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. 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 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.

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.
   a. Supplement existing SARS-CoV-2 PCR tests with multiplexed molecular testing for multiple respiratory viruses.
   b. Prioritize low-cost rapid tests usage for screenings and shift away from PCR tests for low-risk screenings.
   c. 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.
   d. Scale distribution programs in community locations including pharmacies, grocery stores, corner stores, and schools to better reach underserved populations and those who move frequently.
   e. 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.
   f. Hold industry accountable for monitoring, reporting on, and acting to resolve supply chain issues.
   g. 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.
   a. Centrally negotiate prices through an agreed-upon purchaser for testing kits to ensure access to low-cost tests.
   b. 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.
   c. Use financial incentives, such as contingency contracts and guaranteed purchases to create predictable demand for manufacturers and low-cost supply for the public.
   d. Require Medicaid to cover the cost of at-home tests, as is now required for private insurers and Medicare.
   e. Encourage private insurers to create billing codes for rapid tests to avoid the current long and unwieldy reimbursement process that relies on retail receipts.
   f. 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).
   a. 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).
   b. 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 sociodemographic information (see Chapter 9: Health Data Infrastructure).