

ROADMAP TO PANDEMIC RESILIENCE

Massive Scale Testing, Tracing, and Supported Isolation (TTSI) as the Path to Pandemic Resilience for a Free Society

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Many of the undersigned do not typically take institutional positions. Moreover, some may differ with aspects of the report, and have stressed other matters of primary focus. But all have signed on as an urgent call to respond to a national crisis, and have done so with the greatest sense of vital unity.

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ABOUT HARVARD'S EDMOND J. SAFRA CENTER FOR ETHICS

The Edmond J. Safra Center for Ethics seeks to **strengthen** teaching and research about pressing ethical issues; to **foster** sound norms of ethical reasoning and civic discussion; and to **share** the work of our community in the public interest.

The Edmond J. Safra Center for Ethics at Harvard University has worked in the space of ethics and public affairs for more than thirty years. We help people do integrated policy work that always keeps values and ethical choices front and center. Any big problem will be multidisciplinary. The Center has a long history of doing work in the bioethics space specifically. Harvard's Center for Bioethics developed out of our center, and we are also closely affiliated with the Petrie-Flom Center for Law and Bioethics. As the COVID-19 crisis took shape, we saw a need to connect public health expertise to economic expertise, legal expertise, political science, and philosophical/ethics expertise. So we set out to build a space for that integrated policy conversation.



CORRECTION: The April 20, 2020, 6 a.m. posting of the "Roadmap to Pandemic Resilience" contained an error, which has been corrected in the 12 p.m. posting. The earlier version attributed to the Broad Institute (Cambridge, MA) estimates of a capacity to achieve 1 million tests per day. This was a reporting error. The correct information is that the Broad Institute, which analyzed 250,000 samples a day for the Human Genome Project, is a good example of the kind of lab that might be stood up to achieve a capacity of 1 million tests per day.



EXECUTIVE Summary

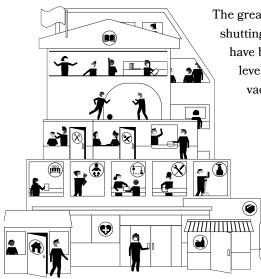
COVID-19 IS A PROFOUND THREAT TO OUR DEMOCRACY, COMPARABLE TO THE GREAT DEPRESSION AND WORLD WAR II. As ever, the greatest bulwark of democracy is us. What we do together—*for* one another and, even more, *with* one another—to fight this terrible disease, protect human life, secure our institutions, and prevent the destruction of our economy will determine whether free societies will prove resilient in the face of existential emergency.

What we need to do is much bigger than most people realize. We need to massively scale-up testing, contact tracing, isolation, and quarantine—together with providing the resources to make these possible for all individuals.

Broad and rapid access to testing is vital for disease monitoring, rapid public health response, and disease control.

We need to deliver 5 million tests per day by early June to deliver a safe social reopening. This number will need to increase over time (ideally by late July) to 20 million a day to fully remobilize the economy. We acknowledge that even this number may not be high enough to protect public health. In that considerably less likely eventuality, we will need to scale-up testing much further. By the time we know if we need to do that, we should be in a better position to know how to do it. In any situation, achieving these numbers depends on testing innovation.

Between now and August, we should phase in economic mobilization in sync with growth in our capacity to provide sustainable testing programs for mobilized sectors of the workforce.



The great value of this approach is that it will prevent cycles of opening up and shutting down. It allows us to steadily reopen the parts of the economy that have been shut down, protect our frontline workers, and contain the virus to levels where it can be effectively managed and treated until we can find a vaccine.

We can have bottom-up innovation and participation and top-down direction and protection at the same time; that is what our federal system is designed for.

> This policy roadmap lays out how massive **testing** plus contact **tracing** plus **social isolation** with strong social supports, or TTSI, can rebuild trust in our personal safety and the safety of those we love. This will in turn support a renewal of mobility and mobilization of the economy. This paper

is designed to educate the American public about what is emerging as a consensus national strategy. The work has been produced in partnership with The Rockefeller Foundation and builds on important work already released by Johns Hopkins Center for Health Security, the Duke Margolis Center for Public Health Policy, Center for American Progress, and the American Enterprise Institute.

KEY POINTS IN THIS ROADMAP INCLUDE:

- The level of testing and supported isolation we need depends on how effectively we can trace people's contacts, warn those contacts about their exposure and need for a test, test them, and isolate those who are COVID-positive.
- 2. To succeed, isolation must be supported with job protections, resource support, and health care.
- Testing and public health response—in programs established by states and administered by local health authorities—can and should be fully aligned with civil liberties, due process, non-discrimination, data and health privacy protections, and health ethics.

TO ACHIEVE THESE THINGS, WE NEED THE FOLLOWING:

- Innovation in testing methodologies.
- A Pandemic Testing Board set up by the federal government with strong but narrow powers that has the job of securing the testing supply and the infrastructure necessary for deployment of testing.
- Federal and/or state guidance for state testing programs that accord with due process, civil liberties, equal protection, non-discrimination, and privacy standards.
- Readiness frameworks to support local health leaders, mayors, tribal leaders, and other public officials in setting up test administration processes and isolation support resources.

- Organizational innovation at the local level linking cities, counties, and health districts, with specifics varying from state to state.
- Federal and state investment in contact tracing personnel, starting with an investment in 100,000 personnel (recommendation from JHU Center for Health Security).
- Clear mechanisms and norms of governance and enforcement around the design and use of peerto-peer warning apps, including maximal privacy protection, availability of open source code for independent and regulatory audit, and prohibitions on the use of any data from these apps for commercial purposes, ideally achieved through pre-emptive legislation.
- Support for quarantine and isolation in the form of jobs protections and material support for time in quarantine and isolation as well as access to health care.
- An expanded U.S. Public Health Service Corps and Medical (or Health) Reserves Corps (paid service roles), and addition of Health Reserves Corps to the National Guard units of each state.
- National Infectious Disease Forecasting Center to modernize disease tracking (Recommendation from Scott Gottlieb, AEI).

Consensus is emerging about what we need. How to do it is beginning to come into view. The time for action has arrived.

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INTRODUCTION

COVID-19 IS A PROFOUND THREAT TO OUR DEMOCRACY, in certain respects comparable to the Great Depression and requiring levels of public-private coordination last seen in World War II. As ever, the greatest bulwark of democracy is us. What we do together—*for* one another and, even more, *with* one another—to fight this terrible disease, protect human life, secure our institutions, and prevent the destruction of our economy will determine whether free societies prove resilient in the face of existential emergency. What we need to do is much bigger than most people realize. We need to deliver 5 million tests per day to deliver a safe social reopening. This number will need to increase over time to 20 million a day to fully remobilize the economy. We acknowledge that even this number may not be high enough to protect public health. In that considerably less likely eventuality, we will need to scale-up testing much further. By time we know if we need to do that, we should be in a better position to know how to do it. Achieving this will depend on testing innovation.

If we rely on collective social distancing alone to tide us over until a vaccine is available, the economy will be shut down on and off for 12 to 18 months, costing trillions of dollars. We can instead fully restart the economy by August through a program of massive investment in public health infrastructure, especially diagnostic and serological testing, combined with effective contact tracing-and-warning programs, and supported individual quarantine and/or isolation. By warning, we refer to alerting those who have been exposed to an infection of their exposure and the need for a test. Those tracing-and-warning programs might be manual only or manual with opt-in digital supports or fully hybrid. We estimate that steady-state testing levels that would permit replacing collective stay-at-home orders as the main tool for disease control with a testing—tracing-and-warning—supported-isolation, or TTSI, methodology will eventually need to reach a capacity to test 2 to 6% of the population per day, or between 5 and 20 million people per day.

Creating the complex supply and delivery chains required for testing at this scale will require a rapid coordination of business activity unprecedented since World War II. But the cost of such a testing and tracing, or TTSI, program—\$50 to 300 billion over two years—is dwarfed by the economic cost of continued collective quarantine of \$100 to 350 billion *a month*. Furthermore, this calculus neglects the lives being lost every week among workers in essential sectors and the vulnerable populations they serve who remain exposed to the virus even when stay-at-home advisories are in place. It also neglects the fraying of the social fabric created by extended collective quarantine. Through swift, focused, and ambitious action across civil, public, and private sectors, we can accelerate the process and help avoid a severe depression. Also, we need to achieve these ambitious aims while protecting civil liberties, justice, and constitutional democracy.

This roadmap to Pandemic Resilience lays out the key concepts behind a pandemic response that massively scalesup a program of testing—tracing-and-warning—supported-isolation in order to control the disease without recourse to collective stay-at-home orders (section 2); lays out a phased sectoral approach for mobilizing the economy for pandemic resilience, beginning with essential workers (section 3); charts the specific responsibilities for such a plan of the different tiers of our federal system (section 4); lays out the role for business (section 5); lays out the role for workers (section 6); lays out the role for civil society (section 7); endorses key proposals from other policy groups (sections 8-10); and summarizes our recommendations (section 11).

OUR ANCHOR RECOMMENDATION IS THIS:

Between now and August, we should phase in economic mobilization in sync with growth in our capacity to provide speedy, sustainable testing, tracing and warning, and supported isolation and quarantine programs for mobilized sectors of the workforce, or TTSI. We do not propose a modest level of TTSI intended to supplement collective quarantine as a tool of disease control. Rather we recommend a level of TTSI ambitious enough to replace collective quarantine as a tool of disease control. TTSI should replace stay-at-home.

In addition, we endorse the recommendations of the Duke Margolis report on disease surveillance, the recommendations of the Johns Hopkins University Center for Health Security on investing in massively scaling up the nation's contact tracing personnel, and the recommendations of the McChrystal group on innovating organizationally at the local level.

CORE CONCEPTS

TO DEFEAT COVID-19, WE MUST RAPIDLY DECELERATE THE PACE OF VIRAL TRANSMISSION, mobilize the economy to fight the pandemic, ensure that mobilization of economic sectors beginning from essential workers and ending with full mobilization can be done safely and swiftly, and prevent resurgence of the virus. Also, we need to achieve these ambitious aims while protecting civil liberties, justice, and constitutional democracy.

In the absence of a vaccine and given the profound economic costs and harms to civil liberties, justice, and constitutional democracy of indefinite, long-term, and/or repeated applications of mass social distancing orders, we need to develop alternative approaches to deceleration and disease suppression. More specifically, we need to invest in the infrastructure of **pandemic resilience**—the tools that permit a society to control a highly infectious disease while preserving essential public institutions, mobilizing the economy to provide surge capacity to fight the disease, and keeping the rest of the economy maximally open.

The public health toolkit uses testing in four ways for infectious diseases: first, therapeutically as a diagnostic tool; second, as a tool for finding cases and tracing known contacts (either by testing the symptomatic or testing more broadly); third, in the form of "sentinel testing," which has the purpose of discovering and tracking the prevalence of a disease and how it spreads in community settings ("sentinel testing" sometimes but does not always use random methods); and fourth, in the form of antibody testing to find immunity and the degree to which an infection has penetrated a community.

Because of the extraordinary threat presented by the present pandemic, we need to use all these testing tools immediately.

We focus on the use of testing in its mode as a tool for disease control that operates by finding cases, tracing and warning known contacts, and isolating all cases. Testing in this fashion is part of what we call a TTSI (testing, tracing, and supported isolation) program for disease control.

As we consider massively scaling up COVID-19 testing to build TTSI programs whose purposes are intervention and disease control, the most important decision is the scale at which we test. What should the target be? There are three possibilities.

- 1. **BROAD QUARANTINE:** In this approach, tests are used for those who are symptomatic and those with reasons to presume exposure, (e.g., health care workers). Their contacts are traced, symptomatic contacts are isolated, and asymptomatic contacts are quarantined but not tested. (The Johns Hopkins Center for Health Security National Plan recommends this level of testing, supported by a massively scaled up manual contact tracing program.)
- 2. **TARGETED ISOLATION:** In this approach, tests are used for those who are symptomatic and those with reasons to presume exposure based on community spread (e.g., health care workers), but also for all of their contacts,

including asymptomatic contacts, so that COVID-positive contacts can be isolated but contacts who test negative do not have to be quarantined. Asymptomatic contacts who test negative on a first test would have to be tested multiple times over the course of the incubation period but would not necessarily need to be quarantined. Alternatively, these individuals might choose to quarantine rather than to be tested. (Pandemic Resilience Roadmap)

3. UNIVERSAL TESTING: Diagnostic tests are used for those who are symptomatic, for those with reasons to presume exposure based on community spread (e.g., health care workers), and for symptomatic and asymptomatic contacts of those in the first two groups, but also in broadly applicable mandatory employer, school, and benefits-based testing programs. (Pandemic Resilience Roadmap)

The first level of testing is unlikely to provide disease control without complementary use of social distancing methods because of the high rate of asymptomatic carriers with COVID-19 (somewhere in the range of 20 to 40% of cases). Also, when disease prevalence is high, as it is now, the broad quarantine approach is likely to result in many COVID-negative people nonetheless having to endure quarantine. The second level of testing will provide disease control if contact tracing is highly effective. The third level of testing provides maximal possible intervention for disease control. Both targeted isolation and universal testing are sufficiently robust from a disease control point of view to support **phased mobilization of the economy**, especially if rolled out on a sector-by-sector basis. We call this **phased sectoral mobilization**. With targeted isolation as the basic tool, and universal testing as a backup approach, it should be possible to keep the economy open as the disease slowly decelerates further over time. On all three levels, we need clear protocols to define when people are no longer infectious, typically in the form of guidance provided by the CDC.

We recommend using targeted isolation as the best method of pandemic response.

Contingent on test supply, test administration, and test analysis capacity, we also recommend developing the capacity to support universal TTSI programs, for use in emergency contexts as an alternative to national collective quarantine, which is economically devastating.

In the targeted isolation approach, a policy of **massively scaled TTSI** breaks from the conventional public health approach along three dimensions: first, this approach tests to find COVID-positive individuals not only pre-pandemic, but all the way through the pandemic; second, this approach tests all contacts (including asymptomatic contacts), rather than simply quarantining them; and third, even during periods of social distancing, this approach tests to maintain the pandemic resilience of critical sectors that must remain at work and then gradually expands the testing program to encompass more of the population.

More specifically, an effective strategy of **pandemic resilience** requires a number of key elements.

- Testing innovation
- A national Pandemic Testing Board to oversee supply and distribution
- Scalable manual contact tracing and warning methods
- Peer-to-peer warning-sharing apps
- Testing status certificate or card-reading equipment

- An expanded paid U.S. Public Health Service Corps and/or Medical or Health Reserves Corps (based on volunteer enrollment, not conscription)
- Disease monitoring infrastructure
- · A cross-jurisdictional consensus plan for phased sectoral mobilization
- Federal- and state-level pandemic testing guidance, and tribal and local government administration of pandemic testing, all in accord with due process, civil liberties, equal protection, non-discrimination, and privacy standards
- Readiness frameworks to support local health leaders, mayors, tribal leaders, and other public officials in establishing test administration processes and isolation support resources, as well as innovative cross-jurisdictional organizational structures, especially linking cities, counties, and health districts, with specifics varying from state to state.

TESTS

Massive testing is essential because it is more finely targeted—more of a precision device than a blunt instrument. Rather than giving an entire city a stay-at-home order of indefinite duration, only those who are infected would need to stay at home or in a medical facility, and only for the specific amount of time required by the course of the disease. This achieves the proportionality of response and clear time bounds that are among the basic criteria of appropriate use of quarantine authorities.

The policy of massively scaled up testing for pandemic resilience uses tests not for purposes of disease surveillance (general monitoring of the spread of the disease) but to connect COVID-positive individuals to treatment and/or isolation with support and to suppress the disease. Massively scaled up testing robust enough to control the disease requires either a targeted isolation approach to testing or a universal testing approach. In the targeted isolation approach, which we recommend as the first priority strategy, the numbers of tests needed range from 2 to 6% of the population per day or approximately 5 to 20 million people per day. This would have to be coupled with careful monitoring of rates of transmission and prevalence. If TTSI interventions at this level do not succeed, and we have not developed capacity to test broadly and at much higher levels in work and school community settings (e.g., 30 to 100 million a day), we would need to revert to collective social distancing.

Testing programs would use both PCR tests (polymerase chain reaction tests that identify genetic material) to identify the presence of the virus itself and serological tests to identify the presence of antibodies to the virus in a patient. The point of the latter is typically to assess disease prevalence and/or immunity after infection. Because research is still uncertain about what percentage of the U.S. population has already been infected, the durability of any immunity conferred by antibodies, and the rate of asymptomatic carriers, it is too early to say how the balance will shift over time between the two testing methodologies. For now, we should presume that we will need to deploy PCR testing broadly.

In addition, testing to determine who needs to be isolated also allows public authorities to say who can safely move about. Those who have tested negative within a very recent window and those who show immunity in reliable antibody tests (assuming these prove feasible) should be free to return to work. **Certificates of immunity should be used only in contexts where people have equal access to PCR testing and where a recent negative test result on a PCR test provides the same access to mobility as immunity. Any other use of immunity certificates would be likely to violate constitutional equal protection requirements.**

Achieving a testing program at this scale requires supply-chain management and production capacity to deliver 5 to 20 millions of tests per day; distribution capacity to get these millions of tests to last-mile delivery personnel at

the local level; and test administration personnel—a combination of local health care workers and service corps members, reinforced by state and national service corps (including entities like the Medical Reserves, U.S. Public Health Service Corps, and National Guard and, during the period of the emergency, AmeriCorps and Service Year Alliance). These service corps would need to be expanded.

Massively scaling up testing itself will require (1) coordinating the ramp-up of existing capacity for test production and analysis; (2) integrating the ramp-up of innovation-based capacity; and (3) building the supporting infrastructure.

There are two possible forward pathways to increase the number of tests and the speed of analysis. We can seek to **scale-up existing** test production, distribution, sample collection, and analysis methods, or we can simplify the methodologies through innovation and **build even greater scale through process simplification**. Probably we need both. We need to maximize what we can already do while innovating to do much more. Please see appendix B for more details.

The economy is hemorrhaging \$100 billion to \$350 billion a month. Given the substantial benefits to increased capacity in testing, better treatments, and vaccines, the government should not hesitate to pay substantial sums to incentivize the private sector to apply ingenuity and speed to develop solutions. Prizes and advance market commitments are two tools to be considered.

PANDEMIC TESTING BOARD

Implementation of such a complex supply chain at this speed requires tight coordination most naturally facilitated by a Pandemic Testing Board (PTB), akin to the War Production Board that the United States created in World War II. The market has not so far supplied the necessary scale of test production. The basic problem is a classic one of coordination and planning that almost always afflicts complicated supply chains that need to be set up rapidly. Almost every link in the testing architecture from the final mile in cities and states back through the laboratories that process tests, the machine manufacturers, the factories producing RNA reagents, etc. report almost an identical story. All fault the other links in the chain for either lacking the relevant supply or demand to scale up, and all argue that what they have heard from others is that further supply is impossible or further demand is not forthcoming. Technologists argue that there is little point in producing tools for contact tracing given the lack of testing capacity, while test producers claim no one will want tests. All report that messages from the national government and public health community indicate that levels of testing only slightly above those at present (in the hundreds of thousands per day) will be sufficient to satisfy national goals and that, in this sense, "the testing phase of the pandemic is coming to a close."

Such systemic finger-pointing, lack of common understanding, and disintegration are the classic hallmarks of the coordination failures that occur in complex, interdependent systems that need to rapidly change to serve a new demand. In virtually every successful historical example of such rapid coordination, a central authority has set goals and ensured that each part of the chain meets the interlocking goals required for the chain to succeed. This authority must have clarity on the levels in the supply chain and the kinds of output required at each level to reach desired targets and must induce all parts of the chain to act in conformity with this plan, to avoid failure in one part that would sow systemic distrust. This complex interconnecting system can be removed from many other parts of the mobilization, such as vaccinations, the supply of treatments and treatment equipment to hospitals, etc. This is in fact desirable as it allows great scope for innovation and experimentation. Only the parts that must be tightly coupled to achieve confidence need be managed by the same central authority, and such centralized management will be necessary only for the length of the crisis, as in wartime.

The Pandemic Testing Board would consist of leaders from business, government, academia, and labor and would be tasked with two projects: (1) a Pandemic Testing Supply Initiative; and (2) a Pandemic Testing Deployment Initiative. See Appendix A for a full description.

MANUAL CONTACT TRACING PROGRAMS

The Johns Hopkins Center for Health Security recently sketched the components of a scaled-up TTSI program. As they put it, "contact tracing approaches will need to be adapted to jurisdictions based on existing public health infrastructure" (Watson et al. 2020, p. 12). Scaling up should be managed by "state and territorial public health departments" and "local and tribal health departments should be involved to coordinate contact tracing activities in their jurisdictions." Pointing to the importance of something like a "fusion cell" model for information sharing and decision support for leaders, they write, "Incorporation of mayors, community leaders, and faith leaders into planning and discussions will maximize the ability of jurisdictions to successfully support contact tracing at the community level." The goal is a "multi-agency and multi-sectoral coordinated approach." With the goal of tracing every diagnosed case of COVID-19 in the U.S., and basing their estimates of the workforce needed on contact tracing programs for COVID-19 in other countries, the JHU team recommends that we "at least start by adding an extra 100,000 contact tracers across the United States." These contact tracers would move among hot spots.

PEER-TO-PEER WARNING SHARING APPS

In addition to using manual contact tracing and warning to identify candidates for diagnostic tests, it may also be possible to use Bluetooth and/or GPS-based opt-in and adequately privacy-protecting app-based tools that permit peer-to-peer warnings to supplement manual contact tracing programs. When an app user tests positive for the virus and the medical record officer at the testing agency reports that to the app, all app users who have recently traveled through the same spaces as the COVID-19-positive individual receive an alert on their phone and a recommendation to be tested. Those who receive positive tests are connected to treatment and/or advised to isolate, with social supports in place to incentivize them to do so. In some contexts, those social supports will need to be significant. The impact of the disease has exposed race-ethnic and socioeconomic inequities in the U.S. that specifically point to where deeper investment in health resources is necessary for collective success in beating the disease. Other countries have created publicly funded spaces in support of quarantine and isolation. Apps and accompanying support policies have recently been used to great effect in Taiwan and are being proposed for adoption in several European countries.

Optimally more than 70% of the population would have these applications installed, although lower penetration could also be combined with other contact tracing interventions. One study estimates that 40% would be the minimum penetration required for the app to provide effective contact warning, while another study indicates 60 to 80% would be the minimum penetration required to be broadly effective. In the U.S., <u>96% of Americans (excluding undocumented immigrants) own a cellphone of some kind and 81% own smartphones</u>, according to Pew Research, though not all are capable of running such technology. Minimally viable WiFi-equipped cell phones or Bluetooth dongles should be made available through Medicare and Medicaid for those without phones who choose to opt into the use of such programs.

At the time of writing, Apple and Google have announced a joint initiative to enable peer to peer contact tracing apps with privacy protections and a plan for scaling to a large fraction of the population very quickly. Several

significant uncertainties remain, including successful integration with public health tracing, wide-scale adoption, and confirmation that Bluetooth proximity is sufficiently reliable. We believe a clear oversight regime must be developed for the design and deployment of this technology. With such a regime in place, we believe this initiative could deliver impactful results.

CERTIFICATE OR CARD READING EQUIPMENT

Testing programs—whether sectoral or universal—will need to provide those who are tested with a medical records ID card that would be readable by employers, schools, and social service agencies. For those opting into app-based peer-to-peer contact warning programs, they might also carry the relevant medical records certificate on their phone. Please see Appendix C for a preliminary sketch of how a universal testing program might work at the local level and how such ID card certification could operate.

EXPANSION OF THE U.S. PUBLIC HEALTH SERVICE CORPS AND MEDICAL RESERVE INTO A BROADER HEALTH RESERVES CORPS

Using customized online education modules, it is possible to upskill nurse's aides, physician's assistants, and other paramedical positions to expand the number of frontline health workers able to expand testing and to work with COVID-positive patients and their families and friends. In addition, for contact tracing personnel, a high-school level education and just-in-time training and management can suffice. A corps of community health workers, an approach used in countries around the world, can help build the trust necessary in some communities to expand testing. (Partners in Health is currently using this approach in Massachusetts.) The Department of Health and Human Services Medical Reserves Corps and the U.S. Public Health Service Corps should be expanded into a broader Health Reserves Corps and parallel state-level Health Reserves Corps should be established in conjunction with each state's National Guard. These corps can also support contact tracing.

DISEASE MONITORING INFRASTRUCTURE

One of the core responsibilities of the public health profession is monitoring the emergence and spread of infectious disease. This work has historically been called "disease surveillance." Currently, within the federal government, the CDC is responsible for disease surveillance. For instance, the CDC runs a data system called ILINet to track influenza patterns each year via flu tests. In the case of COVID-19 too, testing data will help inform disease monitoring. Monitoring would be used to indicate if there is a need to shift from testing using the targeted isolation approach to universal testing in anticipation of a potential surge. Such monitoring would also be necessary to determine whether hot spots are emerging that require a return to collective social distancing and/or internal travel restrictions between jurisdictions.

As proposed in the AEI Roadmap to Reopening and reaffirmed in the Duke Margolis Report, we should establish a National Infectious Disease Forecasting Center, and aim for the standards of disease surveillance set by Singapore, though such longer-term efforts should not distract existing agencies from focusing on the immediate threat.

SECTORAL PHASING

As we discuss when and how to reopen the economy, we miss a fundamental point—40% of the economy is already open. According to the Department of Homeland Security, approximately 40% of the U.S. workforce is currently in essential services. Unfortunately, however, this essential workforce has not been equipped with the resources needed for pandemic resilience. As a result, doctors and nurses have fallen ill, and 17% of the New York Police force is sick or quarantined. This highlights the importance of focusing our aspirations not on "opening" the economy but on mobilizing a pandemic-resilient economy. This entails achieving pandemic resilience for the portion of the economy that is already open, and then phasing in additional sectors of the economy in sync with our capacity to provide pandemic resilience to each sector.

While critical sectors are increasingly endeavoring to maintain the highest possible hygiene standards, until we can broadly and rigorously test, trace and warn, and provide supported isolation within the population of critical workers, there are fundamental limits to the success of collective social distancing efforts, as they cannot be applied in these sectors. Our first priority for a massively scaled up pandemic testing program should be to stabilize the essential workforce, and also develop a reserve corps who fill in for essential workers who test positive for COVID-19 and require treatment and/or isolation. In addition, it will be important to address risks to workers due to comorbid conditions and age and to determine protocols for offering job protection and/or unemployment insurance when people cannot safely redeploy. For sectors with high exposure to the virus, it may make sense to consider setting up alternative accommodations so they don't risk bringing COVID-19 home.

Rather than expecting that reopening would proceed in the first instance on a region-by-region basis, we should expect it to proceed sector by sector and in tandem with growth in a capacity to test, trace and warn, and provide supported isolation. Depending on the situational context, however, some areas/populations may progress through the phases more rapidly and others more slowly, while still following the overall model of sectoral mobilization and reopening. See section 3 for details.

FEDERAL- AND STATE-LEVEL PANDEMIC TESTING GUIDANCE, AND TRIBAL AND LOCAL GOVERNMENT ADMINISTRATION OF PANDEMIC TESTING

The initiation of testing programs should depend on guidance from federal and state governments linked to declarations of a public health emergency. Federal health agencies should disseminate guidance on the prevalence levels at which either the targeted isolation or the universal testing approach should be used. The Model State Emergency Health Powers Act should be updated as needed to incorporate guidance for the design of massively scaled up testing programs that adhere to robust data privacy standards, civil liberties protections, and due process and equal protection guarantees.

PANDEMIC RESPONSE FUSION CELLS

The U.S. public health system is massive, fragmented, and diverse. State public health agencies work with tribal, county, metropolitan, and municipal health agencies as well as, in some cases, with regional health collaborations.

Federal public health agencies also work with all of the above as well as with tribal health agencies. In the context of an event such as a pandemic, state and federal health agencies also work in coordination with state and federal emergency management agencies. Importantly, the federal agencies both work in support of and through states, and also work directly with affected populations, particularly under-resourced communities.

Success in activating all tiers depends on distributed organizational structures that support successful flows of information both vertically and horizontally as well as cross-agency, co-development of "decision support for government leaders at a local, metropolitan, region or state-level" (Fussell, Keister, and Pellegrini 2020). An organizational form known as a "fusion cell" that was used by U.S. Special Operations as led by General Stanley McChrystal in the fight against the networked threat of al Qaeda in Iraq may provide an illustrative model for interagency/intergovernmental coordination. See Appendix C for further detail.

In summary, all the elements described above are available to us and could be combined into an infrastructure for pandemic resilience that would hasten the deceleration of this current pandemic wave, support sector-by-sector phased mobilization of a pandemic resilient economy, reconnect people to opportunity, maintain control over the spread of the virus once this wave is over, and avoid resurgence. We need to add massively scaled up TTSI programs to our national toolkit for pandemic response.

SECTORAL Phasing

As analyzed by the CDC and Department of Health and Human Services in the Pandemic Intervals Framework, pandemics have six intervals: (1) investigation of novel viruses; (2) recognition of increased possibility of transmission; (3) initiation of a pandemic through easy transmission; (4) acceleration; (5) deceleration; and finally, (6) preparation for future waves, as the virus acquires a seasonality. See Figure 1.

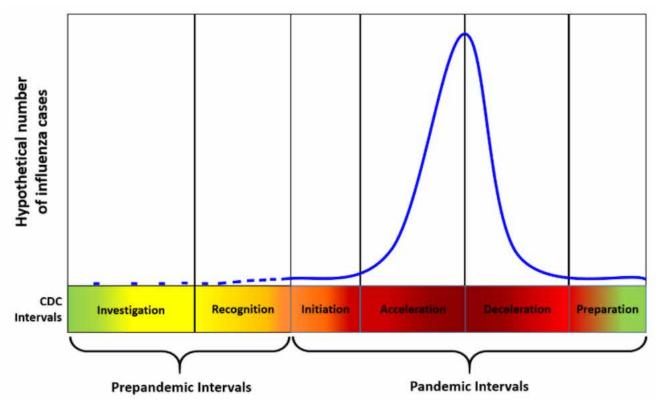


FIGURE 1. PREPAREDNESS AND RESPONSE FRAMEWORK FOR NOVEL INFLUENZA A VIRUS PANDEMICS: CDC INTERVALS

Content source: Figure 1 from <u>Pandemic Intervals Framework (PIF)</u>, <u>Centers for Disease Control and Prevention</u>, <u>National Center for Immunization and</u> <u>Respiratory Diseases (NCIRD)</u>

In the current COVID-19 pandemic, the United States is currently in the acceleration interval and stay-at-home orders and advisories are aimed at decelerating the pandemic or "flattening the curve." The transition from acceleration to deceleration is defined by success at reducing the reproduction number (the average number of secondary cases each case generates) to a non-exponential level (from R>1 to R<1). Recognizing where we currently are on the Pandemic

Intervals Framework, our roadmap lays out four phases for making the transition from the acceleration to the deceleration period.

Most of the very limited testing capacity available today is being used therapeutically (to ensure correct diagnosis for treatment) or in an unprioritized manner based on private willingness and ability to pay. Once we have enough testing capacity for all therapeutic purposes, our strategy would prioritize testing to systematically allow the phased reopening of the economy as outlined below.

The focus here is on stabilizing and gradually expanding essential sectors of the economy (mobilization) in addition to reopening the economy that existed prior to the crisis. The pre-existing economy was not pandemic resilient. The country's existing infrastructure of pandemic readiness was too exclusively focused on responding to influenza viruses. We need to widen the lens and achieve not only readiness but resilience—the capacity to keep the economy open while living through a pandemic. This will entail significant investment in the infrastructure of pandemic resilience during the course of this pandemic. The goal should be to ensure that by the end of a process of investment and infrastructure build-out, our economy, and the global economy too, no longer have the vulnerability to pandemic shocks that we had at the end of 2019. Just as the lesson of the 2008 financial crisis was that we needed to build financial stability into the global economy, the lesson of this pandemic is that we need to build pandemic resilience into the ongoing and sustainable structure of the global economy.

Consequently, in addition to reopening, our goal should be to mobilize a pandemic-resilient economy. This approach reallocates economic activity to where it is most required and prioritizes economic activity in the near-term period of pandemic response based on public health needs just as in wartime, economic prioritizations follow the needs for wartime mobilization, including ensuring economic stability on the home front.

This plan assumes that approximately 40% of the workforce is currently in essential roles, 15% are needed to fill shortages in essential roles, 15% are in expanded definitions of essential roles, 10% are in none of these categories but cannot productively work from home, and 20% can productively work from home. Most of the qualitative features of this plan should follow even if these numbers are somewhat off. Furthermore, while we discuss these phases as distinct in what follows, the transitions will not be abrupt and they build on each other continuously. As such the Pandemic Resilience strategy gradually incorporates more and more workers into a steady-state testing and certification regime, and thus allows ever more workers to return to work safely.

In general, the timeline and sectoral percentage numbers provided below are intended to be illustrative, not determinative. Depending on the situational context, some areas/populations may be able to progress through the phases more rapidly, and others more slowly, while still following the overall model of sectoral mobilization and reopening.

We recommend four phases: (1) stabilize essential sectors; (2) expand essential workforce; (3) end economic misery from collective stay-at-home orders; and (4) reopen most activity and stay open. Throughout all four phases, research and development of both therapeutics and vaccines should proceed aggressively with the goal of accelerating the transition to phase 4 and hopscotching over the intermediate phases.

We estimate that the economy has the capacity to reach Phase 4 by early August if fully mobilized in this direction.

PHASE 1: STABILIZE ESSENTIAL SECTORS WHILE COLLECTIVE SOCIAL DISTANCING IS IN FORCE

Approximately 40% of the U.S. workforce is in essential services, according to the Department of Homeland Security. Currently we do not have sufficient capacity to test this workforce at levels that ensure that the virus is not propagating out of control within it. While essential sectors are increasingly endeavoring to maintain the highest possible hygiene standards, until we can effectively test within the population of essential workers, there are fundamental limits to the effectiveness of collective social distancing efforts, as they cannot be applied in these sectors.

Therefore, any application of large-scale testing infrastructure must first aim to test essential workers with increasing frequency, beginning with the sectors that carry the largest risk of disease spread because they involve close contact with vulnerable populations (especially medical, testing, and care work), then spreading to sectors with extensive contact with less vulnerable populations (such as delivery work), essential labor-intensive production work, and eventually to the entire essential care workforce.

Given how large this population is, once we have a testing regime in place that is capable of controlling the disease within this population, we will be much of the way to a regime that can control it within the entire population.

This means that this initial stage is an essential dry run for the phases that come afterwards. We break this phase down further:

1. IDENTIFY, TREAT, AND SUPPORT ISOLATION FOR INFECTED MEMBERS OF THE ESSENTIAL WORKFORCE

WITH SUPPORTS. First, we must aim to find essential workers currently at work who may be spreading the disease. Particularly high priority should be given to essential workers in medical and care work for vulnerable populations. Employment protections should be part of this program so that the need to seek treatment or isolate does not result in job loss. In addition, because so much care work is performed by vulnerable groups, the programs of isolation and treatment must be supported with public investment to ensure employment protection and basic economic security. Further supports for isolation can include telehealth resources, care packages, grocery and food deliveries, and access to free entertainment resources. These sorts of supports can and should be organized at the local level by mayors, county health officials, and tribal governments.

In addition, it will be important for public health reasons that the testing regimes not exclude any population of Americans, including the undocumented population. They too need to be safely included or the net we build to catch the disease will have too many gaps and vulnerabilities.

2. SIMULTANEOUSLY RETRAIN NONESSENTIAL WORKERS TO TEMPORARILY REPLACE COVID-POSITIVE MEMBERS OF THE ESSENTIAL WORKFORCE DURING THE PERIOD OF THEIR TREATMENT AND/OR

ISOLATION. Phase 1 relies heavily on simultaneous recruitment and training (discussed above and below) of substitute temporary workers currently unable to work in their jobs outside the essential sectors, and moving them into paid roles in the essential sector. Such retrained workers can temporarily take the place of essential workers who must be isolated and also develop the capacity to serve in an ongoing way in a paid Health Reserves Corps (based on volunteer enrollment, not conscription) that would exist permanently beyond the crisis to provide surge capacity for the health system.

This substitution process will typically happen in an indirect fashion, where substitute workers move into

low-skill tasks within essential sectors, allowing more experienced workers to move up to temporarily fill roles vacated by those isolated. This stage also begins to provide critical intelligence to epidemiologists and policymakers about the prevalence rate of the disease within the essential workforce, which is probably the segment with greatest prevalence at present. This intelligence is a crucial input into all other aspects of planning, such as medical infrastructure and especially the scale of testing likely to be required in later stages. Intelligence will also be gained about immune responses, false negative rates of tests, the size of asymptomatic populations, etc.

3. **CONTROL THE DISEASE WITHIN THE ESSENTIAL WORKFORCE.** As testing scales further, we can move from a primary aim of *identifying, isolating, and temporarily replacing sick* workers from the essential worker population to *controlling the disease* within this population. Controlling the disease within the population requires us to institute an effective disease control program for this population. All such programs involve massive, regular testing and the provision of those tested either with instructions to isolate or with test status certificates they may use to prove to others they had a recent negative test.

With strong investment in community-driven manual contact tracing or high adoption of peer-to-peer warning systems, it should be possible to control the spread with a number of tests per day equal to roughly 20 times the number infected. For example, if within the 40% of workers who are essential workers, there is a prevalence rate of one in a thousand, we should be able to fully stabilize the population with *very strong warning techniques* once we can test 2 million people per day.

The importance of building successful tracing and warning programs cannot be overstated. If warning is understaffed, has limited take up, or runs into technical difficulties, the alternatives would be reversion to collective social distancing again or fully random testing, whose requirements are generally independent of prevalence and require testing the entire population randomly about twice a week, requiring 36 million tests per day. While we argue that this country should elevate its ambitions to achieving the capacity to deliver tests at this level for emergency circumstances, achieving such capacity in the very near term is a stretch goal, something like FDR's call to the nation to turn out 50,000 planes a year.

4. **INCLUDE THE VULNERABLE.** Simultaneous to these efforts to build sustainable testing, tracing-and-warning, and supported isolation programs for the essential workforce, we should also do the same for nursing home populations, incarcerated populations, and unhoused and housing-insecure populations. Members of these populations are in frequent contact with members of the essential workforce and consequently should be integrated into this first stage of developing a massively scaled up testing program. They have also all been left distinctively exposed in the early phases of our collective pandemic response.

5. EXPERIMENT WITH STEADY-STATE TESTING AND TRACING PROTOCOLS AND CERTIFICATION

INFRASTRUCTURE. It will be crucial to learn as much as possible during this phase, through rigorous experimentation, to figure out how effective manual tracing and tech-based peer-to-peer warning regimes will be in practice. This in turn will affect planning for the other phases. In addition to experimenting with the testing capacity and protocols required to stabilize this population, it will be crucial to experiment with certification procedures that could also be scaled to the entire population. Through this process, we will learn how many people take up contact tracing applications, which certification protocols seem to be socially acceptable, and how prevalent the disease is in the broader population.

6. **IMPROVE STANDARDS OF INFECTION CONTROL.** Workplaces will need to achieve new standards of hygiene and infection control. "A myriad of approaches, systematized by the Occupational Safety and Health

Administration and specific to each business sector, could contribute to suppressing the risk of spread. Resumption of economic activity does not mean doing things the same way as before the time of coronavirus" (Fineberg 2020).

PHASE 2: EXPAND ESSENTIAL WORKFORCE AND BEGIN Relaxation of collective social distancing orders

By the time Phase 1 is complete, the essential workforce, which comprises about 40% of the population, will be stably back at work with effective testing and disease-control measures in place. They will be the foundation for a pandemic-resilient economy. The next phase, Phase 2, builds on Phase 1 to swiftly expand the set of people who are in the essential sectors and incorporate them into the rigorous testing and certification programs. Phase 2 will involve the expansion of the workforce in place from 40% to 70% of the population, thereby expanding the workforce by 75%. This will proceed through three channels.

- ADDRESS CONTINUED SHORTAGES IN THE ESSENTIAL SECTOR. First, as mentioned in Phase 1.3 above, stabilizing the essential workforce will require retraining those currently working in nonessential sectors, ideally through an expanded Health Reserves Corps, to reinforce those in essential sectors who must isolate. In addition, many workers will be retrained to meet expansions that address the shortages in the medical, care, delivery, test and medical production, medical research, and other sectors that are expanding beyond their present capacity during the crisis. These demands will expand the essential workforce.
- 2. EXPAND DEFINITION OF "ESSENTIAL" WORKERS. The definition of "essential workers" varies widely in different jurisdictions. In Phase 2, we will gradually expand the definition to include more and more workers. While Phase 1 returns short-term essential workers to work, Phase 2 focuses on returning medium- and long-term essential workers to work (e.g., maintenance and construction of essential facilities, research and development to support these, etc.). This expansion of the definition will add another 15% of workers to the workforce. They will be incorporated in the same kinds of testing programs established for the short-term essential workforce.
- 3. MODIFY SOME SOCIAL DISTANCING PRACTICES. With somewhere between 55 and 70% of the workforce now mobilized and integrated into testing programs that provide pandemic resilience, it will be possible to relax many of the most extreme social distancing measures. Milder, less intrusive ones would remain in place. For example, limits on public gatherings of larger sizes will remain. Public transport will need to be modified and rethought, following the lead of Singapore where more subway and bus vehicles are deployed along common routes to decrease the number of people in each vehicle and density restrictions are enforced using a combination of physical barriers and point-of-entry metering. The labor needs required to support these changed practices will pull additional people into the essential workforce of a pandemic resilient economy.

PHASE 3: END ECONOMIC MISERY FROM COLLECTIVE STAY-AT-HOME ORDERS

Phase 3 is a very simple expansion of Phase 2. Once Phase 2 is complete, about 70% of the workforce will be at work in sectors deemed essential in the short, medium, and long term. There will be a testing and certification protocol in

place, and the most extreme social distancing measures will be relaxed for those with required testing certification, while the most reasonable ones will be kept in place. Phase 3 concerns the re-entry of the 10% of workers who cannot productively work from home who have not re-entered the workforce by the end of Phase 2, and are therefore currently facing economic hardship. These workers are those in manufacturing of nonessential items, personal services, and so on. In addition, this phase concerns the integration into testing programs of vulnerable populations not participating in the formal economy, for instance those with felony convictions, undocumented immigrants, and individuals receiving public benefits.

- 1. MOBILIZE ANOTHER 10% OF WORKERS TO NONESSENTIAL SECTORS. Just as the expansion of the workforce occurred in Phase 2, we will continue the expansion of the workforce to include more workers in nonessential sectors in Phase 3. This phase will involve gradually extending testing and certification procedures to more workers via employer-based programs (see Appendix B). The primary condition for return to the workforce will shift in this stage, as all essential and extended-essential workers will already be in the workforce. Now the primary criterion will shift to economic need, that is, the workers for whom the inability to work is creating the greatest hardship will be enabled to return to work in sync with the expansion of testing capacity.
- 2. RECRUIT TRUSTED COMMUNITY ORGANIZATIONS AND SOCIAL SERVICE AGENCIES TO ADMINISTER TESTING PROGRAMS FOR SPECIFIC COMMUNITIES OF NEED. Local testing and contact tracing-and-warning programs have long been in existence, particularly in relation to HIV, tuberculosis, measles, and syphilis. A particularly good example is the program based in each of New York's boroughs. Grouped under the title New York Knows, these programs involve community organizations as partners in recruiting people to be tested and in conducting contact tracing subsequent to positive tests. They have set the goal of ensuring that every borough resident has an HIV test. Community organizations and/or social agencies that are trusted by the populations they serve can build and administer testing programs that restore mobility and opportunity to members of vulnerable populations in ways that are successfully attentive to issues of justice, civil rights, and wellness.
- 3. **TEMPORARILY RELAX REGULATIONS TO ALLOW FOR NECESSARY MODIFICATIONS TO NONESSENTIAL SECTORS.** Regulations must be relaxed so that these workers can modify their business practices to serve clients who may remain under shelter-at-home measures, e.g., through expansions of delivery or at-home services.

As Phase 3 is an extension of Phase 2, it should not take too long, perhaps as little as a few weeks.

PHASE 4: FULLY MOBILIZE THE PANDEMIC RESILIENT ECONOMY

Following Phases 1 through 3, a total of about 80% of workers will have been mobilized in a newly pandemicresilient economy. Also, vulnerable populations will have been included in the mobilization. Their ability to come and go safely will have been stabilized through rigorous testing and certification programs, as well as changed business practices pertaining to hygiene, sanitation, and de-densification. The next stage involves the return of the 20% of the population whom the Labor Department estimates can work from home without too much loss of productivity, including most white-collar workers. These workers drive a large amount of consumption that maintains demand in the nonessential sectors addressed in Phase 3. In addition, we should seek to minimize the amount of time that any sector, including this sector, has to endure the infringement of civil liberties occasioned by collective stay-at-home orders.

- 1. RETURN 20% OF AT-HOME WORKERS TO WORK. Swiftly incorporate at-home workers into testing and certification regimes, allowing them to return to normal social lives. Since these workers do not face too much of a productivity shock, this phase can itself be phased, for example by having workers return to their physical offices a few days a week (after taking a test) and then have to take the rest of the week at home, and then gradually expanding that to five days a week and weekends.
- 2. REOPEN SCHOOLS. Swiftly incorporate teachers and students into testing and certification regimes, allowing them to return to normal social lives.

In Phases 1 through 3, it is essential that all tests are rationed and freely available, and are not allocated through anything that resembles a price mechanism. In Phase 4, however, many in this 20% of the population are supported by private insurance, and tests should be funded by private insurance pools. The funds raised in this manner can be used to support the public infrastructure.

CONTINUOUS WITH PHASES 1 THROUGH 4: AGGRESSIVE RESEARCH AND DEVELOPMENT

Phase 1 should begin as soon as we have the testing capacity in place to deliver a TTSI program for the 40% of the workforce that is not participating in collective social distancing. Subsequently, the triggers for moving from Phase 1 to Phase 2, from Phase 2 to Phase 3, and from Phase 3 to Phase 4 are: (1) affirmative assessment of a declining case rate; (2) affirmative assessment that hospital capacity is sufficient to meet the disease burden in the community; and (3) affirmative assessment that testing capacity is sufficient to meet the testing requirements of the phase.

Throughout all four phases, research and development of both therapeutics and vaccines should proceed aggressively with the goal of accelerating the transition to Phase 4 and hopscotching over the intermediate phases.

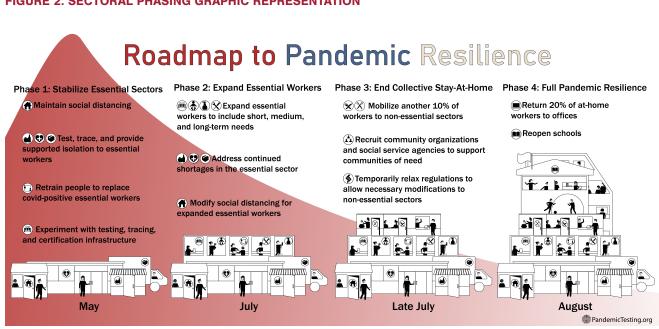


FIGURE 2. SECTORAL PHASING GRAPHIC REPRESENTATION

ROADMAP TO PANDEMIC RESILENCE

PHASE 1: SLOW THE SPREAD, BUILD PANDEMIC RESILIENCE, AND MOBILIZE ESSENTIAL WORKERS SAFELY

Should begin now; should take about two months.

Slow the transmission of COVID-19 across the U.S. by reducing the effective reproduction number of infections through social distancing and broad testing and contact tracing.

- Ensure the health care system has the capacity to safely treat both COVID-19 patients and others requiring care.
- 2. Establish a Pandemic Testing Board and National Director of Testing Supply.
- Increase testing capacity to 2 million PCR tests a day to accommodate the ability to test: (1) everyone with symptoms and their close contacts; (2) those in the essential workforce; (3) nursing home populations; and (4) incarcerated populations.
- 4. Increase the production of personal-protective equipment to mobilize a pandemic resilient essential workforce.

- Scale up the national- and state-level health reserves, integrate into testing programs, train, and deploy to reinforce essential workers.
- Successfully integrate 40 to 55% of the workforce into a pandemic resilient economy with testing programs; reconfigure workplaces for hygiene and sanitation (e.g., Local Infection Control).
- 7. Accelerate the production of therapeutics and vaccines.

PHASE 2: EXPAND ESSENTIAL WORKFORCE AND BEGIN RELAXATION OF COLLECTIVE SOCIAL DISTANCING ORDERS

Begins when a testing program for the essential workforce is successfully and stably in place, case rates are declining, and public health capacity is sufficient to meet need; should take about a month.

- Integrate mid- and long-term essential workers (e.g., maintenance and construction) into the pandemic-resilient economy, thereby achieving integration of approximately 70% of the workforce.
- 2. End universal stay-at-home orders, preserving them only for those sectors that can telecommute without economic cost.
- Maintain milder, less-intrusive social distancing orders; for example, limits on public gatherings of larger sizes will remain. Public transport will need to be modified and rethought.
- Establish a culture of universal mask wearing in "hotspot" areas during outbreaks, and increased standards of hygiene and decontamination.

- For older adults (those over 60 years old), those with underlying health conditions, and other populations at heightened risk from COVID-19, it should still be recommended that they limit time in the community.
- 6. Identify and mitigate new hot spots at their earliest point of emergence.
- 7. Continue the work of accelerating the production of therapeutics and vaccines.

ROADMAP TO PANDEMIC RESILENCE

PHASE 3: END ECONOMIC MISERY FROM COLLECTIVE STAY-AT-HOME ORDERS

Begins when the testing supply has grown to sufficient scale to support 80% of the workforce within localities, case rates are still declining, and public health capacity continues to be sufficient to meet need; should take 1 to 2 weeks.

- Integrate nonessential workers who cannot telecommute into the pandemic-resilient economy, bringing the workforce integration level to 80%.
- Establish community organization and social service agency-based testing programs to integrate vulnerable populations into a pandemic resilient economy.
- Temporarily relax regulations to permit experimentation with new business practices in the nonessential sector.
- 4. Establish a National Infectious Disease Forecasting Center.
- 5. Address governance vulnerabilities.

PHASE 4: FULLY MOBILIZE THE PANDEMIC-RESILIENT ECONOMY & STAY OPEN

Begins when the testing supply has grown to sufficient scale to support 100% of the workforce, case rates are still declining, and public health capacity continues to be sufficient to meet need.

- Integrate remaining nonessential workers into the pandemic-resilient economy, bringing the workforce integration level to 100%.
- Activate private insurance to fund testing for this remaining cohort of workers (all testing in Phases 1 through 3 should be funded through public investment).
- Integrate students into testing programs and reopen schools.
- Monitor disease rates in order to be able to increase rates of testing if needed and/or reestablish collective stay-at-home orders.

JURISDICTIONAL RESPONSIBILITIES

Pandemic resilience depends on converting the flexible, modularized nature of our federal system into an asset. Success requires activation at all levels of the federal system.

THE FEDERAL GOVERNMENT SHOULD:

- 1. Provide surge capacity in support of health infrastructure.
- 2. Establish a Pandemic Testing Board to organize the testing supply chain and invest in testing innovation.
- 3. Continue to provide scientific and policy guidance to states from the Department of Health and Human Services and CDC, supported by the National Academy of Sciences.
- 4. Modernize national disease surveillance, for monitoring disease outbreaks and trajectories.
- 5. Maintain liquidity and fiscal viability in the system as a whole.

STATE GOVERNMENTS SHOULD:

- 1. Activate state and national public health infrastructure surge capacity.
- 2. Establish design principles for tribal and local government administration of social distancing, travel restriction, and pandemic-testing programs, based on updated model state public health emergency legislation and fully integrating alignment with public health standards, equal protection standards, due process, non-discrimination standards, civil liberties, privacy protections, and labor protection standards.
- 3. Ensure access to personnel and supply resources for all counties to administer testing programs to target levels.
- 4. Provide free access to testing and subsequently necessary medical treatment for COVID-positive individuals for the first 80% of workers reintegrated into the economy; work with insurers to provide access for the final 20%.

TRIBAL AUTHORITIES AND COUNTY, METROPOLITAN, MUNICIPAL, AND REGIONAL AUTHORITIES SHOULD:

- 1. Deploy public health surge capacity to support treatment of the ill and provide support to the isolated.
- 2. Design and administer pandemic testing programs (TTSI) for their communities in accordance with state frameworks.
- 3. Via public health and clinical laboratories, collect and report up to state and federal governments pandemic relevant data in support of ongoing disease surveillance.

For more detail on these responsibilities, how they interact, and what the incentive structures are that would support their operation, please see Edmond J. Safra Center COVID-19 Rapid Response Whitepaper #8, "Federalism Is an Asset."

DOMAIN	TRIBAL/LOCAL	STATE	FEDERAL
Disease Surveillance and Epidemiology	Support upwards reporting of data.	 Surveillance and epidemiology. Coordinate localities to ensure they have local solution on testing delivery. Ensure universal access to a Wi-Fi-enabled rudimentary smartphone as necessary health tool (via Medicaid). Maintain individual case confirmation standard and contact tracing and warning throughout. 	 Define standards for testing. Advise testing for asymptomatic as well as symptomatic. Ensure supply chain for production of sufficient number of tests. Ensure alignment of all executive branch agencies with the chosen testing level approach (broad, targeted, or universal) Ensure alignment of all state governments with the testing approach (broad, targeted, or universal). Monitor for changes in epidemiology. Maintain enhanced surveillance. When appropriate, transition surveillance to severe disease and syndromic surveillance.
Laboratory	Ensure local test administration has capacity to successfully transfer hazardous waste testing samples to laboratory.	 Provide laboratory confirmation of all cases. Implement revised specimen submission protocol per CDC guidance as appropriate. 	 Continue monitoring virus characteristics to identify changes in virulence, transmission, or antiviral resistance markers. Transition to virologic testing of a sample of viruses submitted from states. Distribute to state public health laboratories recommendations that outline revised specimen submission protocol as needed.

DOMAIN	TRIBAL/LOCAL	STATE	FEDERAL
Community Mitigation	 Activate appropriate community mitigation measures. Activate approved community testing program. Call up service corps members to meet surge capacity needs for test administration and provision of isolation support. Monitor impact of testing programs and mitigation programs. Mitigate impact of testing programs and mitigation programs. 	 If needed, activate appropriate community mitigation measures for affected communities (such as temporary closure of child care facilities and schools, school and workplace social distancing measures, and postponement or cancellation of mass gatherings), simultaneously activate the approved testing program. Monitor effectiveness of community mitigation measures. Monitor effectiveness of community testing programs. Monitor adverse impact of community mitigation measures on society, and coordinate with local response agencies to address the impact if possible. Monitor adverse impact of community testing programs on society, and coordinate with local response agencies to address the impact if possible. 	 Provide, evaluate, and revise recommendations for use of community mitigation measures. Ensure alignment of all executive branch agencies with the chosen testing level approach (broad, targeted, or universal). Ensure alignment of all state governments with the testing approach (broad, targeted, or universal). Deploy federal responders or assist states in other ways to evaluate the effectiveness and potential adverse effects of community mitigation measures. Deploy federal responders or assist states in other ways to evaluate the effectiveness and potential adverse of the effectiveness and potential adverse of the effectiveness and potential adverse effects of testing programs.

DOMAIN	TRIBAL/LOCAL	STATE	FEDERAL
Medical Care and Countermeasures	Call up service corps members to meet surge capacity needs for health care and support.	 Monitor and respond to surge in health-care needs, including setting up alternative care sites. Educate clinicians and the public about the need for prompt treatment of ill persons. Review and prepare to deploy mortuary surge (or mass mortality) plan. Consider deployment of state/local caches of supplies (e.g., PPE). 	 Monitor antiviral use, effectiveness, and adverse events. Advise on implementation of mitigation strategies for the surge in health-care needs (e.g., activation of alternative care sites and modalities, and implementation of situation-appropriate standards of care). Monitor the health-care surge and stress on the health-care system, including provision of key medical resources and tools, as needed. Modify guidance documents based on situation as appropriate. Consider additional deployments from the Strategic National Stockpile.
Risk Communication	 Regularly engage community leaders and stakeholders in ongoing evaluation of community impacts. Disseminate updated risk messages. Share updated information regarding testing. 	 Disseminate updated risk messages. Share updated information regarding testing. Continue to provide regular updates to partners, stakeholders, elected officials, and the media. 	 Disseminate updated risk messages. Share updated information regarding testing. Continue to provide regular updates to partners, stakeholders, elected officials, and the media.

THE ROLE OF BUSINESS

To achieve the plan sketched in this roadmap will require extremely tight coordination along a multistage supply chain for testing. Integration and optimization of this supply chain is by far the most important and least coordinated component. It would especially benefit from the integration of IT. Achieving this without central coordination in such a short period of time will be impossible, and time is of the essence as each day of continued stay-at-home orders costs the U.S. economy billions or possibly tens of billions of dollars and probably hundreds of lives.

Given the far greater and crucially *broader* trust levels in the business community as a whole and the current partisan nature of US politics, **it is unlikely that this plan will succeed unless business and the academy are seen as also leading on this policy initiative and are plainly doing so in support of and in tight coordination with the White House. Just as business leaders played the central role creating and staffing the British Ministry of Production (though it was eventually under the sovereignty of the British Crown), we believe progress here depends critically on business taking a leading role.**

As history has shown us, in wartime it is often necessary and expected that the private sector invest assets in efforts required by the public sector to help the public sector defend the infrastructure on which the profits of the private sector depend. Many assets in the hands of the private sector need to be invested in the public sector here, but the most important and most valuable are expertise and trust. With regard to the latter, <u>trust in government in the United</u> <u>States is 15 points lower than trust in business</u>, and trust in companies like <u>Amazon</u>, <u>Disney and Tesla is 30 or more points higher</u>.

An emergency equity injection of trust from leading businesses into the public is not just desperately needed. We also believe that, while risky, such an investment could pay handsome returns both in avoiding the collapse of the public infrastructure on which business success depends and in the appreciation of that trust if business leads successfully. Of course, this investment must offer some control rights as well as return on the investment of trust in the form of increases of trust. It is also critical that the proper role of the private sector is restored after the emergency, and that during the emergency, governance structures ensure public accountability.

THE ROLE OF WORKERS

Another key component in developing needed trust in these measures is ensuring that workers have a voice in pandemic resilience. A tripartite response—labor, management, and government—to workforce issues ensures that stakeholder interests are taken into account. Worker voice is essential also because workers have expert knowledge about how to make their jobs safe and when safety-related rules are not being followed. Workers' representatives should have an institutionalized role in program design and implementation and in monitoring of compliance.

THE ROLE OF CIVIL SOCIETY

The special resource of a constitutional democracy in confronting a crisis, in contrast to an autocratic or authoritarian regime, is solidarity. While China and Singapore have achieved disease control with draconian measures that interfere with basic rights, in the United States we need to find ways to control the disease that respect and protect civil rights and civil liberties. Germany, South Korea, and Taiwan provide models that combine robust investment in health infrastructure and privacy-protective approaches to contact tracing. We need to maximize the degree to which we can rely on voluntary compliance with social distancing orders, individual isolation orders, and the requirements of a testing and tracing regime. The best way to maximize voluntary compliance is by activating solidarity, and by recognizing that we are all in this together. To make this idea of being in it together real, we also need to recognize and respond to the differential burdens on different groups. That is essential to a program of voluntary compliance. The resources of solidarity necessary to fight a pandemic in a democracy depend on materially meaningful social contract commitments (Cammett and Lieberman 2020).

In addition, the safety of each one of us depends on the actions of every other one of us. Each of us has been called to perform innumerable "small missions," in the language of Congressman Dan Crenshaw. Yet our "small missions" add up to the tactical foundation for our collective strategic success.

An important part of achieving solidarity flows from activating and expanding service commitments—the commitments of all of us to one another and to constitutional democracy. Companies should readily accept prohibitions on stock buybacks and not focus on fears about brand management.

This is a moment for service. California's chief service officer, Josh Fryday, has established programs activating significant volunteer communities in support of isolated seniors. We ought all to be looking for an opportunity to serve.

Indeed, this is a moment where we might at last establish a universal expectation of service, calling up millions of civilians into a scaled-up, paid Health Reserves Corps and activating other service entities on behalf of COVID-19 mobilization. A call for service in the United Kingdom yielded 750,000 volunteers in a matter of days. We too should recognize this as our moment to serve and each find the mission to which we've been called.

ENDORSEMENT OF THE DUKE MARGOLIS CENTER REPORT ON MODERNIZING DISEASE SURVEILLANCE

A massively scaled-up TTSI program is not the only element of pandemic resilience and response that is now needed. Other roadmaps contribute other important parts of the architecture. In particular, we endorse the report on modernizing the country's disease surveillance system from Duke's Robert J. Margolis Center for Health Policy "A National COVID-19 Surveillance System: Achieving Containment." As that report puts it,

"Every region of the country should aim for the following outbreak surveillance and response capabilities:

1. TEST AND TRACE INFRASTRUCTURE: CAPACITY FOR WIDESPREAD DIAGNOSTIC TESTING AND DATA SHARING TO ENABLE RAPID CASE-BASED INTERVENTIONS

a) The capacity to conduct rapid diagnostic testing for everyone with COVID-19 symptoms and those with exposures or at higher risk of contracting or transmitting the virus (health care workers, those in congregate settings), with a robust sentinel surveillance system that routinely monitors for infection among samples of the population to enable early identification of small outbreaks, particularly in vulnerable populations;
b) Routine, straightforward, and secure electronic data sharing to support surveillance;

2. SYNDROMIC SURVEILLANCE: INTEGRATION OF TEST AND TRACE INTO AN ENHANCED NATIONAL SYNDROMIC SURVEILLANCE SYSTEM

a) Surveillance based on syndromic indicators of spikes and falls in potential COVID-19 related symptoms, building on existing public health syndromic surveillance capabilities

b) Timely and transparent reporting of COVID-19 outbreaks and testing and response capacity at the local level

3. SEROLOGIC TESTING: CAPACITY TO CONDUCT WIDESPREAD SEROLOGIC TESTING TO IDENTIFY RELIABLE MARKERS OF IMMUNITY

a) The development of regional measures of community exposure and immunity

b) The use and integration of accurate serologic testing of individuals for effective surveillance and containment

4. RAPID RESPONSE: CAPACITY FOR ISOLATION, CONTACT TRACING, AND QUARANTINE

- a) The capacity to isolate new cases and trace, test, and quarantine contacts rapidly
- b) The capacity to treat new COVID-19 cases effectively, at home or in a hospital."

ENDORSEMENT OF THE JOHNS HOPKINS UNIVERSITY REPORT ON MASSIVELY SCALING UP THE NATION'S CONTACT TRACING PERSONNEL

Success at contact tracing will require massively scaling up contact tracing personnel. We also endorse the report "A National Plan to Enable Comprehensive COVID-19 Case Finding and contact Tracing in the U.S." from Johns Hopkins' Center for Health Security. They recommend a \$3.6 billion investment in hiring and training 100,000 new contact tracing personnel.

ENDORSEMENT OF THE MCCHRYSTAL GROUP REPORT ON THE USE OF INNOVATIVE ORGANIZATIONAL STRATEGIES TO FIGHT COVID-19

Fighting a pandemic on a scale unprecedented in our lifetimes requires innovative organizational structures. The team at the McChrystal Group has given thought to how to translate the "fusion cell" structure of the U.S. Special Operations in the fight against al Qaeda in Iraq to the fight against COVID-19. We endorse their "Fusion Cell Playbook" and their argument that success in activating all tiers of our federal system depends on distributed organizational structures that support successful flows of information both vertically and horizontally as well as crossagency, co-development of "decision support for government leaders at a local, metropolitan, region or state-level" (Fussell, Keister, and Pellegrini 2020).

CONCLUSION

We have no time to waste. We can save lives, save our health infrastructure, mobilize our economy, protect our civil liberties, and secure the foundations for a resilient constitutional democracy. We can be democracy's bulwark against this existential threat if we elevate our ambitions and determine to act swiftly and with purpose.

OUR ANCHOR RECOMMENDATION IS THIS:

Between now and August, we should phase in economic mobilization in sync with growth in our capacity to provide speedy, sustainable testing, tracing and warning, and supported isolation and quarantine programs for mobilized sectors of the workforce. We do not propose a modest level of testing, tracing, and supported isolation intended to supplement collective quarantine as a tool of disease control. We recommend a level of TTSI ambitious enough to replace collective quarantine as a tool of disease control.

We need to deliver 5 million tests per day by early June to deliver a safe social reopening. This number will need to increase over time (ideally by late July) to 20 million a day to fully remobilize the economy. Achieving these numbers depends on testing innovation. We acknowledge that even this number may not be high enough to protect public health. In that considerably less likely eventuality, we will need to scale testing up much further. By the time we know if we need to do that, we should be in a better position to know how to do it.

An effective strategy of **pandemic resilience** requires the following:

- Innovation in testing methodologies.
- A Pandemic Testing Board established by the federal government with strong but narrow powers that has the job of securing the testing supply and the infrastructure necessary for deployment.
- Federal and/or state guidance for state testing programs that accord with due process, civil liberties, equal protection, non-discrimination, and privacy standards.
- Readiness frameworks to support local health leaders, mayors, tribal leaders, and other public officials in establishing test administration processes and isolation support resources.
- · Organizational innovation at the local level linking cities, counties, and health districts, with specifics varying

from state to state.

- Federal and state investment in contact tracing personnel, starting with an investment in 100,000 personnel (recommendation from JHU Center for Health Security).
- Clear mechanisms and norms of governance and enforcement around the design and use of peer-to-peer warning apps, including maximal privacy protection, availability of open source code for independent and regulatory audit, and prohibitions on the use of any data from these apps for commercial purposes, ideally achieved through preemptive legislation.
- Support for quarantine and isolation in the form of jobs protections and material support for time in quarantine and isolation as well as access to health care.
- An expanded U.S. Public Health Service Corps and Medical (or Health) Reserves Corps (paid service roles), and addition of Health Reserves Corps to the National Guard units of each state.
- National Infectious Disease Forecasting Center to modernize disease tracking (recommendation from Scott Gottlieb, AEI).

Consensus is emerging about what we need. How to do it is beginning to come into view. The time for action has arrived.

APPENDIX A: PANDEMIC TESTING BOARD

The Pandemic Testing Board would consist of leaders from business, government, academia, and labor and would be tasked with two projects.

- 1. **PANDEMIC TESTING SUPPLY INITIATIVE.** The PTB's goal would be to develop the scale of testing needed first to stabilize the United States, and then to offer exports to foreign countries that are facing shortages. It would have authority to identify supply chain elements necessary for manufacturing, procuring, scaling, and deploying any items related to testing, the power to procure these materials via contracting with producers and servicers, and the power to mandate production or services, akin to authorities in the Defense Production Act. Contracting firms would be required to follow all existing labor laws, including maintaining collective bargaining agreements.
- 2. **PANDEMIC TESTING DEPLOYMENT INITIATIVE.** In order to deploy testing at scale, there will need to be sufficient personnel to test individuals outside of hospitals and doctors' offices. The PTB would:
 - Craft recommendations for states to use the national guard to deploy testing in conjunction with business, labor, nonprofits, and academia,
 - If necessary, be authorized to create a Pandemic Response Corps, comprised of tested civilians, to assist in the testing
 - · Make recommendations on tracking the spread of the virus
 - Before disbanding, craft recommendations on long-term preparedness.

DESIGN OF THE PANDEMIC TESTING BOARD

The Pandemic Testing Board could be designed in one of two ways:

- 1. **NATIONALIST MODEL:** The board would consist of no more than nine members, chosen either by the president or another government official, and would be required to include members from business, labor, academia, and current government officials.
- FEDERALIST MODEL: Congress would pass a law authorizing the states to create an interstate compact. The lead states would select a board of no more than nine members including members from business, labor, academia, and government. In this model, the board would serve the states—rather than work through the federal government—but it would be funded by a congressional appropriation.

TRANSPARENCY, ANTI-CORRUPTION AND ETHICS MEASURES, AND OVERSIGHT

The PTB would be required to take measures to ensure transparency, anti-corruption, and oversight.

TRANSPARENCY MEASURES

- Make immediately public all procurement contracts, including the terms, timing, and delivery
- Make immediately public its deployment decisions
- Produce a report to Congress and the American people detailing the PTB's activities and progress, on no less than a monthly basis

ANTI-CORRUPTION AND ETHICS MEASURES

- Prohibit contracting firms from raising CEO pay or offering bonuses for the contracting years and two years thereafter
- · Prohibit stock buybacks for the contracting years and two years thereafter
- Prohibit members of the PTB from purchasing stock in any company related to the PTB's activities for the duration of their time on the PTB plus an additional year

OVERSIGHT

The president or other government official (if the nationalist model) or board (if federalist model) shall appoint an inspector general who will be tasked with: (a) monitoring contracts for waste, fraud, and abuse; (b) producing a report of the PTB's progress every two months; (c) monitoring the anti-corruption and ethics requirements; and (d) conducting any other relevant oversight of the PTB's activities.

ACTION RECOMMENDATION

The Pandemic Testing Board could be created either by the president through the Defense Production Act or by Congress. Either way, we recommend Congress appropriate sufficient resources to fund the PTB and massively scale up testing production and deployment. Supportive flexibility from the FDA via Emergency Use Authorizations has been and will continue to be important.

APPENDIX B: MECHANICS OF THE TESTING SUPPLY CHAIN

We need to deliver 5 million tests per day, with results returned in 12 to 24 hours, to deliver a safe social reopening. This number will need to increase over time to 20 million a day to fully remobilize the economy. Achieving this will depend on testing innovation. We acknowledge that even this number may not be high enough to protect public health. In that considerably less likely eventuality, we will need to scale testing up much further. By the time we know if we need to do that, we should be in a better position to know how to do it.

ELEMENTS OF THE PLAN

Massive-scale testing would involve rapid development of:

- streamlined sample collection—for example, involving simple saliva samples ("spit kits"), rather than deep nasal swabs that have to be taken by health care workers (an innovation that should soon be available);
- · transportation logistics systems able to rapidly collect and distribute samples for testing;
- mega-testing labs, each able to perform in the range of 1 million tests per day, with automation, streamlined methods, and tightly managed supply chains;
- · information systems to rapidly transmit test results; and
- technology necessary to certifying testing status.

A testing system big enough to restore trust and get the economy moving again would mean testing tens of millions of Americans per day—enabling those who test negative to go to work, while at the same time isolating those who test positive and tracing their contacts to choke off transmission. With such a system, the number of new cases will drop dramatically.

The cost for large-scale testing is projected to be roughly \$15 billion per month (over the next year or more until reliable treatments and vaccines are available), and would likely fall over time as technology progressed—compared to an estimated cost of \$100 to 350 billion for every month of continued collective quarantine. A ramp up to 5 million tests per day and deployment of required information systems should be possible by late June.

MECHANICS OF MASSIVELY SCALING UP TESTING

Massively scaling up testing will require: (1) coordinating the ramp up of existing capacity; (2) integrating the ramp up of innovation-based capacity; and (3) building the supporting infrastructure.

There are two possible forward pathways to increase the number of tests and speed of analysis. We can seek to

scale up existing test production, distribution, sample collection, and analysis methods, or we can simplify the methodologies through innovation and build even greater scale through process simplification. Probably we need both. We need to maximize what we can already do, while innovating to do much more. A Pandemic Testing Board should consider all options for scaling before deciding precisely how to combine these two pathways.

SCALING EXISTING TEST CAPACITY (ACHIEVING THE FIRST 2 MILLION)

In aggregate, the country's existing virus testing capacity (using PCR) would probably be sufficient to handle an order of magnitude more testing above the current test levels if it were better organized and coordinated with demand. From channel checks with major commercial labs (beyond LabCorp, Quest, BioReference, etc.), it is clear that latent capacity is present as long as there is a sufficient demand signal to expand and a better means to coordinate with the demand, and where the economics are rational for these players to make fixed cost investments. This requires overcoming some CDC regulations, accelerating the production of the materials for test kits, and building megalabs with higher throughput. The current limiting factors include the volume of swab production and PPE production, as well as lab throughput. Both swab and PPE production could be addressed by repurposing idle plant capacity, in the textile industry in the first instance and in plants in Puerto Rico in the second instance. A broader survey of available capacity should be done. Higher rates of lab throughput could be achieved by building megalabs.

A core of megalabs around the country should be the rallying point for creating new capacity; a single megalab should be capable of handling more than 100,000 PCR tests/day. These megalabs can be either existing labs that have a footprint to grow or greenfield labs that are set up near population centers. These labs should be created in consultation with key equipment and reagent suppliers (e.g., Roche and Thermo Fisher) who can supply their newest machines and dedicate increasing reagent supply.

Other key elements would need to be part of an industrial ramp up include collection kits, test tubes, transport medium, and barcoding systems. For manufacturing of general-purpose biomedical supplies, excess capacity in plants across the country and in Puerto Rico can meet this need.

Samples must be collected somewhere by someone. Three options are point-of-care testing (e.g., doctor's offices, urgent care facilities), newly established testing sites (e.g., drive-through sites), and at-home test kits. The first two would require setting up separate spaces for infection control as well as PPE. The third has the lowest demand on personnel and infrastructure and should be a high priority for the FDA. Mayors and county health officials are already engaged in determining how they could support ramp up of testing locations. A key component for ramp up would be a Health Reserves Corps, working alongside the National Guard, that could remobilize the unemployed for employment in this industry.

INNOVATING FOR SCALE (ACHIEVING A MORE EFFICIENT 2 MILLION AND GETTING TO 100 MILLION)

A potentially more powerful approach may be to develop simpler protocols. We are indeed seeing rapid innovation to accomplish this—for example, replacing nasal swabs with spit kits. Rapid innovation would favor lab structures with generic robots and plates that can be easily adapted. Innovative lab designs can then be cloned and replicated.

New capacity of this type is already coming online. A good example of the elements and pace for establishing a new high throughput lab can be found in this account of the rapid transformation of the Broad Institute: <u>https://news.harvard.edu/gazette/story/2020/03/broad-institute-races-to-enable-coronavirus-testing/.</u> With prior experience analyzing 250,000 samples a day for the Human Genome Project, the Broad Institute is a good example of the kind of lab that might be stood up to achieve a capacity of 1 million tests per day. Setting up approximately 30 megalabs

across the country to do high throughput processing (1 to 3 million a day) with 12- to 24-hour turnaround would achieve the necessary maximum scale. Entities like the Los Alamos National Laboratories could also play a valuable role.

The best way to redesign and maximize the efficiency of testing is to focus on removing choke points and scaling up through simplification and reliance on generic solutions. To pursue this innovation pathway, it would be necessary to set up and coordinate multiple work streams focused on eliminating *all* these choke points.

CHOKE POINTS	SOLUTIONS
The need for PPE for staff who collect the samples	Taking saliva samples: FDA granted EUA for the first saliva kit on April 13 (an application from Rutgers, with more expected); many companies (such as 23&Me) routinely collect samples with spit kits, which can be obtained from generic suppliers. Also necessary would be a validated at-home sample collection protocol using lower nasal and/or throat swabs that can be transported at ambient temperature to a central lab facility. For the last, the FDA must work with academic labs and entities like the Gates Foundation to validate an at-home sample collection protocol.
The need to transport the samples as biohazardous waste	Use a <u>viral inactivation buffer</u> in the test tube collecting the saliva sample-then the material is no longer a biohazard for transport, and you can use an easy infrastructure of drop-off facilities or boxes.
The need for reagents to purify RNA.	Eliminate the need for RNA purification: Various labs (e.g., Color Genomics in California) are working on this; right now, the demand signal is not significant enough for them to invest in this but if it were, they could accomplish this quickly.

FURTHER DETAIL

EXISTING FIRMS AND PRODUCTS

The FIND website has a list of all tests available; however, most manufacturers haven't given detailed commentary. Many of the commercial players would probably comment on their earnings. With regard to production levels, Quest Diagnostics said they can do 45k tests per day now. <u>https://www.finddx.org/covid-19/pipeline/?section=molecular-assays#diag_tab</u>

CURRENT STATE OF SUPPLIES

Swabs & PPE

Sample collection has been a choke point for increasing testing throughput in the United States, in part due to a shortage of swabs from the two manufacturers (Copan, Puritan). There are only approximately 6 million per week nasal swabs being made now (1 million from Puritan and 5 million from Copan) and that needs to increase significantly to meet any testing goals. FDA has a list of alternatives due to shortages, but we don't know much about their supply.

Nasopharyngeal

Puritan: 25-3316-H, 25-3316-U, 25-3317-H, 25-3317-U, 25-3318-H, 25-3318-U, 25-3319-H, 25-3319-U, 25-3320-

H, 25-3320-U, 25-3320-H EMB 80, 25-3320-U EMB 80, 25-3320-H EMB 100, 25-3320-U EMB 100, 25-1406 1PF 50ff, 25-800 1PD 50**, 25-800 1PD ALUM 50**

Copan: 503CS01, 518CS01, 501CS01, 502CS01

BD: 220252, 220251

DHI/Quidel: 503CS01.DHI

Fisher Healthcare: 23600952, 23600956, 23600950

Oropharyngeal

Puritan: 25-1506 1PF SOLIDf, 25-1506 1PF 100f, 25-3206-H, 25-3206-U, 25-3706-H, 25-806 1PD** and 25-806 1PD BT**

Copan: 502CS01, 519CS01, 164KS01**, 175KS01**

BD: 220250

Fisher Healthcare: 23600950, 23600957, 1490650**

Mid-Turbinate

Copan: 56380CS01, 56750CS01, 56780CS01

Anterior Nares

Puritan: 25-3206-H, 25-3206-U, 25-3706-H, 25-1506 1PF 100f, 25-1506 1PF solid f, 25-1506 1PF BT^f, 25-1506 1PF TT MC^f, 25-1506 2PF BT f, 25-1406 1PF BT***^f

Copan: 502CS01, 519CS01

BD: 220144^f, 220145 f, 220250

DHI/Quidel: 20103f

Fisher Healthcare: 23600950, 23600957

f Foam swab

** Polyester swab

Additionally, swabs may be provided with transport media as identified below.

Transport Media

VTM/UTM (virus transport media/universal transport media) remains the preferred transport media. Examples of universal transport media for viruses and molecular transport media are listed here. All of the products listed below include a nasopharyngeal (NP) flocked swab unless noted otherwise.

Copan: 305C, 307C, 360C, 519CS01*

Puritan: UT-367, UT-317, UT-302*, UT-366**, UT-300***

Hardy/Healthlink: 330CHL

BD: 220526, 220527, 220528*, 220529, 220531

DHI/Quidel: 330C***

Fisher Healthcare: 23001718, 23600952, 23600956, 23600950, 23600957*

PrimeStore MTM: LH-1-02, LH-1-03***

* flocked oropharyngeal swab

** Polyester swab

*** no swab

In the absence of VTM/UTM, alternative transport media can be used to collect and transport patient samples for molecular RT-PCR SARS-CoV-2 assays. These recommendations apply to swab-based specimen collection by health care providers, and to anterior nares (nasal) and mid-turbinate specimen collection onsite by self-collection. The best available evidence indicates that these transport media will stabilize the SARS-CoV-2 RNA without meaningful degradation.

Labs can create their own viral transport media. Refer to <u>CDC's SOP#: DSR-052-01: Preparation of Viral Transport</u> <u>Media</u>. Specimens can be stored for up to 72 hours at 4°C.

Liquid Amies media may be used for viral transport when universal transport media is not available. Specimens can be stored in liquid Amies media for up to 72 hours at 4°C. All of the products listed below include a nasopharyngeal (NP) flocked swab unless noted otherwise.

Copan: 481C, 482C 480C*, 480CFA*

Puritan: LA-117, LA-116-H, LA-100***

BD: 220246, 220532, 220245*

ThermoFisher: R723481, R723482, R723480*

Hardy/Healthlink: 481C, 482C 480C*, 480CFA*

VWR: 89136-656, 89136-658, 89136-654*, 76181-494*

Fisher Healthcare: 23600901, 23600902, 23600900*, 23600905*

* flocked oropharyngeal swab

*** no swab

Other solutions may also be used for viral transport when universal transport media is not available. FDA recommends use of phosphate buffered saline (PBS), including molecular grade PBS when available, and other similar formulations including Delbecco's PBS, to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays. If PBS is not available, normal saline may be used. FDA believes that a sterile glass or plastic vial containing between 1mL and 3mL of PBS or normal saline is appropriate. Specimens can be stored up to 72 hours at 4°C. All the products listed below are examples of 1mL to 3mL of normal saline distributed in a vial without a swab.

ThermoFisher: R064430, R064432, R064434, R064436 and R064438

Hardy/Healthlink: D185, K248, R45 and R55

Edge Biologicals: T-0625 and T-0110f

There is limited data available on test performance with specimens which have been frozen in any transport media; therefore, specimen stability should be investigated if freezing is necessary.

Inventory Management & IT Support

The capacity of test sites to deliver tests could also be increased by improvements on the website support for identifying testing locations. A website should allow individuals to provide information on their symptoms, risks, and exposures with an authorization (i.e., a QR code) that would provide direction on where to get tested along with a fast-pass prioritization for the appropriate testing provider. The highest risk exposures would get prioritized for test supply that is most proximate to the individual (e.g., a drive-through site with a POC system) while lower-risk exposures would get routed to less immediate test channels (e.g., self-administered home test kit). More often than not, the system would direct someone to a testing channel that is not embedded in the health care system (e.g., ER/ hospital, clinic). In addition to specific test recommendations, the system should have visibility into the availability of specific test centers/locations/services along with estimated wait times; every capable COVID testing site or service should be mandated to provide near-real-time data on capacity, utilization, and forward visibility for supply-demand management. This dynamic matching of supply with demand is critical to overcome the supply chain bottlenecks of the current paradigm of lab testing in health care, which is not designed for high-frequency routing of tests to a federation of lab vendors. Some effort at experimentation has already been made in this direction.

Ramp up Production of Abbott Machines

These machines are too slow (four samples per hour) to meet the scale needed, but can contribute by increasing testing availability in rural areas.

Additional Possibilities for Scale

Enhance asymptomatic surveillance capacity with community- or household-based sample pooling.

To maximize existing testing capacity and throughput for asymptomatic surveillance, each household or community should be offered the option of daily sample pooling to facilitate early detection of the virus. This strategy assumes that the FDA will validate and allow for self-administered nasal or throat swabs without provider interaction and that an efficient supply chain can be set up between homes through carriers and lab service providers.

APPENDIX C: KEY CONCEPTS FOR A UNIVERSAL TESTING PROGRAM

UNIVERSAL TESTING PLUS CONTACT TRACING

How would jurisdictions administer universal testing and contact tracing programs if that turns out to be what we need in order to control the disease without reliance on collective stay-at-home orders? Here we discuss the general concepts out of which such a program should be built. (In our white paper "Federalism Is an Asset," we also sketch the mechanics of a hypothetical local program.)

GENERAL CONCEPTS

Currently, 56% of American employers use drug testing programs in both pre-employment and random testing contexts. Employees or prospective employees can visit any number of available and certified drug testing facilities; often urgent care facilities play this role. A "medical recording officer" at the facility reports the result of the test to the employer. In this regard, the medical recording officer functions much like any other public authority responsible for licensing.

In addition to this use of drug testing by employers, states have also pushed aggressively for drug testing for those receiving public assistance.¹ This was blocked in a 2003 Michigan Court of Appeals case. *Marchwinski v. Howard* ruled that such tests were not allowable on the grounds "that subjecting every welfare applicant in Michigan to a drug test without reason to believe that drugs were being used, was unconstitutional." Between 2011 and 2014, however, twelve states passed lezgislation requiring drug testing, having designed programs that complied with the standard set in *Marchwinski*.²

There are important differences between drug testing and COVID-19 testing. Although the legal landscape is changing rapidly, drug testing can reveal behavior connected to illegal narcotics activities and generates stigmatizing associations between the individual tested and illegal activity. Nor is drug testing typically used to connect people to health care (though perhaps it should be). COVID-19 testing, in contrast, has the goal of ensuring that all who need

¹ The National Conference of State Legislatures reports: "Substance abuse issues have long been part of public assistance policy discussions. States have proposed drug testing of applicants and recipients of public welfare benefits since federal welfare reform in 1996. The federal rules permit drug testing as part of the Temporary Assistance for Needy Families (TANF) block grant. In recent years, nearly all states have proposed some form of drug testing or screening for applicants. In 2009, over 20 states proposed legislation that would require drug testing as a condition of eligibility for public assistance programs. In 2010 at least 12 states had similar proposals. None of these proposals became law because most of the legislation was focused on "suspicionless" or "random" drug testing, which is at odds with *Marchwinski v. Howard*." https://www.ncsl.org/research/human-services/drug-testing-and-public-assistance.aspx

² The National Conference of State Legislatures reports: "The proposals gained momentum beginning in the 2011 session. Three states passed legislation in 2011, four states enacted laws in 2012, two states passed legislation in 2013, and three states passed legislation in 2014, bringing the total number of states to twelve. In 2013, Kansas enacted legislation to require drug testing for applicants and recipients suspected of using controlled substances. In 2012, Utah passed legislation requiring applicants to complete a written questionnaire screening for drug use and Georgia passed legislation requiring drug tests for all applicants for TANF. Tennessee approved a bill to require the department to develop a plan for substance abuse testing for all applicants and Oklahoma passed a measure requiring all applicants for TANF to be screened for illegal drug use." https://www.ncsl.org/research/human-services/drug-testing-and-public-assistance.aspx

treatment for COVID-19 receive it and that those who are infectious without being symptomatic do not pass the virus on to others. The consequence of testing positive for COVID-19 is not a no-hire decision or loss of employment. Indeed, this needs to be written into legislation for the program. Testing positive is instead a recommendation to isolate and/or seek treatment for a 14- to 28-day period, with job protection guarantees. This is not meant to suggest that problems of stigma will not arise for COVID-19 as they have for other diseases. Indeed, this is a problem that we should anticipate and seek to ward off. Nonetheless the policy objectives for COVID0-19 testing should be plainly directed at allocation of access to health resources. Tests should be designed to be an opportunity for connection to care, not a form of surveillance. While testing for illegal narcotics is also typically justified on health and safety grounds, in the case of illegal narcotics, it is the community that is being protected. In the case of COVID-19 testing, it is both the individual and community. An important part of any COVID-19 testing program will be the provision of adequate health resources to all.

In relation to the contrast between drug testing and COVID-19 testing, it is important to note that the Appeals Court basis for invalidating any effort to connect broad drug testing to provision of public benefits does not pertain in the case of COVID-19. The argument in the former case is that the state cannot require drug tests of public benefits recipients "without reason to believe that drugs were being used." But with COVID-19, the point of testing is precisely that we have good reason to believe that any of us might in fact be carriers of the virus, even if we do not display symptoms. In other words, COVID-19 testing should survive a Fourth Amendment challenge on probable cause grounds.

Local-level pandemic testing programs can be built with a similar structure to drug testing programs, drawing on the state's public authority to license, as in the instance of driving, but with a clear focus on the objective of providing health care to the tested individual as well as on protecting the health of the broader community. Employers, schools, and public assistance programs all have a reasonable basis on which to require tests, and the state could mandate that they do. Penalties for failure to test would fall on these entities, not on the individual.

Similarly, local contact tracing programs have long been in existence, particularly in relation to HIV, tuberculosis, measles, and syphilis. A particularly good example is the program based in each of New York's boroughs. Grouped under the title New York Knows, these programs involve community organizations as partners in recruiting people to be tested and in conducting contact tracing subsequent to positive tests. They have set the goal of ensuring that every borough resident has an HIV test. Importantly, the motivation for contact tracing programs of these kinds is the duty we all bear to warn others of their imminent danger, if and when we learn of it and if we have it within our power to warn them.

APPENDIX D: INNOVATIVE ORGANIZATIONAL STRATEGIES AT THE LOCAL LEVEL

The U.S. public health system is massive, fragmented, and diverse. State public health agencies work with tribal, county, metropolitan, and municipal health agencies as well as, in some cases, with regional health collaborations. Federal public health agencies also work with all of the above as well as with tribal health agencies. In the context of an event such as a pandemic, state and federal health agencies also work in coordination with state and federal emergency management agencies. Importantly, the federal agencies both work in support of and through states, and also work directly with affected populations, particularly under-resourced communities.

Success in activating all tiers depends on distributed organizational structures that support successful flows of information both vertically and horizontally as well as supporting cross-agency co-development of "decision support for government leaders at a local, metropolitan, region or state-level" (Fussell, Keister, and Pellegrini 2020). An organizational form known as a "fusion cell" (from the U.S. Special Operations as led by General Stan McChrystal in the fight against the networked threat of al Qaeda in Iraq) may provide an illustrative model for interagency/ intergovernmental cooperation, though additional experimentation around coordination models and best practices should also be encouraged.

Under this organizational form, some 2,000 people came together every day on a common call to share information and under the centralized authority of McChrystal to ensure that they had "shared consciousness" and a general plan. Then they split into teams that were empowered to make decisions on their own adapting to circumstance "empowered execution." In the context of the pandemic, the general plan around which "shared consciousness" forms needs to be a fully integrated policy roadmap that integrates health, economic, civil liberties, justice, and education policy at a minimum.

As with the military case, response to the pandemic similarly needs a centralized authority for information gathering/ dissemination, oversight of national production, and surge capacity, but it also needs a distributed capacity for execution that can respond quickly and flexibly to local circumstance. That distributed capacity needs nodes that bring together the several and not perfectly overlapping jurisdictions that characterize the health space within any given state. To succeed, those nodes should also connect the relevant network of health decision-makers to those working in the other substantive policy domains needed for an integrated solution to the crisis. Where an incident command system brings together all the portfolios within a specific jurisdiction, a fusion cell networks that jurisdictional structure with the other jurisdictional structures with which it overlaps and seeks to achieve "shared consciousness" across the overlapping jurisdictions around a set of shared and integrated set of policy goals.

Federal, state, tribal, county, metropolitan, and municipal governments, and hospital systems might all have multi-disciplinary incident command structures, but they should replace bilateral communications among those independent incident command structures with a fusion cell. For instance, rather than having chains of communication from state to counties, states to cities, federal health agency to tribal health authorities, federal health agency to state public health offices, and so on, each state might link all these communications together in a daily call

using a fusion cell structure. Those who staff the fusion cell would surface the data needs of decision-makers, elicit the relevant data, and provide access to it across the fusion cell. State and federal incident command systems would need to align policy goals for the fusion cells. Local level fusion cell participants would be empowered to implement shared policy goals emanating from aligned state and federal incident command systems.

An excellent example of the relevant kind of coordination is already available in the collaboration between the City of Tyler, Texas, Smith County, and the Northeast Texas Public Health District. Instead of having independent operations centers for a crisis, for the first time they have a joint operations center where municipal, county, and health district teams think and plan together. This partnership has permitted the county and district health officials to build out a contact tracing strategy using personnel redeployed from the municipal level, for instance fire and police personnel and restaurant inspectors. The organizational innovation has permitted a marriage of public health expertise with municipal resource capacity. Without their structure being called a "fusion cell," these local leaders have innovated in the organizational direction described above to make contact tracing possible in their community.

APPENDIX E: SUMMARY OF RECOMMENDATIONS

Our anchor recommendation is this: Between now and August, we should phase in economic mobilization in sync with growth in our capacity to provide speedy, sustainable testing, tracing and warning, and supported isolation and quarantine programs for mobilized sectors of the workforce. We do not propose a modest level of testing, tracing, and supported isolation intended merely to supplement collective quarantine as a tool of disease control. We recommend a level of testing, tracing, and supported isolation ambitious enough to replace collective quarantine as a tool of disease control.

We need to deliver 5 million tests per day by early June to deliver a safe social reopening. This number will need to increase over time (ideally by late July) to 20 million a day to fully remobilize the economy. Achieving these numbers depends on testing innovation. We acknowledge that even this number may not be high enough to protect public health. In that considerably less likely eventuality, we will need to scale testing up much further. By the time we know if we need to do that, we should be in a better position to know how to do it.

An effective strategy of pandemic resilience requires:

- Innovation in testing methodologies.
- A Pandemic Testing Board established by the federal government with strong but narrow powers that has the job of securing the testing supply and the infrastructure necessary for deployment.
- Federal and/or state guidance for state testing programs that accord with due process, civil liberties, equal protection, non-discrimination, and privacy standards.
- Readiness frameworks to support local health leaders, mayors, tribal leaders, and other public officials in setting up test administration processes and isolation support resources.
- Organizational innovation at the local level linking cities, counties, and public health districts, with specifics varying from state to state.
- Federal and state investment in contact tracing personnel, starting with an investment in 100,000 personnel (recommendation from JHU Center for Health Security).
- Clear mechanisms and norms of governance and enforcement around the design and use of peer-to-peer warning apps, including maximal privacy protection, availability of open source code for independent and regulatory audit, and prohibitions on the use of any data from these apps for commercial purposes, ideally achieved through preemptive legislation.
- Support for quarantine and isolation in the form of jobs protections and material support for time in quarantine and isolation as well as access to health care.
- An expanded U.S. Public Health Service Corps and Medical (or Health) Reserves Corps (paid service roles), and addition of Health Reserves Corps to the National Guard units of each state.
- National Infectious Disease Forecasting Center to modernize disease tracking (Recommendation from Scott Gottlieb, AEI).

Consensus is emerging about what we need. How to do it is beginning to come into view. The time is here for action.

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