospitals, nursing homes, rehab facilities, primary and specialty practices — should be analyzed to ensure there is adequate workforce and care delivery infrastructure to meet the needs of long Covid patients. These delivery system investments should be implemented with an eye towards applications for conditions related to long Covid, such as ME/CFS and post-ICU syndrome.

Local programs need to be established to provide patient-centered, community-level outreach, support, and care coordination.

78 Carbajal E, Gleeson C. 66 Hospitals, Health Systems That Have Launched Post-Covid-19 Clinics. *Becker's Hospital Review*. Published February 9, 2022. Accessed February 20, 2022. <https://www.beckershospitalreview.com/patient-safety-outcomes/13-hospitals-health-systems-that-have-launched-post-covid-19-clinics.html>

79 American Academy of Physical Medicine and Rehabilitation. AAPM&R Long COVID Consensus Guidance Statements Published on Diagnosing and Treating Long COVID Symptoms of Breathing Discomfort and Cognitive Symptoms. Published December 14, 2021. Accessed February 20, 2022. <https://www.aapmr.org/members-publications/member-news/member-news-details/2021/12/14/aapm-r-long-covid-consensus-guidance-statements-published-on-diagnosing-and-treating-long-covid-symptoms-of-breathing-discomfort-and-cognitive-symptoms>

80 Long Covid Physio. Accessed February 20, 2022. <https://longcovid.physio/>

81 Survivor Corps. Post-Covid Care Centers. Accessed February 20, 2022. <https://longcovid.physio/>

Long Covid Strategic Goals

1. Establish a long Covid Task Force to coordinate interagency activities for addressing long Covid.

- a. Establish a long Covid task force, chaired by the Surgeon General to coordinate interagency activities for long Covid, create a central node of accountability across the government for Long COVID, and to engage the public.
- b. Complete a first convening of the task force within 30 days, and issue monthly progress on milestones for each of the long Covid priorities below: scientific research, clinical care, and disability and health services.

2. Create a unified scientific and regulatory response for definitively characterizing the incidence, causes, and therapies of long Covid.

- a. Direct HHS, DOD, and the VA to leverage all ongoing US-based cohort and cross-sectional studies for long Covid research. The NIH should coordinate across these departments, and within 90 days issue a public report indicating number of participants with applicable data and outlining key operational steps for rapid answers to questions about incidence, risk factors, and identifying biological causes of long Covid.
- b. Establish a platform within 90 days for integrating long Covid data from all existing and new studies into a single system to enable data and biospecimen sharing, in alignment with patient consent.
- c. Ensure any long Covid studies or registries collect and report relevant sociodemographic data, with detailed information on race and ethnicity, to assess health disparities associated with the syndrome.
- d. Direct the CDC to create an official counter of long Covid patients, analogous to reporting for Covid infections, that is updated at regular intervals and incorporates data from preexisting and new cohort studies. The counter should be updated to include morbidity estimates as data becomes available.
- e. Execute a national public relations campaign to drive enrollment for long Covid cohort studies within 90 days.

- f. Create a public database of all federally-funded long Covid projects and provide quarterly status updates for public accountability.
- g. Require the FDA and CMS to issue guidance on expected evidentiary standards for long Covid in the next 90 days.
- h. Direct the NIH to issue a public plan for multi-center experimental pharmacological and care delivery interventions for long Covid in the next 90 days.

3. Develop consensus-based guidelines and interdisciplinary care models for clinical management of long Covid that are frequently updated.

- a. Direct an independent entity, such as the National Academy of Medicine, to convene patients, clinical leaders, and professional societies to issue and continuously update guidelines for long Covid. An initial set of guidelines should be published within 90 days, and all guidelines should be communicated to both clinical and lay audiences.
- b. Request the US Surgeon General issue a public advisory on long Covid after guidelines are published and initial data from cohort studies becomes available.

4. Ensure adequate health and social support for long Covid patients.

- a. Establish a dedicated hotline and website providing information about disability eligibility and health insurance coverage requirements for long Covid patients in the next 90 days.
- b. Require SSA to issue guidance establishing long Covid as a medically determinable impairment.
- c. Establish parity between insurance coverage for long Covid and for already recognized disabilities.
- d. Analogous to the “Ryan White Act” for HIV/AIDS, propose legislation investing in local support systems for long Covid emphasizing rehabilitation, caregiving, and mental health, and care delivery workforce and infrastructure.



09

Health Data Infrastructure

Summary

The United States has been forced to rely on Britain and Israel to provide crucial insights about the Covid pandemic because a patchwork health data infrastructure leaves the country partly blind. To better protect American lives, jobs and communities, the federal government must spend money and effort to create a national health data platform with constant and consistent inputs from every state and territory.

A Tattered Quilt of Dislocated and Disorganized Data

During a pandemic, real-time data acquisition, analysis, and sharing is essential for informed decision-making. The current health data infrastructure is fragmented and underfunded, which has led to five primary challenges hindering effective public response. The first is a lack of a secure, standardized, and real-time national data platform for SARS-CoV-2 and other health threats. Second, there are significant variations in data quality and source from public and private entities. Third, insufficient linkages across data types hinder analysis. Fourth, the timing of reports varies and are often delayed. And fifth, data analyses are generally limited, non-transparent and delayed as well.

Epidemiological analysis, outcomes tracking, and vaccine safety reporting and effectiveness have increasingly come to rely on the United Kingdom and Israel (among other nations) in large part because their health data infrastructures are more comprehensive, reliable, and timelier than that of the United States.

The nation's health data infrastructure needs a complete overhaul. In the meantime, accelerated efforts are needed to

standardize, consolidate, and link data in the short term while preparing the ground for a thoroughgoing modernization. The bipartisan PREVENT Pandemics Act introduced in the United States Senate offers some hope that both can be accomplished. The Act calls for the CDC Director to develop a comprehensive plan for strengthening both the government's internal systems and improving the bridges to private sector approaches, although it does not address the CDC's lack of legal authority to collect Covid-related data after the public health emergency declaration expires, nor its lack of authority to require that states collect and report public health data to the federal government, both of which should be addressed in future congressional legislation.



How Things Got So Bad

A core feature of the nation's health infrastructure is its decentralized structure, a legacy of federalism. Most of the funding comes from the federal government, and most of the data comes from the states. While empowering fifty state "laboratories" can be beneficial in identifying and evaluating good policy, the federalist model has been a disaster for efforts to identify and fight infectious diseases, contaminated food outbreaks and other national health threats because there is no centralized, real-time data platform for most public health data.

Much of the needed data are scattered across different and often incompatible computer systems.

To be sure, some states like Arizona have invested in a robust public health reporting infrastructure and do a good job tracking threats. But others like Florida have done little. This spasmodic approach prevents the collection of comprehensive data, leaving the nation partly blind to the emergence of virus variants. It also hinders the ability to assess virus contagiousness and severity or track the success of community and medical interventions. Crucial inputs are often unreliable or unavailable. Among the most important are the vaccination status of hospitalized patients as well as those who died. When vaccination status is recorded, it needs to be more than a binary choice between yes and no since there are multiple shots against Covid and other illnesses. Race, ethnicity, geographic, and other socio-demographic factors also need to be reported.

Much of the needed data are scattered across different and often incompatible computer systems. For example, Covid testing information is collected and reported by

hospitals, physician practices, laboratories, independent testing sites, schools, employers, and nursing homes. Deaths may be reported by local or state authorities. Vaccinations are delivered and tracked by companies like CVS, health insurers, cities, and state health departments. Wastewater and genomic surveillance are reported by academic institutions and private firms, among others. Some of these data are shared with federal authorities. Some are not. Tracking it all down is all but impossible.

Getting information about how vaccine recipients fare after getting their shots is another crucial but nearly impossible task. In some cases, there are legal or privacy barriers to linking different types of data. In other cases, the systems just can't handle it. Getting systems to talk to each other is a vital but expensive and time-consuming task since doing so is the only way the government can get the kind of information needed for an effective pandemic response.

Certain kinds of crucial information are not actively collected at all. Rather, the country relies on random, often incomplete reports and guesswork. Bad reactions or outcomes to drugs, vaccines and medical devices fit this category. Last year's pause in the administration of the Johnson & Johnson vaccine to evaluate the frequency and severity of rare adverse reactions is just one example. Having a real-time, comprehensive data hub tracking and analyzing adverse reactions to vaccines would have either uncovered the problem far earlier or given officials the confidence to avoid the pause altogether.

The Covid pandemic has highlighted data problems researchers and public health officials have been complaining about for decades. Finally, legislators have begun to realize these problems aren't just academic concerns but are threats to national security. Pandemic lockdowns cost trillions in

Pandemic lockdowns cost trillions in economic activity, and each day's delay in lifting them costs billions.

economic activity, and each day's delay in lifting them costs billions. But the health information needed to guide such decisions in the United States is all but impossible to get. So, policy makers have been forced to rely on information from Great Britain, Israel and other countries where the data are better and more timely. This is unacceptable. American leaders need to know how an infectious agent is affecting Americans, who are unique in crucial socio-demographic ways. And they need to understand how it is traveling through New York and Dallas, not London or Tel Aviv. Why is the United States relying on other countries to fight its battles against deadly threats?

Why is the United States relying on other countries to fight its battles against deadly threats?

Establishing Centralized Public Health Data Platform(s)

Ultimately, the federal government must strive to build and operate a secure, standardized, and real-time national data platform for SARS-CoV-2 and other health threats.

The United States already has data repositories for a considerable amount of public health data, but it is not standardized, coordinated, complete or timely. The closest approximation is the National Syndromic Surveillance Program (NSSP), a collaborative effort between the CDC and local public health stakeholders that collects, analyzes, and reports on patient encounters mostly in emergency rooms. The platform currently collects data from more than 6,000 health facilities across 49 states, receives data

within 24 hours of initial encounters, and covers more than 70% of the country's emergency departments. This data is then used to identify and inform responses to potential public health threats. The NSSP should either be expanded to collect and report on a broader set of standardized public health data, or a similar platform should be created to do so.

Standardizing Data Inputs and Quality

The reporting of some items is standardized while other categories are not, making for an often confusing mess. If everything were standardized, officials wouldn't have to perform the time-consuming and arduous task of cleaning data. A classic example of this are death certificates, which would be a powerful tool to track serious health threats if the information on the certificates was consistent. It is not. For instance, the date on the document is sometimes the date of death, sometimes the date the death was reported and sometimes the date the certificate was created. Such differences matter. Agreement must be reached on how jurisdictions collect and report on:

- Case counts (type of tests, location of tests, deduplication of results, dating method)
- Positivity rate for testing (as above)
- Hospitalizations and hospital census (inpatient with information on ICU admission or not, and of vaccination status)
- Deaths
- Immunizations (clear identification and timing of 1st, 2nd, 3rd, Nth dose versus boosters, especially with heterologous vaccinations)
- Population immunity
- Animal reservoir testing (date of testing, population size, variant types)
- Wastewater sampling (date of sample, copies per milliliter)
- Genomic surveillance (variants tracked regionally and by percent of cases)

Death certificates would be a powerful tool to track serious health threats if the information on the certificates was consistent. It is not.

Notably, data collection should be prioritized, as government and other healthcare stakeholders have limited time and resources. FQHCs and other safety-net providers operate with especially constrained resources. Since the data they collect is crucial to understanding health disparities and designing policy responses, resources should be specifically granted to them and other organizations supporting underserved communities.

Some consideration should be given to establishing digital certificates that provide vaccination status and previous infection records to simplify tracking of breakthrough cases and reinfection frequency.

Linking Disparate Data Types and Sources

While data standardization would go a long way towards accelerating analysis and subsequent public health responses, many analyses are impossible or extremely difficult if data aren't sufficiently linked. For instance, death reports and vaccination data might be standardized and separately available but figuring out which John Smith is which in two separate databases can be a bear. This is why even a seemingly simple analysis comparing deaths amongst the vaccinated and unvaccinated is often fraught.

Much of this isolation results from a simple lack of funding. Most recently, researchers have called for

upgrading the country's genomic surveillance systems to incorporate wastewater surveillance and link data to downstream clinical outcomes. While this would likely prove extremely helpful in early detection of variants, the cost would be substantial. At scale, the CDC's Data Modernization strategy has not been fully funded but would take meaningful steps towards linking these data types and sources.

Similarly, the Office of the National Coordinator for Health Information Technology (ONC) has a significant role to play in collecting, linking, and storing various data sources but does not have sufficient resources to comprehensively do so. Public-private collaboration may be needed to encourage private data collectors to standardize and ease linkages across systems.

Notably, some linkages are difficult or currently impossible due to legal and regulatory barriers, many of them reflecting privacy concerns. For example, linking human genomic data to vaccination status and clinical outcomes runs into HIPAA compliance challenges, as genomic data is considered private and is theoretically impossible to de-identify since everyone's DNA is unique. These privacy concerns have some merit, as an individual's genomic data provides significant information on their health and could be used in a discriminatory manner. An independent advisory council composed of epidemiologists, data scientists, and public health decision-makers should be established to clarify and reevaluate regulations related to genomic data linkages and other data types where legal barriers impede public health response.



Standardizing Timely Reporting Cadences

Inconsistent schedules for reporting data can add to confusion. The government must rationalize reporting timelines. Results and data must be rapidly conveyed to both patients and public health officials, to promote both good patient care and effective pandemic response. Any entity that collects critical data must be able to report it to a centralized repository within 24 hours, as has been achieved by the NSSP.

Accelerating Insight Generation and Provide Public Access to Data

Investments in automated data analysis and insight generation are needed to realize the full benefits of any centralized repository. Automated analysis should prioritize real-time evaluation of incoming public health data, and algorithms should be developed to translate these analyses into actionable insights and practical public health guidance.

Critically, the federal government needs to be able to host data in ways that can be used by leaders, researchers, journalists, and the general public. Repositories must have access points for secure downloading and uploading of data, as well as easy-to-use visualizations, graphics, and analytical tools. And it must be appropriately staffed, including round-the-clock technical support for users.

Fifty states, hundreds of municipalities, and even universities have established best practices for public reporting that can be leveraged. As an example, Arizona has a rich state-level dashboard.⁸² Israel also has a transparent and consistent means of reporting most vital health measures quickly and publicly.⁸³ Modeling a public reporting hub on the Covid Tracking Project would provide a strong starting point, given its strengths as a centralized one-stop shop for all Covid-related metrics, clear explanation of standards, graphical representations of data for use by journalists and the public, and open access to data.⁸⁴

Since journalists, researchers, and the general public will all access the site, explanations about the data and reports available must clearly delineate what is modeled, what is adjusted, and what is raw, unadjusted data.



⁸² Arizona Department of Health Services. Covid-19 Data Hub. Accessed February 18, 2022. <https://www.azdhs.gov/covid19/data/index.php>

⁸³ Israel Ministry of Health. Covid-19 Data Dashboard. Accessed February 18, 2022. <https://datadashboard.health.gov.il/COVID-19/general>

⁸⁴ The Covid Tracking Project. Last updated March 7, 2021. Accessed February 18, 2022. <https://covidtracking.com/>

Designing Infrastructure to Promote Health Equity

America's health data infrastructure can and should be redesigned to promote health equity.

America's health data infrastructure can and should be redesigned to promote health equity. Sufficient standardized collection of socio-demographic data, including race, ethnicity, and sex linked to key medical data is necessary to evaluate disparities in incidence, treatment, and outcomes.

As public health experts' usage of algorithms, machine learning, and artificial intelligence accelerates, efforts must be made to reduce programming biases. In one of many such examples, an algorithm attempting to predict patient health using health care costs as a proxy mistook Black patients' lower spending on health care as an indicator of better health, suggesting less need for follow-up care.⁸⁵ A similar study found that algorithmic genetic risk predictions were less accurate for non-White populations as the dataset used to inform predictions consisted of data primarily from White study participants.⁸⁶ These inaccurate and biased algorithms are likely to exacerbate health disparities. Going forward, algorithms must be built on data that is representative of the populations being

served, and public health guidance must be tailored to communities as well as specific ethnic and racial groups.

Notably, the January 25th draft of the bipartisan PREVENT Pandemics Act would authorize a new program to evaluate and identify best practices when collecting demographic information to support public health responses. This provision has the potential to play a meaningful role in improving linkages across demographic and health outcomes data, and it could make meaningful strides towards improving socio-demographic data collection that supports advances in health equity.



⁸⁵ Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. *Science*. 2019;366(6464):447-453. <https://doi.org/10.1126/science.aax2342>

⁸⁶ Roberts M, Khoury M, Mensah G. Perspective: The clinical use of polygenic risk scores: Race, ethnicity, and health disparities. *Ethnicity and Disease*. 2019;29(3):513-516. <https://dx.doi.org/10.18865%2Fed.29.3.513>

Acknowledging and Overcoming Implementation Challenges

None of this will be easy. Federal agencies and local actors have made significant strides in overcoming some challenges but have long faced barriers that are worth special mention.

None of this will be easy.

Money is the primary one. There has not been sufficient or dependable funding at either the federal or state levels to truly modernize America’s health data infrastructure. Even in instances when the federal government made necessary investments, infrastructure gaps and outdated systems at the local level impeded standardized and timely data collection. Most recently, the National Center for Health Statistics has taken the lead on attempting to modernize the country’s health data infrastructure but has struggled to overcome insufficient investments and engagement at the state and local levels. Providing performance-linked federal funding for state modernization efforts may accelerate state innovation and promote cooperation.

Another useful case study to consider is the National Vital Statistics System (NVSS), which collects direct and indirect mortality data and has received significant attention during the Covid pandemic. The limitations of the NVSS are well known —data collection is decentralized, there is a shortage of forensic pathologists and other critical staff, states are not required to report data to

federal authorities, the CDC only partially funds data acquisition and analysis, and automation is limited. All of these problems have clear solutions. Among them are mandating state reporting, charging non-government users of the data like insurers to establish new revenue streams that fund collection and reporting efforts, bolstering forensic pathologists’ salaries and establishing loan forgiveness programs, and investing in sophisticated artificial intelligence tools that can minimize manual efforts. Funding limitations have long hindered progress in implementing these solutions. Given the importance of the NVSS’s data collection and reporting efforts in the midst of the pandemic, the funds should finally be made available.⁸⁷ Another problem is that the size and complexity of public health data have ballooned and will continue to do so. By 2030, there will be 25 petabytes of genomics data.⁸⁸ The country will need to incentivize and deploy substantial advances in machine learning and artificial intelligence to analyze data at this scale.

Lastly, the country’s health data infrastructure is complicated by numerous legal barriers. While some of these restrictions reflect legitimate privacy concerns, an independent advisory board should conduct a comprehensive reevaluation of the hodgepodge of laws and regulations that have been developed over the last 50 years.

⁸⁷ Gerberding J. Measuring pandemic impact: Vital signs from vital statistics. *Annals of Internal Medicine*. 2020. <https://doi.org/10.7326/M20-6348>
⁸⁸ Banks M. Sizing up big data. *Nature medicine*. 2020;26(1):5-6. <https://doi.org/10.1038/s41591-019-0703-0>

Health Data Infrastructure Strategic Goals

1. Empower and fund the CDC to rapidly develop standardized, national, real-time, comprehensive, and secure data platform(s) to monitor respiratory viruses and illnesses.

- a. Require and provide sufficient funds for the CDC to evaluate existing national health data repositories, to understand current gaps and opportunities for consolidation.
- b. Require the CDC to augment existing health data repositories or create new secure data platforms that can collect comprehensive, standardized, and anonymized data from states, localities, and health care providers on major respiratory viruses and illnesses.
- c. Eliminate overlapping reporting requirements between the CDC and other federal agencies.

2. Direct HHS to establish consistent national data standards by identifying critical metrics, defining them clearly, and establishing collection, linkage, and reporting requirements.

- a. Evaluate and select a limited set of real-time and near real-time metrics that provide meaningful information on respiratory virus spread and severity, prioritizing those that are straightforward to collect, report, and analyze, as well as those that meaningfully inform public health decision-making. These metrics likely include hospitalizations and positivity rates, cross checked against vaccination or prior infection status and comorbidities.
- b. Invest in automation of data collection and reporting wherever possible, to minimize impact on delivery system.
- c. Establish standardized reporting pathways and protocols, including collection and reporting cadence, data quality standards, and triage approaches.
- d. Fund the CDC and make resources available to the private sector to collaboratively develop processes and

protocols to link anonymized data across disparate sources into a single centralized destination and identify required and/or recommended data linkages. (e.g., test results, outcomes, vaccination status, age, sex, race, ethnicity, and other socio-demographic information).

- e. Establish an independent advisory council to reevaluate legal and regulatory barriers to linking disparate data types where these barriers impede public health response, reporting to the CDC within 90 days
- f. Develop forward-looking long-term data standards that address current constraints and hold stakeholders responsible for continual improvement against stage-gated benchmarks.

3. Direct HHS to financially incentivize or require real-time reporting from states, localities, health providers and at-home test-takers, to include secure and de-identified test results, vaccination status, vaccine breakthrough and re-infection status, age, sex, ethnicity, race, job, workplace, and other essential socio-demographic information.

- a. Fund and incentivize states, localities, health providers, and other stakeholders to establish automated data collection and reporting systems, as well as maintain, routinely update, and upgrade these systems.
- b. Require reporting on above data types from states, localities, and health providers, across the public and private sectors.
- c. Create a pathway to incentivize automated individual reporting of verified at-home tests. One way to do this might be to offer a dollar for each home test result returned.
- d. Launch nationally funded, duration-limited regional data hubs to provide transitional support to states, health providers, and other stakeholders, that are responsible for the implementation of reporting systems and standards.
- e. Create direct linkages from the CDC to state and local

public health officials, as well as health providers and other public and private stakeholders, to establish bi-directional communication channels and promote collaboration.


4. Direct and fund the CDC to accelerate insight generation and provide open access to data.

- a. Invest in machine learning, artificial intelligence, and algorithms that automate analysis and speed development of actionable insights.
- b. Establish a centralized real-time reporting dashboard, for Covid and other respiratory viruses, with easy-to-read key metrics including hospitalizations, deaths, positivity rates, vaccine breakthroughs / re-infections, and long Covid cases, and link metrics to designated public health actions triggered by escalations in disease spread and severity.
- c. Produce regular actionable reports for the public, municipalities, states, and national decision-makers to inform public health actions.
- d. Establish a real-time open data hub, with both pre-built analytical tools and de-identified raw data files, that provides access to reporters, researchers, and other interested parties.
- e. Establish a searchable, real-time research hub for pre-print and peer-reviewed analyses managed by the CDC (or a new agency), with staff escalating critical findings to agency leadership.

5. Direct HHS and the CDC to design health infrastructure to promote health equity and mitigate racial, ethnic, occupational and gender disparities.

- a. Collect sufficient standardized socio-demographic data including race, ethnicity, and sex, linked to key medical data, to better evaluate disparities in incidence, treatment, and outcomes.
- b. Base algorithm design on datasets that are representative of target populations, to protect against bias and discrimination.



A woman with dark hair, wearing a white lab coat and blue nitrile gloves, is focused on using a black pipette. She is looking down at the tip of the pipette. The background is a blurred laboratory setting with blue and white tones. A large, light blue circular graphic is overlaid on the left side of the image, containing the number 10 and the text 'Public Health Infrastructure'.

10

Public Health Infrastructure

Summary

The nation's public health system suffered catastrophic failures during the Covid pandemic, mostly due to chronic underfunding. A comprehensive fix will require sustained funding, to support better data to track threats, more analytical capacity to inform policies, improved staffing, serious upgrades to communication infrastructure, and better coordination across government.

Public Health Failures never lead to Fundamental Reforms

Following the deadly attacks on 9/11, the federal government restructured the nation's intelligence and law enforcement agencies. After the terrible events of Hurricane Katrina, Congress reorganized the Federal Emergency Management Agency. And the 2008 financial crisis led to a wholesale reshaping of the nation's financial regulatory system.

The Covid pandemic cost far more lives and vastly more money than all of those other disasters combined in part because of gaps in the nation's public health infrastructure, but so far there is limited fortitude in Congress or the White House for the thorough examination to overhaul the system to ensure these catastrophes are never repeated.

Warnings about the need for national reforms have been issued and largely ignored for decades. There were the anthrax attacks in 2001, the SARS-CoV-1 outbreak in 2003, the influenza pandemic in 2009, Ebola from 2014 to 2016, and Zika from 2015 to 2016. The after-action reviews drawn from these crises temporarily bolstered certain preparedness capabilities and funding, as well as training, drilling

and exercising, and risk communication tools. Likewise, BARDA, NIH, CEPI, academia, industry, and many others have invested in the development of new countermeasures for known threat agents and the expansion of certain components of the Strategic National Stockpile.

Unfortunately, these and other advances tended to follow a predictable cycle of crisis, response, modest and temporary improvements, and then a return to complacency. As a result, the United States was woefully unprepared for both the acute shock and long duration of the SARS-COV-2 pandemic. As the initial shortages of PPE, ventilators, and tests revealed, the nation fought the latest infectious disease crisis with outmoded systems and tools. This deficient public health system is evidenced by the United States' low vaccination rates, high death rate, and significant health disparities as compared to other high income countries, including Taiwan, South Korea, Germany, France, and Denmark. Since when has the United States contented itself with last place in its ability to respond to deadly crises?

Warnings about the need for national reforms have been issued and largely ignored for decades.

A thorough after-action assessment and secure long-term funding will be needed to implement a comprehensive public health and biosecurity modernization program.

This response must start now while the need is obvious and motivation is high. In the meantime, the current pandemic is not over, and immediate public health actions should be taken to accelerate successful mitigation and transition to the next normal.

This data modernization needs to start now, be adequately funded, and be advised by an external board.

Crucial Investments

The most overarching deficit in public health preparedness is the lack of a coherent, comprehensive, and long-term biosecurity strategy across federal, state, local, tribal, and global jurisdictions. Fixing the system will not only protect the country from pandemics and bioterrorism but save lives from routine threats every day.

Effective public health requires 5 sequential elements: 1) reliable and real-time data, 2) a capacity to analyze those data, 3) a workforce to implement public health measures, especially in vulnerable communities, 4) effective messages to facilitate policy adoption, and 5) the ability to coordinate these measures across geographies and jurisdictions. Building such an enhanced public health system puts in place many of the tools needed to better reach vulnerable populations and address the racial and socioeconomic disparities that currently plague American healthcare.

Reliable Data for Timely Decisions

The CDC’s Data Modernization Initiative (DMI) was designed to address gaps in timely acquisition of reliable health data necessary to monitor and respond to biosecurity threats and pandemic crises. Unfortunately, the first funding for this was not approved until FY2020, the initiative remains woefully underfunded, and it has neither been fully implemented nor updated in light of the pandemic’s revelation of data deficiencies.

As *Chapter 6* made clear, the nation’s data infrastructure needs extensive improvements. This data modernization needs to start now, be adequately and sustainably funded, and be advised by an external board. The external board should include representation from state, local, tribal, and territorial (SLTT) public health officials, as well as the Council of State and Territorial Epidemiologists. The effort should link federal public health funding for states, territories, municipalities, and tribes to the adoption of real-time electronic reporting in a standardized format that encompasses various essential public health measures. Key measures include morbidity data, vital statistics on disease-specific outcomes, the results of wastewater testing for infectious pathogens, vaccination status, and hospital occupancy, all of which can inform efforts to fight disparities. By merging non-traditional environmental surveillance data with traditional clinical and epidemiological data, officials can better track outbreaks and target containment in the event of infectious disease threats (see *Chapter 3: Testing and Surveillance*).

Additionally, healthcare providers’ reporting of individual disease cases is a foundational component of public health surveillance. While timely and accurate reporting is mandated through jurisdictional laws, required case reports are often delayed, incomplete, or never submitted. This results in major data gaps. Public health data needs CMS’ full commitment and support to ensure effective delivery of clinical encounter and healthcare data to public health.

Modernized Data Analytic Capacity

Existing data need to be re-analyzed to be translated into actionable insights that inform public health policies. The public health system needs a range of analytical tools like artificial intelligence and machine learning to improve the speed of insights. Robust support for data cleaning and deduplication are necessary to organize and prepare data for analysis. There also needs to be a real-time, easy-to-use data platform for non-governmental researchers to find and publicize additional insights.

Public Health Workforce Modernization

Long before Covid, the public health workforce in minority, rural, tribal, and other communities was short-staffed and tenuous. Through verbal and physical threats, firings, and burnout, the pandemic has depleted this vital cadre even more.

The workforce needs to be restored to its pre-pandemic levels and more. To do so, the public health workforce has to overcome challenges in recruitment and retention. This can be initiated by financially incentivizing multiple talent pools, including those in public health schools and related health professions, as well as retirees.

But more needs to be done since the pre-pandemic workforce was already short-staffed. Extending the traditional workforce to integrate diverse community health workers, ambulatory care clinicians, epidemiologists, laboratorians, and school nurses will help. Online coaching and retraining of existing workers will improve practice-based mitigation strategies, as well as reduce wasted efforts.

Several initiatives should be started to address workforce issues more systematically. First, financial assistance should be allocated to states, municipalities, and tribes to develop comprehensive community health worker programs targeted at vulnerable communities. These workers should be able to manage public health needs during a pandemic, as well as address the day-to-day challenges of these communities. Funding should sustain approximately 20,000 community health workers on a permanent basis, and payment models that support reimbursement for their services would support this effort. Second, public supports for student loan repayment and fellowship programs (such as those operated by national public health associations) would promote long-term sustainability.

School-age children need special post-pandemic attention to help with vaccinations, long Covid, and mental health issues. Augmenting school nurse programs with better training and compensation and linking them more closely to public health needs would go a long way.

Finally, schools of public health need to be supported to train students and develop public health workers with advanced skills in data science, modeling, epidemiology, behavioral economics, public health emergency preparedness, risk communication, and health promotion.

Extending the traditional workforce to integrate diverse community health workers, ambulatory care clinicians, epidemiologists, laboratorians, and school nurses will help.

Communication

The CDC has a long tradition of communication leadership during public health emergencies. In past crises, the CDC leveraged the Joint Information Center to coordinate information with its federal counterparts. Unfortunately, these approaches were not effectively used in the current pandemic, and too often the CDC's communications proved unreliable.

As outlined in *Chapter 13*, the CDC needs to revive its Joint Information Center approach and create centralized information dashboards to help Americans better understand the status of the pandemic in their locality. It should also conduct regular table-top communication exercises that bring together federal, state, local, tribal, and private sector communicators to work through real-world public health crisis scenarios.

The CDC must address the trust deficit with a steady drumbeat of practical evidence-based information. Key public health leaders across jurisdictions, influential scientists, and trusted local community leaders should be involved in creating and assessing messages well before they are disseminated. As recommended in *Chapter 13*, an independent advisory council to the CDC could vet and coordinate strategies.

These experts can help define ongoing critical information needs, provide real-time input into guidance for communication decisions, and assess the impact of these decisions, all with a lens towards vulnerable communities. These new structures and processes will help restore trust and improve the front lines of effective communication.

The CDC must address the trust deficit with a steady drumbeat of practical evidence-based information.



Coordination

Effective public health response requires coordination across federal, state, local, tribal, and territorial health agencies. During a public health emergency, policies can be developed centrally but the front line of public health response is local. Coordination requires leadership, inclusive multidirectional exchanges of information and learnings, and clear processes for identifying and addressing resource needs.

National leadership requires a White House-led coordination effort, which can be achieved by elevating the White House lead on biosecurity to a Deputy Assistant to the President for Biosecurity and building a White House biosecurity team that reports to this Deputy Assistant (see *Chapter 12: Communication and Education*). The Deputy Assistant and their biosecurity leadership team can delineate roles and responsibilities for the CDC, as well as state, municipal, and tribal public health officials in an emergency. The Deputy Assistant must review and revise the National Incident Management System and empower a Joint Information Center and unified command system at the federal level to coordinate communications in all jurisdictions. The White House Biosecurity leadership team needs to conduct regular exercises to test and refine coordination during a threat or emergency.

Public Health Strategic Goals

1. Strengthen public health leadership at all levels of government.

- a. Establish a permanent White House team to oversee biosecurity strategy development and coordinate execution.
- b. The White House Biosecurity leadership team should expeditiously delineate the specific authorities, directives, tasks, and other responsibilities of the CDC and other federal agencies to state, local, tribal, and territorial governments for addressing biosecurity threats and pandemic outbreaks. The leadership team should include representation from SLTT jurisdictions.
- c. The White House Biosecurity leadership team should review –and where needed, adapt– the National Incident Management System to improve the unified response to the current pandemic and future biosecurity threats.
- d. The White House Biosecurity leadership team should establish and empower a Joint Information Center inclusive of CDC, FEMA, SLTT, and other stakeholder communicators to assess, monitor, coordinate, and cascade evidence-based communications and guidance that address critical public information requirements across federal and SLTT jurisdictions.

- e. The White House Biosecurity leadership team should review existing biosecurity and emergency public health legal and regulatory authorities and strengthen them where necessary to improve emergency response effectiveness, data acquisition and situation awareness, and cross-jurisdictional coordination.
- f. The White House Biosecurity leadership team should clarify the oversight, mission, capabilities, capacities, and content of the Strategic National Stockpile.
- g. The White House Biosecurity leadership team should conduct ongoing pandemic operational “action reviews” and biosecurity exercises at the federal and SLTT levels to identify response strengths and address critical areas for improvement.
- h. Create a CMS Public Health workgroup to ensure public health efforts receive full commitment and support from CMS.

2. Address critical gaps in the pandemic response frontline workforce.

- a. Provide sufficient emergency funds to retain, recruit, re-employ, and otherwise augment the current public health frontline pandemic response workforce across federal and SLTT jurisdictions.
- b. Deploy experienced CDC and U.S. Public Health Service Commissioned Corps personnel to SLTT health departments to support the pandemic response.
- c. Provide funds to expand community health worker and public health nurse programs to provide home and outpatient testing, early treatments, vaccines, and other services in tribal communities, rural settings, and other communities where health disparities are prevalent.
- d. Fund school nurse programs to assess and triage acute illnesses and behavioral and mental health needs, as well as provide preventive care and immunizations.
- e. Professionalize and expand recruitment for community health workers and navigators in specific communities of need and make these roles more available.



- f. Require that all healthcare institutions receiving federal funding submit documentation that demonstrates they have engaged with and reflected communities' priorities in their plans, particularly those related to pandemic response.
- g. Ensure pandemic response public health workers are provided safe working conditions and proper personal protection equipment, allotted adequate time off from work, and receive hazard pay.
- h. Require that public health workers be overseen by healthcare or other leaders that are not politicians, to mitigate politicization or dilution of necessary public health measures.
- i. Require fully funded mental health and wellbeing services for the public health pandemic workforce.
- j. Expand investment in the Ready Reserves Corps, to deploy during public health emergencies.
- k. Support fellowship programs for specialized public health areas, including applied public health epidemiologists and those that will support work in SLTT jurisdictions.
- l. Support retention through student loan repayment programs, across both federal and SLTT jurisdictions.

3. Initiate the modernization and expansion of the federal and SLTT public health workforce, with an emphasis on biosecurity and pandemic preparedness.

- a. The White House Biosecurity leadership team should expeditiously conduct a comprehensive assessment of both current and future public health workforce requirements to address biosecurity threats including pandemics, encompassing geographic and jurisdictional capacities, capabilities, diversity, and salary structure, etc., and then develop a responsive national strategy.
- b. Fund the recruitment and training of permanent public health workers to bring the workforce up to requisite size and capability to address biosecurity threats including pandemics.
- c. Require federal and SLTT multi-sector biosecurity emergency preparedness plans and regular exercises with a special emphasis on viral respiratory pandemics.

- d. The White House Biosecurity leadership team should collaborate with the private sector to develop and exercise federal SLTT contingency plans to augment the public health workforce when emergency surge is required or the risk of burnout is increased.

4. Finance the CDC's accelerated development of standardized, national, real-time, secure data platforms related to SARS-CoV-2, other respiratory viruses, and broader health outcomes.

- a. Fully fund expansion and accelerated implementation of the CDC Data Modernization strategy. Funding must be sustained and include support for SLTT jurisdictions.
- b. Fund modernized real-time data collection platforms to collect and analyze information on 1) cases of viral respiratory illnesses regardless of site of test, and 2) hospitalizations and deaths from viral respiratory illnesses. Ensure the data are linked to de-identified relevant health and socio-demographic information (see *Chapter 9: Health Data Infrastructure*).
- c. Fund modernized, real-time surveillance systems encompassing environmental (e.g., wastewater) and animal testing, genetic variants, and population immunity (see *Chapter 3: Testing and Surveillance*).
- d. Fund the five foundational disease surveillance enterprise efforts: electronic case reporting, electronic laboratory reporting, nationally notifiable disease surveillance system, national syndromic surveillance program, and vital statistics. (see Chapter 3: Testing and Surveillance)
- e. Fund data cleaning and deduplication tools necessary to organize and prepare data.

5. Improve public health decision-making by accelerating analysis and translation of data inputs into actionable insights and practical guidance across all jurisdictions.

- a. The CDC should establish an independent advisory council including epidemiologists, modelers, data scientists, public health decision-makers, and frontline personnel, responsible for managing and interpreting local data to oversee and enhance data collection and analysis, as well as define ongoing critical data needs.
- b. The CDC should establish transparent protocols for how the evidence for guidance is obtained and how guidance issues and options evolve with stakeholder input in a timely manner.
- c. The CDC should collaborate with the White House Biosecurity leadership team to establish transparent standards for how streamlined clearance of guidance will be managed without political interference, how messages will be vetted and effectively communicated, how well implementation is achieved, and what results ensue.
- d. The CDC should monitor and report the trust and credibility of its public health preparedness and response.
- e. The CDC should establish formal processes to meaningfully engage SLTT leadership throughout decision-making processes.

6. Develop a tailored public messaging strategy on Covid for the next 8-10 months that bolsters the CDC's credibility and communication capacity via new internal decision-making processes and diverse sources of external input.

- a. Empower the CDC to rebuild trust and credibility in its public messaging apparatus with a steady drumbeat of practical, evidence-based information related to boosters, mask-wearing, social distancing, air filtration, and other topics of day-to-day importance for Americans.

- b. The CDC should create a new independent advisory council of community leaders and science communication experts to advise it in determining information needs and crafting public messages, particularly those directed towards vulnerable populations (see *Chapter 12: Communication and Education*).
- c. Delineate a process for determining the need for and value of proposed guidance and messages before they are disseminated.



11

Healthcare Workforce

Summary

With the onset of Covid, some of the existing challenges facing the healthcare workforce were both laid bare and exacerbated. Burnout and exhaustion have increased, demoralizing many healthcare workers and endangering the system. To get to the next normal, the United States must have a fully functional healthcare system in which routine visits, tests, and treatments can be provided across the full range of illnesses. This requires supporting the health care workforce through improved wages, health benefits (including mental health), tuition assistance, loan forgiveness, and safe working conditions. Additionally, the U.S. should incentivize the automation of routine chores and paperwork. To institutionalize and expand both telemedicine and various forms of home care, the U.S. government should make emergency regulatory (including licensure) and reimbursement flexibility permanent. Finally, ensuring a flexible pool of workers available in emergencies is also necessary.

A Courageous Two Years

Healthcare workers labored valiantly to serve patients during the Covid pandemic, sometimes with inadequate supplies of protective equipment, ventilators, beds, and most importantly other colleagues. Currently, there are a record number of health care jobs unfilled and burnout among those working is dangerously high.

About 22 million people work in the American healthcare system, three-quarters of them women and one-quarter Black. Many faced dangerous conditions, particularly in long term care facilities and home care. Hundreds of thousands were infected by SARS-CoV-2 and thousands died from work-related exposures. Despite such

profound risks, pay is so low for some that they must work more than one job to make ends meet.

Not surprisingly, many healthcare workers are experiencing burnout and others have exited the field or are considering doing so. About 3 in 10 health care workers considered leaving their profession over the past two years, and about 6 in 10 said pandemic-related stress had harmed their mental health, according to a recent poll. Among physicians, half recently reported feeling burned out.

Covid-related exhaustion and staff shortages have disrupted all forms of healthcare for Americans. For example, the volume of preventive cancer screenings dropped sharply during the onset of the pandemic.⁸⁹ Despite a recent rebound, such checks remain well below pre-pandemic levels. As a result, the number of newly diagnosed cancers has also dropped significantly.⁹⁰ The worry is that many of these missing cases will be detected at a more advanced stage, leading to

89 Mast C, Munoz del Rio A. Delayed cancer screenings —a second look. Cosmos Study Update. Published July 17, 2020. Accessed February 25, 2022. <https://epicresearch.org/articles/delayed-cancer-screenings-a-second-look>

90 Kaufman H, Chen Z, Niles J, et al. Changes in the number of US patients with newly identified cancer before and during the coronavirus disease 2019 (Covid-19) pandemic. JAMA. 2020; 3(8). doi:10.1001/jamanetworkopen.2020.17267

Covid-related exhaustion and staff shortages have disrupted all forms of healthcare for Americans.

more suffering and death. This lack of preventive screening, diagnosis, and treatment extends to many other areas of health.

Staffing shortages are the main limit on the health care system's ability to provide quality care. The limitation on "beds" is often not the lack of physical space for a patient, but rather the staffing of these beds with appropriate physicians, nurses, respiratory technologists, perfusionists, and other personnel.

More Telemedicine and At-home Monitoring, Less Paperwork

Fixing the systemic stressors requires moving to institutionalize and normalize many effective practices that were rapidly adopted during Covid, including virtual care and telemedicine, remote at-home monitoring and home care, and automation of repetitive tasks. The pandemic demonstrated that virtual care and telemedicine can be effective interventions for patients and providers alike, lowering stress and expenses for all. The regulatory and reimbursement changes that allowed for the rapid adoption of virtual care and telemedicine during the pandemic need to be made permanent.

At-home monitoring tools, like pulse-oximetry, traditional telemetry, and home testing, were widely and effectively embraced by patients from a variety of educational backgrounds. The pandemic showed that even more complex care, including cancer chemotherapy and

wound care, can be safely provided at home. Regulatory bodies and insurers must do more to support these shifts.

The American healthcare system is drowning in paperwork, and administrative costs in the United States are higher than in any other industrialized nation. The price of this avalanche of red tape extends far beyond dollars and cents, since it is also an important cause of staff burnout, early retirement, and turnover. That many of the forms are now electronic rather than physical doesn't change the enervating and demoralizing effect they have on physicians, nurses, assistants, and others. Rapid efforts to adopt more automation of rote tasks and efforts to simplify processing of patient registration, insurance eligibility determinations, and quality reporting are urgently needed.

The existing workforce should be better supported. Wages in low-paying jobs at many facilities need to be increased so that everyone receives a livable wage. Full time permanent employment with full benefits should be expanded. Educational loan forgiveness and paid training programs would enable a greater number of low-income and minority individuals to pursue careers and bolster the overall workforce. Expanding the number of community health workers will help address the needs of at-risk patients and vulnerable communities, as well as reduce burdens on emergency departments and other acute care sites.

The January 25th draft of the bipartisan PREVENT Pandemics Act proposes reauthorizing the Public Health Workforce Loan Repayment Program to support staff joining state and local public health agencies. It directs funding towards community health worker recruitment and training, as well as removes substantial barriers to up to 250 HHS appointments during public health emergencies. While necessary, these measures will not be sufficient, given the substantial labor shortages and burnout confronting the system.

The existing workforce should be better supported.

Healthcare Workforce Strategic Goals

1. Fund HHS to evaluate opportunities to facilitate care provision in both normal and emergency circumstances and engage states to do the same.

- a. Revise regulations and reimbursement requirements for home and community-based services and virtual care to enable continued access for all patients in any geography on an ongoing basis.
- b. Maintain flexibility on existing visas for health care workers working in the United States.

2. Direct the DOL and HHS to ensure the healthcare workforce is protected from physical and mental health threats during crises.

- a. Require or recommend that all healthcare facilities and enterprises provide workers with fit-tested reusable N95 FFR equivalent or more protective respirators (see [Chapter 5: Personal Protective Equipment](#)).
- b. Require healthcare facilities to meet revised requirements for adequate ventilation and air filtration (see [Chapter 4: Cleaner, Safer Indoor Air](#)).
- c. Defend the mandate that all healthcare workers at all health providers receiving federal resources be fully vaccinated (see [Chapter 6: Vaccines](#)).
- d. Direct OSHA to issue a final, permanent Covid standard for all healthcare workplaces, including respiratory protection, ventilation requirements, and mandated medical removal protection (see [Chapter 14: Worker Safety](#)).
- e. Enact legislation that ensures all workers have access to paid medical (sick) and family leave for mental health care needs (see [Chapter 14: Worker Safety](#)).
- f. Use advance purchasing agreements, requirements on provider procurement processes, and other mechanisms to ensure the supply chains for relevant medical supplies are resilient to loss of foreign producers.
- g. Improve the wellbeing of the healthcare workforce via wellbeing programming, as well as improved training,

assessments, licensing, insurance, telemedicine coverage, and access to mental health treatment.

- h. Enact legislation raising the minimum wage in nursing homes, long term care facilities, and other healthcare facilities that receive federal funds to \$15 per hour.

3. Direct HHS to require that all healthcare institutions receiving federal funds adopt programs supporting healthcare workforce wellbeing.

- a. Require that all healthcare facilities implement a systematic program for worker wellbeing, such as that outlined in ALL IN: WellBeing First for Healthcare.
- b. Require that all healthcare facilities provide training to organization leaders on workforce wellbeing.
- c. Require bi-annual assessment of healthcare workforce wellbeing beginning in 2022, leveraging financial incentives to promote wellbeing investments.
- d. Require that healthcare facilities' employee health plans fully cover mental health care (and potentially exclude these services from the deductible during PHEs), including allowing employees to seek mental health treatment outside of the system in which they are employed without financial penalty.
- e. Require that licensing forms for all health worker applications and renewals in all states be consistent with the Americans with Disabilities Act.
- f. Modify medical malpractice insurance regulations to eliminate reporting requirements for mental health history or limit inquiries to conditions that currently impair clinicians' ability to perform their job.

4. Direct HHS and/or FEMA to leverage financial incentives and regulatory requirements to augment the healthcare workforce.

- a. Fund the establishment of a pool of flexible health care workers to deploy in emergencies.

- b. Fund the establishment of a voluntary reserve list of trained health care workers —similar to the National Guard —to be deployed in emergencies.
- c. Augment investments in existing emergency workforce pools, including the National Disaster Medical System and the Medical Reserve Corps.
- d. Create a ‘national service’ financial incentive for retired health care workers to re-enter the workforce during emergencies.
- e. Incentivize within-region shared labor pools across health systems to help flex resources to communities in need.
- f. Modify regulations and reimbursement models to allow for within-region sharing of labor pools and physical capacity across health systems and nursing homes during public health emergencies.
- g. Expand educational loan forgiveness programs and develop additional financial incentives to bolster enrollment in healthcare worker training programs for physicians, nurses, respiratory support staff, lab technicians, nursing home workers, and other critical staff, with a specific focus on low-income and minority trainees.





12

**Communication
and Education**

Summary

U.S. public health communications must be redesigned to reduce infection risk and regain public trust in the fast-moving, deeply polarized battle to promote the best health outcomes for Americans. A public health strategy must ensure truthful and effective government communications that promote healthy behavior and strengthen trust in government and its public health institutions such as the Centers for Disease Control (CDC). To achieve this, and other critical coordination goals, the White House should appoint a Deputy Assistant to the President for National Security Affairs and Biosecurity. This expert and office would ensure the development of a sufficient number of science-based and effective communications and behavioral interventions. Improvements in communication infrastructure, educational programs, and awareness of misinformation are also required for Americans to have the skills, values, trust, and knowledge necessary to navigate future infectious disease outbreaks.

Shifting and Subpar Communications

Leadership and public health communications during the Covid pandemic have been disjointed and unclear. For example, President Trump dissolved the National Security Council Directorate for Biosecurity, which would have helped to coordinate communication and other aspects of the pandemic, delegated communication responsibilities to the states, and disseminated information from the White House. Meanwhile, other sources, especially social and for-profit partisan media, which have been at times sources of foreign disinformation campaigns, frequently misinformed the public, particularly about vaccine efficacy and safety.

Another demonstration of poor public health communications has been the lack of a standardized federal government protocol of government communications

to the public, such as departmental or White House briefings tailored to different levels of public health alarm. Periods of daily briefings have alternated with periods lacking systematic, regularly scheduled, predictable communication. The messages communicated by government officials have had limitations as well, although many were difficult to anticipate. The CDC has well-articulated manuals for Crisis and Emergency Risk

Leadership and public health communications during the Covid pandemic have been disjointed and unclear.

Communication (CERC) with the following principles: “be first,” “be right,” “be credible,” “express empathy,” “promote action,” and “show respect.” Unfortunately, these principles, which this chapter endorses, have not always been followed in communications during the Covid pandemic, confusing a public that was not prepared for the shifting advice from government officials, pundits, and news outlets. Left unclear were the boundaries between the knowns and unknowns of the virus, as well as the meanings of basic terminology like what “safe” means when applied to schools or “mild” when describing Omicron.⁹¹ There was a lack of clear guidance from responsible governmental entities directed at local institutions, ranging from overwhelmed health departments to under-resourced school systems, as well as conflicts in the recommendations given to neighboring jurisdictions.

Compounding this complex situation has been the role of legacy media, social networks of communications, social media platforms⁹², and politicization of the pandemic. In the current wave of the pandemic, the unvaccinated are 23 times more likely than the fully vaccinated to be admitted to a hospital. Gallup finds that “Americans’ willingness to get a COVID-19 vaccine varies significantly by underlying

Compounding this complex situation has been the role of legacy media, social networks of communications, social media platforms, and politicization of the pandemic.



partisan and ideological positioning,” with Republicans less likely to be vaccinated and more likely to be hospitalized than Democrats. Partisan differences have also been apparent in opinions on masking, school openings, vaccination mandates⁹³, and holiday celebrations during the pandemic. Possibly, when faced with multiple and often conflicting advice about Covid, Americans might have been left to choose whichever messenger seemed most credible or whichever recommendation best fit with their worldviews. These partisan differences are partly due to exposure to different media outlets, including some embracing unfounded Covid stances and misinforming the public about vaccines, bogus medicines, and infectious disease.⁹⁴

Despite the resilience of many ethnic minorities, the Covid pandemic has exposed and amplified health disparities across racial and ethnic groups. Black populations, for example, are 2.5 times more likely to be hospitalized and 1.7 more likely to die of Covid than White populations. American Indian and Alaska Natives are 3.2

⁹¹ Holtgrave DR, Rosenberg ES. Public health experts: Why we’re going to keep wearing our masks. CNN. <https://www.cnn.com/2021/05/14/opinions/cdc-new-mask-guidance-concerns-holtgrave-rosenberg/index.html>. Published 2021.

⁹² Chan, M-P S., Jamieson, K.H., & Albarracín, D. (2020). Prospective associations of regional social media messages with attitudes and actual vaccination: A big data and survey study of the influenza vaccine in the United States. *Vaccine*, 38, 6236-6247.

⁹³ Albarracín, D., Jung, H., Song, W., Tan, A., & Fishman, J. (2021). Rather than inducing psychological reactance, requiring vaccination strengthens intentions to vaccinate in us populations. *Scientific Reports*, 11, 20796.

⁹⁴ Albarracín D, Albarracín J, Chan MS, Jamieson KH. *Creating Conspiracy Beliefs: How Thoughts Are Shaped*. Cambridge, UK: Cambridge University Press; 2022.

times more likely to be hospitalized and 2.2 more likely to die of Covid than White Americans. Hispanics are 2.4 times more likely to be hospitalized and 1.9 more likely to die of Covid than White individuals. These inequalities go hand in hand with other physical health disparities (e.g., diabetes and Chronic Obstructive Pulmonary Disease) and striking differences in Covid vaccination uptake among both adults and children. Therefore, a public health communication strategy to control infectious diseases should consider how to mitigate these inequalities and

Many county health departments lack the most basic infrastructure, such as social media accounts and a network of followers that could improve the speed and distribution of public health messages.

develop diverse social networks to communicate about vaccination and other precautions early and effectively.

Finally, the Covid pandemic and subsequent division has coincided with a breakdown of what were traditionally held as U.S. community norms and collective values, such as the ideas that some sacrifice for the betterment of one's community is preferable to a focus entirely on individual benefit, health is better than disease, and health equity is better than health disparities. Some of these phenomena have deep roots in American society, which makes addressing them complex. Nevertheless, it is important for policymakers, private sector entities, and civil society leaders to promote educational efforts and other reforms that support community public health and health equity goals.

Improving Government Coordination of Communication

Coordinating public communication during a global pandemic is uniquely challenging. A successful strategy must leverage existing systems for coordination between local, state, and federal communicators and be present during both emergencies and periods of normalcy.

Decisions and planning are necessary to ensure that information flows easily and bidirectionally among government institutions and communities, that information on testing, treatment, and prevention of Covid is centralized and up-to-date, and that consumer guidelines are standardized and science-based. When it comes to coordination of communications, a Joint Information and Communication Center should oversee the sharing of data about infectious diseases. Information dashboards integrating all services relevant to infectious diseases such as vaccination and testing need to be streamlined and better coordinated to better orient the public. Additionally, the FDA and other relevant agencies must standardize information about infectious disease testing to ensure proper interpretation of results. Vaccine Adverse Event Reporting System (VAERS) terminology (e.g., adverse event) and its interpretation in the community should be reviewed periodically. Next, government officials should create an office or mechanism to test and store all communications (e.g., Public Service Announcements and information about testing sites) to ensure efficacy and the ability to analyze their impact by triangulating with real-time surveillance and survey data. Finally, the federal government must establish an infrastructure of effective channels for dissemination of public health messages. For example, an infrastructure of message sources (e.g., communicators and community leaders) and channels (e.g., social networks and social media platforms) needs to be put in place. For example, states still need support to build

a strong communication infrastructure. Many county health departments lack the most basic infrastructure, such as social media accounts and a network of followers that could improve the speed and distribution of public health messages. Health departments also lack personnel to deploy communication efforts and the expertise and technology to improve their messages.

Federal leaders recognize many of these needs, as reflected in the discussion draft of the U.S. Senate’s PREVENT Pandemics Act. The Act would, among other efforts, establish a Public Health Information and Communication Advisory Committee to support the HHS Secretary’s communications with the public, as well as invest in both cross-agency and federal-local collaboration.

Establishing a Deputy Assistant to the President for Biosecurity (DAP-B)

National pandemic policy coordination and prevention efforts, including communications, should be managed by a new Deputy Assistant to the President for Biosecurity. This office would have a series of critical responsibilities to help coordinate response to the current pandemic, as well as to prepare for future variants or other biological threats.

In the event of a national security threat like a pandemic or other national biosecurity emergency, the Deputy Assistant to the President for Biosecurity would be the public facing federal official of a unified government response for all policy decisions. Among other standing working groups chaired by the Deputy Assistant to the President for Biosecurity should be one on public communication. As the next normal for this pandemic arrives, the deputy assistant should augment White House coordination with federal and state health officials. This working group, which should be at the assistant secretary level federally and the state health commissioner level (through regional state task forces), will ensure a successful cross-agency, multi-state biosecurity leadership group that works together regularly on strategy, budgeting, and preparation for rapid response with tabletop and field exercises.

The new Deputy Assistant to the President for Biosecurity should report to the National Security Advisor. This budget-neutral improvement would absorb the role and office of the current NSC Senior Director for Global Health Security and Biodefense. The Deputy Assistant to the President for Biosecurity should provide relevant budget guidance through an Office of Management Deputy Associate Director with cross-subcommittee budget authority over the biosecurity portfolio.



Establishing a Joint Information Center

Before another dangerous Covid variant or another biosecurity threat emerges, the deputy assistant to the president should create an entity to coordinate public communications between local, state, and federal communicators and support public health communications. In the event of another national security threat like a pandemic or another national biosecurity emergency, this Joint Information Center (JIC) would manage all communications across federal agencies and advise across state, local, and tribal public health agencies on the most effective evidence-based public health communication strategies. The JIC should work with private sector firms, communication specialists, and trusted local community networks to build, test, and store public health communications such as PSAs and social media messaging, to deploy the messages with the most potential to benefit the community. The JIC should also be a meeting place for the best messages and best local communicators and community leaders. Channels should include traditional media, social media platforms, and in-person networks. The JIC would be able to help states, counties, municipalities, and tribes build strong communication infrastructure including communication personnel, social media accounts, and a network of followers that may improve the speed and distribution of public health messages in diverse communities.

The JIC should be a meeting place for the best messages and best local communicators and community leaders.

Improving Government Communication

Improving government communications is also necessary. A plan of regular federal health communication during health crises should ensure predictable and optimal schedules and integration of key stakeholders to increase community buy-in. A set of guidelines for the creation and testing of health communication programs and clear nomenclatures for risks and mitigation measures will increase the efficacy of public health communications and maximize positive outcomes. No single message content or source works for all populations, implying that messages might be regularly tested for efficacy among target populations. Finally, the United States needs to invest in public health communication research innovation and instruction, with mechanisms that can generate communication programs fast to address public health concerns in a timely fashion.

The sources of public health communications also need to be carefully considered. As a Wellcome trust survey demonstrates, “No matter how exciting the treatment, how clever the delivery method, or how robust the science, there will be no impact unless the local community is open to it.” Recent surveys have shown that Americans trust their own doctors and nurses more than public health officials, and they trust people in their “cohort” above those who are not. Therefore, trusted messengers should be engaged, including doctors, nurses, physician’s assistants, and pharmacists. The credibility of public health officials should be monitored and protected to ensure they can have an impact when communicating information to the public. Likewise, the JIC should plan across agencies to help deliver infectious disease and messaging training that enables care providers to effectively communicate these messages to their patients.

The channels of government communications deserve attention as well. Contemporary public health strategies must operate in a micro-media, multi-platform environment. The right platforms (e.g., paid ads on partisan television news, Facebook interventions, and Instagram, TikTok, Twitter, or Reddit posts) vary over time and for different populations.

There are CDC guidelines for the use of social media in health promotion, and there is ample experience using influencers and social media in HIV. Similarly, methods to develop interventions by using machine learning methods are being tested in HIV and could be used for other infections as well. Finally, the federal government should support training of new generations of health reporters in scientific, medical, social, and policy topics. Foundations and private-sector leaders (e.g., Knight Fellows) should support this training by sponsoring public health fellowships, scholarships, and programs for diverse public health reporters.

Furthermore, the Covid-19 pandemic has seen an “infodemic” of harmful anti-science messaging. This disinformation is regularly amplified by adversarial nations like Russia, China, Iran, and other profiteers using social media and partisan traditional media channels. Beyond the obvious public health implications of causing “confusion and risk-taking behaviors that can harm health,”⁹⁵ these foreign efforts have taken advantage of a public health emergency to weaken “the international credibility and international cohesion of the United States and its allies and partners.”⁹⁶ The DAP-B should oversee efforts to catalogue, reveal, and respond to public health disinformation efforts. The DAP-B should also chair a working group focused on foreign amplified public health disinformation. This group should coordinate extant U.S. government efforts and include the Department of State Global Engagement Center, Office of the Undersecretary of Defense for Intelligence, the CDC, the Surgeon General, CISA, and the Directorate of National Intelligence to include the Digital Directorate of Information (DNI). Finally, the DAP-B should work with the National Science Foundation (NSF) and Director of National Intelligence (DNI) to establish a public-private Health Information Integrity Partnership to catalogue organized public health disinformation efforts. These public-private efforts should be modeled after the work of the “Election Integrity Project” and “The Virality Project.”

The social media platform companies headquartered in the United States have profound reach and must continue to improve as partners in public health. The DAP-B should support and expand the mission of CISA to work with these social media platforms to greatly improve their efforts to address and remove misinformation. CISA should regularly present validated reports of the misinformation amplified on social media platforms to the platforms themselves. In no way should this replace the responsibility the social media platforms have to police their own content, but CISA will now be empowered with an auditable tool to study social media platforms’ efforts to reduce dangerous disinformation. Members of the new misinformation working group should regularly report on their work to Congress in open session. Likewise, CISA should report to Congress on American social media businesses’ efforts to police health related misinformation. Efforts led by the DAP-B to address the clear and present disinformation threat in public health will be an important salient against the broader threat of adversarial nations amplifying divisive disinformation on powerful social media and traditional media platforms.



95 World Health Organization. Infodemic. Accessed February 27, 2022. https://www.who.int/health-topics/infodemic#tab=tab_1
96 U.S. Department of State. GEC special report: Pillars of Russia’s disinformation and propaganda system. Published August 2020. Accessed February 27, 2022. https://www.state.gov/wp-content/uploads/2020/08/Pillars-of-Russia%E2%80%99s-Disinformation-and-Propaganda-Ecosystem_08-04-20.pdf

Improving Education to Increase Social Trust, Values, and General Capacities

Another key goal to ensure long-term adherence to infectious disease prevention measures among Americans is to educate citizens in the trust, knowledge, motivation, and skills that support public health measures. These include the ability to think critically about scientific topics, knowledge about infectious diseases and pandemics, concern with public health, and understanding of the ethical issues surrounding infectious diseases, including the need for vaccination requirements. These capacities need to be transmitted to children and adolescents, as well as the adult public and health professionals. Addressing social health disparities and truly building equity in health outcomes must involve educational efforts to reduce racism and increase trust in public health measures like vaccination among minority communities. Future outreach efforts to combat hesitancy and misinformation can involve educating trusted community voices and having them deliver the message with medical professionals.⁹⁷

Addressing social health disparities must involve efforts to reduce racism and increase trust in public health measures.



Improving Documentation, Monitoring, and Accountability for Communication Goals

Another important goal is to document, monitor, and examine the achievement of all communication and education goals. These processes should include monitoring and communicating health inequalities, establishing a repository of best practices in government communication about infectious disease, having standards for streamlined clearance without political interference, and ensuring that the CDC receives expert advice on communication about infectious disease. Finally, urging the media to prevent harmful content and maintain these measures permanently is necessary as well.

⁹⁷ Igoe KE. Developing Public Health Communication Strategies—And Combating Misinformation—During COVID-19. <https://www.hsph.harvard.edu/ecpe/public-health-communication-strategies-covid-19/>. Accessed February 5, 2022.

Communication and Education

Strategic Goals

1. Improve government coordination of communication.

- a. Establish the role of Deputy Assistant to the President for Biosecurity and working groups on public communication chaired by this deputy assistant, to include a foreign amplified public health misinformation working group.
- b. Create a Joint Information Center to build and strengthen protocols to ensure effective public health communication and real-time centralized Covid information dashboards; identify a governmental office to create, evaluate, and warehouse health communications and interventions (e.g., delivered by the CDC, FDA, and HHS, as well as state and local governments); and maintain a permanent directory of diverse public health communicators.
- c. Establish community networks of agencies (e.g., religious and political institutions) and media channels for dissemination of public health messages, expand the communication infrastructure of health departments, and increase broadband penetration and access in all areas of the country to promote health equity.
- d. Direct the DAP-B to work with the NSF and DNI to establish a “Health Information Integrity Partnership” (modeled after the Election Integrity Partnership), as a new public, private, and academic consortium to monitor and educate the public about health disinformation efforts. Ask HIIP to regularly report findings to Congress.
- e. Empower the Cybersecurity & Infrastructure Agency (CISA) to regularly present U.S. social media platforms with validated reports of foreign amplified misinformation that they are promulgating. CISA should then audit the performance of these platforms to address and remove these communications. CISA should regularly report on these firms’ performance to Congress, in open session.

2. Improve government communication to control infectious diseases.

- a. Create a regular federal health communication plan for health crises to garner community support to prevent infectious disease.
- b. Create guidelines for the creation and scientific testing of health communication programs for all Americans.
- c. Instruct the FDA and other relevant agencies to develop clear, simple consumer guidelines and ensure proper interpretation of those and VAERS terminology (e.g., adverse event) by the public.
- d. Create a clear nomenclature for risks and mitigation measures, including infographics and color coding that are evidence-based and rapidly tested and vetted for clarity and understanding through community consultation.
- e. Fund centers of excellence and grants to fund innovative, ambitious, and fast-moving research and instruction on health communication and intervention.

3. Improve Education to Increase Social Trust, Values, and General Capacities in Support of Public Health.

- a. Incentivize the review and expansion of annual K-12 health education to equip children with the trust, values (e.g., depoliticization of health and health equity), knowledge, motivation, and skills that support infectious disease prevention.
- b. Promote K-12 training on ethical issues surrounding public health (e.g., effective mitigation measures and vaccine mandates), identification of unbiased sources of information, and critical thinking.
- c. Create grant programs that train K-12 students and community members to navigate the health system, seek health services, and respond actively to neglect, mistreatment, and discrimination within health institutions.

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- d. Create grants to update the education curricula of diverse health personnel to support prevention of infectious disease, including vaccination.
 - e. Create grants to build capacity to eliminate all forms of discrimination in the educational and health care systems, as well as dashboards that disaggregate patient outcomes and satisfaction across populations.

4. Improve Documentation, Monitoring, and Accountability for Communication Goals.

- a. Monitor and report on health inequities within educational, social, and political institutions to increase public accountability systems and support values that promote social wellbeing and health equity in infectious diseases.
- b. Create a clearinghouse of best practices in government communication in infectious diseases.
- c. Establish standards for streamlined clearance of health messages without political interference.
- d. Establish an independent advisory council to the CDC that includes public health, behavioral, social, and communication science and practice experts.
- e. Urge legacy media and social media platforms to design mechanisms to detect, deflect, and deny the posting of harmful and false advice that hurts public health. Ask that they regularly monitor and report on these processes. Support Congressional efforts to consider how to address dangerous foreign misinformation in new regulations for media, including social media platforms.





13

**Schools
and Childcare**

Summary

Pandemic school closures cause such significant and enduring harms to children that far more should be done to avoid them. In Omicron's wake, school-based quarantines should end, masking should soon follow, and a broader appreciation of societal costs should be applied to all infection mitigation measures.

Covid Has Been a Significant Setback for Children's Education

Pandemic-related school closures have affected more than 50 million American K-12 students. In the absence of reliable Covid data, information, or testing, schools were shut down and moved online. By the end of March 2020, every school district but one closed in response to Covid and many remained closed well into 2021.

Data show profound learning loss due to pandemic-related school closures.⁹⁸ By the end of the 2020-2021 school year, students were 4 to 5 months behind in reading and math, on average, with higher gaps observed in majority Black and low-income schools. Absent efforts to address them, these learning losses may cost students from \$49,000

to \$61,000 in lifetime earnings, which would amount to \$128 billion to \$188 billion in losses for the United States economy each year that these students are in the workforce.⁹⁹

Schools provide additional benefits to children besides learning. They offer services that are critical to the growth and development of children: nutritious meals, socialization, counseling, and health screenings. Schools are critical to recognizing and reporting abuse of children. The shuttering of schools resulted in decreased access to these services. Reports of child abuse declined when schools were closed, strongly suggesting that harms to children were being unrecognized.¹⁰⁰

Remote learning hindered some children with disabilities and individualized educational programs from accessing the specialized services and instruction they require. And school closures put severe strains on working parents, particularly women and people of color. Some 40% of American workers have school-age children, and nearly three-quarters of working women have children under the age of 18.

Mental health concerns are also most likely to be detected in schools. Among youth who receive mental

⁹⁸ The World Bank. Learning losses from Covid-19 could cost this generation of students close to \$17 trillion in lifetime earnings. Published December 6, 2021. Accessed February 18, 2022. <https://www.worldbank.org/en/news/press-release/2021/12/06/learning-losses-from-covid-19-could-cost-this-generation-of-students-close-to-17-trillion-in-lifetime-earnings>

⁹⁹ Dorn E, Hancock B, Sarakatsannis J, Viruleg E. McKinsey and Company. Covid-19 and education: The lingering effects of unfinished learning. Published July 27, 2021. Accessed February 18, 2022. <https://www.mckinsey.com/industries/education/our-insights/covid-19-and-education-the-lingering-effects-of-unfinished-learning>

¹⁰⁰ Baron E, Goldstein E, Wallace C. Suffering in silence: How Covid-19 school closures inhibit the reporting of child maltreatment. *Journal of Public Economics*. 2020;190. doi: 10.1016/j.jpubeco.2020.104258

School closures put severe strains on working parents, particularly women and people of color.

health support, 75% get it through their schools.¹⁰¹ The disruptions caused by school closures exacerbated the mental health challenges children face and allowed many of them to go undetected. Rates of anxiety and depression increased dramatically. Emergency room visits for suspected suicide attempts increased by almost 51% for girls aged 12 to 17¹⁰², and visits for mental health disabilities rose among children 5 to 11 substantially, too.¹⁰³ Over 140,000 children lost a primary or secondary caregiver.¹⁰⁴

Childcare centers provide educational programs and health and developmental screening for children. They are an essential support for the workforce. In communities without access to universal pre-K programs, childcare centers provide foundational early learning programs that prepare children for K-12 education. This early education is essential to children’s development and later educational attainment.

Despite the availability of information on Covid transmission and vaccines to prevent serious illness among staff and students, some schools continued to be affected through January 2022 by closures or significant operational restrictions, including quarantines, masking, staggered hours, and limited class sizes. In some instances, closures were unavoidable because of staff shortages. But in too many cases, shutdowns were preemptive efforts to reduce infections.

Pandemic disruptions in schools and childcare centers represent an existential threat to these socially-critical institutions.

Pandemic disruptions in schools and childcare centers represent an existential threat to these socially-critical institutions. Enrollment in public schools declined nationwide during the pandemic, which may lead to losses of federal funding and parental engagement. The nation also saw a decrease in the number of childcare facilities in operation, with non-White families suffering more from these closures and their economic consequences than White families.¹⁰⁵

101 Burns B, Costello C, Angold A, et al. Children’s mental health service use across service sectors. *Health Affairs*. 1995; 14(3): 147-159. doi: 10.1377/hlthaff.14.3.147
102 Yard E, Radhakrishnan L, Ballesteros M, et al. Emergency Department Visits for Suspected Suicide Attempts Among Persons Aged 12–25 Years Before and During the COVID-19 Pandemic — United States, January 2019–May 2021. *Centers for Disease Control: Morbidity and Mortality Weekly Report*. Published June 18, 2021. Accessed February 20, 2022. https://www.cdc.gov/mmwr/volumes/70/wr/mm7024e1.htm?s_cid=mm7024e1_w
103 Leeb R, Bitsko R, Radhakrishnan L, et al. Mental Health–Related Emergency Department Visits Among Children Aged <18 Years During the COVID-19 Pandemic — United States, January 1–October 17, 2020. *Centers for Disease Control: Morbidity and Mortality Weekly Report*. Published November 13, 2020. Accessed February 20, 2022. https://www.cdc.gov/mmwr/volumes/69/wr/mm6945a3.htm?s_cid=mm6945a3_w
104 National Institutes of Health. More Than 140,000 U.S. Children Lost a Primary or Secondary Caregiver Due to the COVID-19 Pandemic. Published October 7, 2021. Accessed February 20, 2022. <https://www.nih.gov/news-events/news-releases/more-140000-us-children-lost-primary-or-secondary-caregiver-due-covid-19-pandemic>
105 Lee E, Parolin Z. The care burden during Covid-19: A national database of child care closures in the United States. *Socius*. 2021;7:1-10. <https://doi.org/10.1177/2F23780231211032028>

A Roadmap to the Next Normal for Schools

From now on, the nation must do far more to avoid closing schools. During an infectious disease outbreak, schools should be the last to close and the first to reopen. While schools may occasionally close for operational reasons due to absenteeism or teacher shortages because of infections, as they have historically done during bad flu years, preemptive school closures should be a last resort. Schools should only be closed after all other community mitigation measures failed.

Though children are often disproportionately affected by respiratory infections, the risks to children of severe disease following infection with the virus that causes Covid has remained low. Although children represented 18.9% of all reported Covid cases since the start of the pandemic, their share of those hospitalized ranged between 1.5% and 4.6%.



A key difference between 2020 and 2022 is the widespread availability of safe and effective vaccines.

Reported hospitalization rates among infected children were between 0.1% and 1.5%.¹⁰⁶ The actual rate is probably lower since the reported numbers include hospitalizations of non-school age children who are at greater risk of severe illness, including older teens and infants.

Over the last two years, the United States has developed or identified numerous tools to greatly reduce risks to those in school and childcare settings. A key difference between 2020 and 2022 is the widespread availability of safe and effective vaccines to prevent serious illness among students, teachers and staff, which should lessen concerns about safety. And the availability of medicines to treat those who are at high risk of developing severe illness and to provide pre-exposure protection to the immunocompromised enhances safety for those with elevated risks.

Other non-pharmaceutical interventions can also help, including improved ventilation and air filtration, symptom-based screening, and cohorting. Some schools have used testing to identify infections in children without symptoms.

The widespread and rapid transmission of the Omicron variant and subsequent decline in hospitalizations created an ideal moment to rethink mitigation strategies. With vaccines widely available and infection-based immunity soaring, school-based quarantines for Covid —never popular or particularly effective —should end. Prior to the Omicron surge, school districts were shifting to test-to-stay policies that utilize rapid testing to allow children who were exposed to Covid cases to remain in school as long

¹⁰⁶ American Academy of Pediatrics. Children and Covid-19: State-level data report. Accessed February 18, 2022. <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/>

School-based quarantines for Covid —never popular or particularly effective — should end.

as they tested negative each day.¹⁰⁷ But Omicron reduced the feasibility of test-to-stay policies in some communities. Some school districts have instead pivoted to using tests only to assess whether mildly symptomatic students can remain in schools. Others should consider similar shifts. In the current environment of declining case counts, schools may consider ceasing asymptomatic testing and shift to symptomatic testing only, while keeping on hand the resources and staffing to reintroduce asymptomatic test-to-stay policies in the event of future variants and case surges.

Beyond quarantines, mitigation efforts must be broadly reconsidered. Masking, for instance, could lead to delays in language acquisition and social-emotional learning and should soon end when appropriate. Improved ventilation and air filtration not only protects against a host of respiratory illnesses but seems to improve student performance. Going forward, mitigation measures that have the potential to cause harm or are not broadly acceptable should be implemented only with clearly defined goals for their use and with established triggers for their implementation and discontinuation. These guidelines may be based on local metrics, such as community incidence of respiratory infections and vaccination coverage. Namely, when community transmission levels fall below a predetermined level tied to (or even higher than) the CDC’s initial cut-offs or when the local vaccination rate reaches above a certain threshold, mask mandates should be lifted

in these counties or localities and mask-wearing made optional, but only if that school has made upgrades in its indoor air quality via MERV 13 or HEPA filters. Having transparent on- and off-ramps is crucial.

Medically vulnerable children and adults who may not be optimally protected by vaccines, masks, and medicines will require additional protections. These might include accommodations for other learning modalities if parents and staff so choose. Schools should work with parents to tailor protections to best meet students’ needs while ensuring that students requiring accommodations are not stigmatized, maintain as much access to the general education setting as possible and additional research into potential health risks is necessary to enable clear communication and identify optimal learning environments. There is no uniform solution for children with disabilities, as they are not a monolith, but ensuring the enforcement of their civil rights protections is critical.

Based on the extensive data and research outlined above, schools and childcare centers can safely remain open by following best practices.



¹⁰⁷ Centers for Disease Control. Test-to-stay options can help keep students in school during Covid-19. Published December 17, 2021. Accessed February 18, 2022. <https://www.cdc.gov/media/releases/2021/s1217-Test-To-Stay.html>

Schools and Childcare Strategic Goals

1. Direct Department of Education (ED) to accelerate vaccinations of teachers, childcare providers, school staff, and students, using financial and other incentives.

- a. Collaborate with teachers' unions and school boards to promote Covid and influenza vaccine uptake.
- b. Require schools and childcare centers to mandate Covid and influenza vaccines for teachers and staff.
- c. Provide financial support for school boards and systems to operate vaccination clinics for Covid, influenza, and other vaccines.

2. Direct the CDC and ED to collaborate to establish and communicate clear guidance on implementation of public health mitigation measures.

- a. Direct CDC to develop specific, tiered guidance for childcare facilities and school districts to guide future public health interventions (including masking, social distancing, quarantining, reduced class sizes, and outdoor learning), considering healthcare stress and vaccination rates. This guidance should consider the best available data on how to protect children and staff who may have residual vulnerability to Covid despite prior vaccination.
- b. Create an ED resource website for use by all stakeholders that outlines the best standards and schedule for testing, ventilation, and filtration to aid in purchasing, use, and maintenance.

3. Direct the ED to develop and implement an educational recovery plan that addresses pandemic-related learning loss and minimizes the achievement gap exacerbated by the pandemic.

- a. Establish and expand programs for students who fell behind, including summer school, individualized tutoring, after-school or extra-school programs.

- b. Provide funding and policy support for states and districts to redesign school curricula to prepare all children to reach a "life-ready" standard.
- c. Provide resources to school districts to effectively engage with and incorporate the perspectives of a diverse and representative group of stakeholders (e.g., families, students, teachers, community members) in developing a recovery plan.
- d. Partner with established organizations to facilitate extra-curricular programs, to reduce burden on schools and staff and ensure that students, especially students of color, students from low-income communities, students with disabilities, students living in poverty or foster care, and other vulnerable students have opportunities to overcome gaps in instruction and attainment exacerbated by the pandemic.
- e. Create resources to help ensure students with significant disabilities can access their services where they are.
- f. Create resources to help school districts prioritize core academic concept areas and curricula for helping students get on track academically and socially.
- g. Provide financial and other incentives to parents and other community volunteers to support school staff.
- h. Partner with disability organizations including Centers for Independent Living and Parent Training and Information Centers to help advocate and provide additional support services.

4. Direct the ED to provide schools and childcare centers with sufficient technical and financial resources to adopt appropriate testing processes and upgrade ventilation and filtration systems.

- a. Fund procurement and provide sufficient quantities of rapid tests for schools, childcare facilities, and student families.
- b. Direct the ED to require states to report on ventilation and filtration in schools and consider additional funding mechanisms to incentivize ventilation upgrades.

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- c. Direct EPA to continue providing guidance to school systems on measuring ventilation and filtration systems and installing upgrades.

5. Fund ED research examining optimal virtual learning modalities to deploy when in-person education is disrupted.

- a. Direct ED to develop a research agenda and award grants examining methods to improve remote learning and determine optimal virtual learning modalities for students of all grade levels and abilities, taking into account universal design for learning.
- b. Direct ED to research how schools can teach via alternative small-group arrangements, hybridizing teacher-led instruction with developed curricular software or materials to deliver more structured remote instruction.
- c. Direct ED to research non-learning impacts of school closures and shifts to virtual modalities and identify opportunities to support students and their families, with a particular focus on vulnerable students from underserved backgrounds.
- d. Fund states' deployment of alternative pathways to certification for school-based staff to address projected staff shortages.



14

Worker Safety



Summary

Millions of workers risked their lives over the past two years to care for the United States' sick and elderly and help put food on tables. The federal government should issue and enforce stronger protection standards in high-risk workplaces, update recommendations and guidance to reflect aerosol transmission, improve data collection, and enable workers to quarantine or isolate when necessary.



An Epidemic of Workplace Illnesses

Covid has been an unprecedented and massive worker safety crisis that resulted in an epidemic of workplace illnesses and deaths. Frontline workers in essential industries have valiantly risked their health and lives to get the job done. Hundreds of thousands of hospital and nursing home workers were infected by Covid at work and thousands died. Grocery store clerks, food processing workers, flight attendants and many others are taking

similar risks. In the meat packing and poultry industry, where workers of color are disproportionately employed, at least 59,000 workers employed by just five companies were infected in the first year of the pandemic.¹⁰⁸

Enormous numbers of workers in other jobs with crowded or public-facing work settings have been infected and sickened, and thousands died. Workers infected on the job go home to infect family members and neighbors, driving community transmission.¹⁰⁹ More than two years into the pandemic, clusters of work-related cases continue to be reported at job sites across the country. Poor reporting and data collection systems mean the true number of worker infections, serious illnesses and deaths is unknown and likely never will be.

Millions of American workers spend 8 or more hours each day in indoor environments or vehicles where they are required to be in close contact with those potentially harboring infections, including coworkers, patients, clients, or the public. While vaccination is critical to prevent serious disease, Omicron has made clear that vaccinations alone will not stop transmission. Healthcare and long-term care facility workers, corrections officers, food industry workers, first responders and others employed in stores, warehouses, public transportation and many other settings are all at greater risk of Covid because of their jobs.

¹⁰⁸ Congress of the United States, House of Representatives, Select Subcommittee on the Coronavirus Crisis. Coronavirus Infections and Deaths Among Meatpacking Workers at Top Five Companies Were Nearly Three Times Higher Than Previous Estimates. Published October 27, 2021. Accessed February 22, 2022. https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021.10.27%20Meatpacking%20Report.Final_.pdf

¹⁰⁹ Taylor CA, Boulos C, Almond D. Livestock plants and Covid-19 transmission. Proceedings of the National Academy of Sciences of the United States of America. 2020; 117(50): 31706-31715. doi: 10.1073/pnas.2010115117.

Failure to control workplace exposures has wreaked havoc on the workforce.

Failure to control workplace exposures has wreaked havoc on the workforce. The results have been catastrophic for many who cannot work remotely. In addition to those who suffered severe Covid-related illnesses, millions of workers with mild or no symptoms have had to take time off of work after being exposed at work, and many workers debilitated by long Covid still drag themselves into work because they cannot afford to quit.¹¹⁰ The US Census Bureau estimates that, as of early February 2022, more than three million workers left the workforce due to concerns about getting or spreading the coronavirus to others.¹¹¹ Many others likely have switched to jobs with lower risk of exposure.

Under the Occupational Safety and Health Act of 1970, employers are required to provide a workplace free of recognized, serious hazards. During the pandemic, OSHA has taken only limited steps to make the requirement for safe workplaces free of hazards a reality.

In June 2021 —16 months into the pandemic —OSHA finally issued a Covid-19 Emergency Temporary Standard covering only healthcare workplaces and then withdrew these protections in December 2021, saying that the law required that emergency protections be replaced by permanent rules within six months. OSHA has committed to issuing a permanent standard covering healthcare workers within an additional 6 to 9 months, although many workplace safety experts doubt the agency can meet the deadline.

OSHA also issued an emergency rule requiring employers outside of the healthcare industry with 100 or more employees to ensure that unvaccinated employees be masked and provide a negative test each week if they report to work. The rule was stayed by the Supreme Court and has been formally withdrawn by the agency.

A handful of states operate their own state OSHA plans for the private sector. Early in the pandemic, a few of these states issued requirements to protect workers in healthcare and other industries. However, only a few of those state-based protections remain in effect, *leaving the overwhelming majority of workers with no workplace protections.*

OSHA's Respiratory Protection Standard requires employers to establish and implement a respiratory protection program for workplaces where respirators are necessary to protect the health of employees from certain inhalation hazards when higher forms of protection are insufficient. However, most workers are not covered by this standard and are in great need of respiratory protection.¹¹² The absence of relevant standards limits OSHA's ability to oversee employers who do not adequately control exposures to workplace hazards. The agency has attempted to address unsafe conditions through enforcement of some applicable



¹¹⁰ Bach K. Is 'long Covid' worsening the labor shortage? Brookings. Published January 11, 2022. Accessed February 22, 2022. <https://www.brookings.edu/research/is-long-Covid-worsening-the-labor-shortage/>

¹¹¹ US Census Bureau. Week 42 Household Pulse Survey: January 26, 2021 —February 7, 2022. Table 3. Educational Attainment for Adults Not Working at Time of Survey, by Main Reason for Not Working and Source Used to Meet Spending Needs. Published February 16, 2022. Accessed February 22, 2022. <https://www.census.gov/data/tables/2022/demo/hhp/hhp42.html>

¹¹² The National Academies of Sciences, Engineering, and Medicine. Consensus Study Report: Frameworks for Protecting Workers and the Public from Inhalation Hazards. Published 2022. Accessed February 20, 2022. <https://www.nap.edu/catalog/26372/frameworks-for-protecting-workers-and-the-public-from-inhalation-hazards>

standards and the general duty of employers to provide safe workplaces, but it has focused primarily on healthcare workplaces where workers already died or high numbers were infected.

Before the Covid pandemic, OSHA had enough inspectors to visit every workplace once every 162 years.

OSHA's enforcement capabilities are severely limited by its modest resources. Before the Covid pandemic, OSHA had enough inspectors to visit every workplace once every 162 years.¹¹³ The pandemic further strained its resources while leading to an enormous backlog of safety and health complaints and allegations of retaliation against workers who raised safety concerns.

Enforcement actions to ensure workplaces free of infection require data on workplace conditions. The limitations of the current systems to collect data about work-related Covid cases and deaths inhibit the ability of OSHA to target its enforcement and compliance assistance efforts. Some of the problems of data collection include the fact that for most Covid cases, no information on industry or occupation is collected. OSHA requires only employers in the healthcare industry to keep track of Covid cases, but even those employers only have to report cases serious enough to result in hospitalization. Employers in other industries only track those they believe are work-related within a narrow scope. Some states like California¹¹⁴ require employers to report workplace outbreaks, but most states do not.¹¹⁵ This lack of occupational health surveillance has severely restricted timely intervention in high-risk workplaces.



Paid Sick Leave, Ventilation, and Vaccinations

Like other workplace hazards, Covid exposures can be prevented and mitigated at work through government policy and workplace actions.

First, the federal government can directly reduce the workplace presence of infectious workers by establishing a national sick leave program. Early in the pandemic, under the emergency sick leave provision of the bipartisan Families First Coronavirus Response Act (FFCRA), workers employed by firms with less than 500 employees received up to two weeks of Covid-related sick leave. Researchers estimated these payments prevented about one case per day for every 1,300 workers covered.¹¹⁶

There is currently no national requirement that employers provide wage payments or medical removal protection benefits to workers who are exposed or infected, or who have to take care of sick family members. A permanent national paid sick leave program covering these situations would remove incentives and requirements that workers come to work sick and risk infecting others.

¹¹³ AFL-CIO. Death on the job: The toll of neglect. Published October 6, 2020. Accessed February 22, 2022. <https://aflcio.org/reports/death-job-toll-neglect-2020>

¹¹⁴ California Government Regulations, Title 8, Subchapter 7. Covid-19 Prevention. Accessed February 22, 2022. <https://www.dir.ca.gov/title8/3205.html>

¹¹⁵ New Mexico Government Regulations, Title 11, Chapter 5. Labor and Workers' Compensation. Accessed February 22, 2022. <https://www.srca.nm.gov/parts/title11/11.005.0001.html>

¹¹⁶ Pichler S, Wen K, Ziebarth NR. Covid-19 Emergency Sick Leave Has Helped Flatten The Curve In The United States. *Health Affairs*. 2020; 39(12): 2197-2204. doi: 10.1377/hlthaff.2020.00863.

A policy requiring paid sick leave would address an important disparity.

A policy requiring paid sick leave would address an important disparity that likely exposes lower- income workers and minorities to illness. Higher-income workers generally work at companies with existing sick leave policies. A national program would bring low-income workers sick leave parity, helping mitigate the health and economic burdens of Covid and other illnesses.

Second, the federal government should establish workplace standards regarding ventilation, appropriate PPE, physical distancing, and other basic public health precautions (see *Chapter 4: Cleaner, Safer Indoor Air* and *Chapter 5: Personal Protective Equipment*).¹¹⁷ Without these standards, OSHA is severely handicapped in requiring effective mitigation measures.

Boosting worker vaccination rates would also help protect employees who face significant risk of exposure to Covid and other respiratory viruses at work. To encourage vaccine uptake, the government can establish a federal paid time-off program for employees to get vaccinated or extend the federal sick leave program outlined above to include time to receive vaccinations and recover from potential side effects. Vaccination mandates can boost vaccination rates but can also increase strains on communities of color that have seen lower vaccine uptake.

Finally, the effectiveness of all workplace safety actions will be limited if there is not widespread public recognition of the importance of workplace precautions and the value of protecting frontline workers. Under the rubric of workplace safety parity and sick leave benefits, the Administration should lead a public educational campaign underscoring the right of workers to be safe at work and the responsibility of employers to provide safe workplaces, which can bolster OSHA and CDC regulatory efforts and recommendations.



¹¹⁷ Michaels D, Wagner GR. Occupational Safety and Health Administration (OSHA) and Worker Safety During the Covid-19 Pandemic. JAMA. 2020; 324(14): 1389-1390. doi:10.1001/jama.2020.16343.

Worker Safety Strategic Goals

1. Strengthen worker protections against Covid and other respiratory viruses through federal agency action and Congressional legislation.

- a. Enact legislation providing all workers with paid medical (sick) and family leave so that they can isolate, quarantine, or take care of a sick family member without loss of pay.
- b. Enact legislation providing all workers with paid medical (sick) leave so that they can be vaccinated against Covid.
- c. Ensure that costs of work-related Covid-19 testing are not borne by workers.
- d. Encourage or incentivize employers to require their workers to be fully vaccinated.
- e. Direct OSHA and the CDC to update guidance, recommendations, and enforcement directives to reflect the primary importance of aerosol transmission of SARS-CoV-2 and the need for employers to implement a comprehensive layered approach to limiting workplace exposures, including effective ventilation and air filtration and appropriate respiratory protection.
- f. Direct OSHA to issue a final, permanent Covid standard for all healthcare workplaces, including respiratory protection and ventilation requirements and mandated medical removal protection pay if a person is required to not work because of illness.
- g. Direct and fund OSHA to increase programmed inspections in high-risk industries where vulnerable workers are disproportionately employed.
- h. Require all establishments participating in OSHA's Voluntary Protection Programs (VPP) or Safety and Health Achievement Recognition Program (SHARP) to follow OSHA and CDC guidance and ensure that all workers are fully vaccinated, with exceptions only for medical and religious reasons.
- i. Direct OSHA to issue a broader Infectious Disease Prevention Standard to protect healthcare and other high-risk worker groups and to prepare for future pandemics.

2. Direct OSHA and HHS to collaborate to educate employers, workers, and the public on controlling workplace exposures to airborne infectious diseases.

- a. Launch a national safe workplace campaign that stresses the importance of controlling workplace exposures to airborne infectious diseases and aerosols, and partner with private sector organizations to extend reach.
- b. Encourage employers to evaluate workplaces' potential aerosol exposure risks and develop Covid safety management plans.
- c. Emphasize the value of worker input in controlling workplace exposures and remind employers that retaliating against workers for raising safety concerns is against the law.
- d. Require that employers provide high-quality face coverings—N95 respirators or equivalent—to workers in high-risk environments. (see [*Chapter 5: Personal Protective Equipment*](#)).

3. Require OSHA and the CDC to expand reporting of workplace infections to identify and prevent outbreaks.

- a. Direct OSHA to immediately issue regulations with new respiratory viral illness recording and reporting requirements, including employer reporting of respiratory viral clusters and outbreaks in their workplaces.
- b. Fund CDC/NIOSH to implement national surveillance of occupational infectious diseases, in coordination with OSHA, the Bureau of Labor Statistics, and the Council of State and Territorial Epidemiologists (CSTE).
- c. Increase CDC collection of infection and vaccination data on workers employed in high-risk industries.
- d. Direct the CDC to fund and require the standardized collection of industry and occupational fields on all Covid cases reported by state health departments. (see [*Chapter 9: Health Data Infrastructure*](#)).

4. Direct and empower OSHA to improve workplace indoor air quality and availability of workplace PPE.

- a. Direct OSHA to issue an enforcement directive clarifying that the agency’s current Respiratory Protection Standard requires employers in high-risk industries to provide at least N95 respirators in situations where risk of airborne infectious disease transmission is high or where indoor working conditions are crowded or public facing (see *Chapter 5: Personal Protective Equipment*).
- b. Direct OSHA to issue an enforcement directive enabling employers to require N95 face coverings use by workers not normally covered by OSHA’s Respiratory Protection Standard (RPS) and not employed in high-risk industries, without triggering the need to comply with the full RPS, as well as emphasize that mitigation measures must go beyond providing respirators and include a layered approach to reducing workplace exposure risk (see *Chapter 5: Personal Protective Equipment*).
- c. Direct OSHA and CDC to incorporate ventilation and air filtration requirements for indoor work environments into OSHA standards and into OSHA and CDC guidance on preventing transmission of Covid and other airborne infectious diseases (see *Chapter 4: Cleaner, Safer Indoor Air*).

5. Fund OSHA and CDC research into prevention of workplace transmission of respiratory viruses.

- a. Direct CDC/NIOSH to establish a research program on occupational airborne infectious disease prevention, including development of improved control technologies and respiratory protection.
- b. Direct CDC/NIOSH to work with CSTE, NACCHO (the National Association of County and City Health Officials) and other organizations to improve local health departments’ capacity to respond to workplace infectious disease outbreaks, conduct hazard assessments, and contain and prevent disease spread. The CDC should also increase related funding for local departments.
- c. Fund OSHA to augment its workforce of standards development experts, compliance officers, and whistleblower investigators.
- d. Increase funding for state-based OSHA consultation programs that provide free guidance to small employers on reducing exposure risk.

