



The Path to Zero: Suppressing COVID-19 through TTSI

Robust contact tracing, testing and supported isolation (TTSI) across the nation will provide pandemic safety and get the United States economy back on track. How to get it done, and how to pay for it:

A policy framework

WHAT IS TTSI?

A TTSI program uses testing (T), contact tracing (T), and supported isolation (SI), to suppress or mitigate highly infectious and dangerous diseases where the diseases have both a long incubation period and a relatively short disease course. A TTSI program is NOT a universal testing program. It is NOT a random testing program. A TTSI program builds on a foundation of viral testing, and also uses antibody testing to support surveillance to increase the effectiveness of the core viral testing programs.

TTSI programs are ideally used to suppress the disease. This means the programs are used at a sufficiently large scale to suppress the disease and drive case incidence to (near) zero, providing a foundation on which to restore a pandemic-resilient economy where people feel safe to go to work, schools and churches without fearing outbreaks.

TTSI for COVID-19

To get to this near zero case incidence level, jurisdictions need to first understand the severity of the outbreak they are responding to. To determine their COVID level, they should assess case incidence levels as follows:

| Covid Risk Level | Case Incidence | | |
|------------------|--|------------------------------------|--|
| Red | >25 daily new cases per 100,000 people | | |
| Orange | 10<25 | daily new cases per 100,000 people | |
| Yellow | 1<10 | daily new cases per 100,000 people | |
| Green | <1 | daily new case per 100,000 people | |

These COVID levels help decision-makers and community members know where they are. The green level aligns with the CDC's low incidence plateau threshold. The levels communicate the intensity of effort needed for control of COVID at varying levels of community spread.

To determine the levels, incidence numbers can be used at county, MSA, or other local health district jurisdiction level, and at the state level. Policy decisions about which strategies of disease response are best for a jurisdiction should be made by looking at both the local level and the state picture and considering the dynamic relationship between them.

In addition to paying attention to the levels, decision-makers should pay close attention to direction of trend and rate of change. While jurisdictions may plateau in yellow, in the orange level spread tends to have more velocity.

Understanding Control Efforts Needed

At the **green level**, jurisdictions are on track for containment so long as they maintain maintenance levels of viral testing and contact tracing, sufficient to control spikes and outbreaks. Viral testing should be used both for symptomatic and asymptomatic individuals, with the latter need for testing flowing from exposure, role in a congregate setting or other critical context (e.g. elective surgery), or other requirements of disease surveillance programs. It is not enough to get to green; one also has to plan to stay green. Viral testing in jurisdictions at the green level should be coupled with rapid contact tracing.

At the **red level**, jurisdictions have reached a tipping point for uncontrolled spread and will require the use of stay-at-home orders and/or advisories to mitigate the disease, even as they also work to ramp up TTSI resources.

At **yellow levels**, there may be some initial community spread. At **orange levels**, community spread has accelerated and is at dangerous levels. At both yellow and orange levels, jurisdictions can make strategic choices about which package of non-pharmaceutical interventions to use to suppress the disease. One jurisdiction may choose stay-at-home orders; another may choose more intensive use of viral testing and tracing programs. All jurisdictions will want some combination of social distancing strategies and infection control.

Robust TTSI programs provide a pathway for disease suppression that also supports the economy by minimizing the need for stay-at-home orders.

In order to understand optionality at yellow and orange levels, decision-makers should review the different "phasing plans" that policy-makers have developed as guidance. They should be equipped to evaluate whether the "phasing plans" will help them meet their goals, having clearly in mind whether their goals are mitigation or suppression.

| Covid Risk Level | Case Incidence | | Intensity of Control Effort Needed | |
|------------------|----------------|------------------------------------|---|--|
| Red | >25 | daily new cases per 100,000 people | Stay-at-home orders necessary | |
| Orange | 10<25 | daily new cases per 100,000 people | Strategic choices must be made about which package of non-pharmaceutical interventions to use for control. Stay-at-home orders are advised, unless viral testing and contact tracing capacity are implementable at levels meeting surge indicator standards (see KPIs below). | |
| Yellow | 1<10 | daily new cases per 100,000 people | Strategic choices must be made about which package of non-pharmaceutical interventions to use for control. | |
| Green | <1 | daily new case per 100,000 people | On track for containment, conditional on continuing use of viral testing and contact tracing for surveillance and to contain spikes and outbreaks. | |

While most jurisdictions in the U.S. are currently using a mitigation strategy, we strongly recommend stepping up to a strategy of suppression.

Closing Capacity Gaps

Concerns about capacity gaps with regard to availability of viral testing and contact tracing have put many states on a path of mitigation rather than suppression. Lab capacity for viral testing has, however, been increasing rapidly. Our assessment is that the resources for a full suppression strategy are now within reach and, if funded today, could be at full capacity by October with a \$25 billion investment, priced at \$25/test. Resources undergirding this analysis are available at https://www.pandemictesting.org/whitepapers/getting-it-done and https://globalepidemics.org/.

Our team has spent the last month designing and evaluating a pathway to pursue an end-to-end TTSI strategy within any given state. We have a technical advisory handbook available here, based on the end-to-end TTSI infrastructure in Massachusetts: https://ethics.harvard.edu/ttsi-technical-handbook.

Finally, we have designed a policy framework to deliver sufficient testing and organizational support to the states, via a combination of technical advice to states, block grants, and funding of inter-state compacts (on the last, see Designing Interstate Compacts).

How to Implement TTSI: State Level

The use of a TTSI program for suppression requires a significant investment in organizational analysis and planning, contact tracing personnel and program management, data management, and lab testing capacity.

TTSI is the strategic and targeted use of viral testing and contact tracing resources to maximize marginal contribution to disease suppression and drive case incidence of the disease back as close to zero as possible.

TTSI programs pursue **data-driven targeted testing of hotspots**, such as eldercare facilities, nursing homes, correctional facilities, and communities experiencing high rates of transmission. In the context of suppressing an outbreak, it will make sense to test the whole staff and resident population of such facilities. Hotspots requiring quick action may also be whole neighborhoods, often also experiencing other kinds of disadvantage.

TTSI programs also pursue **contact tracing based testing**. Symptomatic people or people who believe they have been exposed to the disease present at clinics or testing sites for a diagnostic test, or they are found in hotspots. A positive test result activates a contact tracing team that identifies those who may have been exposed to the virus by the COVID-positive individual. Those exposed contacts have a test appointment scheduled for them, regardless of whether they are symptomatic or asymptomatic, and are encouraged to quarantine until the results are known. Further contact tracing is conducted for every positive test. **In conditions without stay at home orders and minimal compliance with masking and social distancing, the goal would be that every COVID-positive test should result in 25 further tests. In conditions with moderate compliance with masking and social distancing, the goal would be that every COVID-positive test should result in 12 further tests. Those who are positive are connected to treatment or self-isolate, to help break the chain.**

Participation is voluntary but public messaging needs to drive home the importance of contributing to the fight against COVID through acceptance of getting a test if one has been identified as a contact of an infectious person and acceptance of self-isolation to break the chain.

In addition to **viral testing of chains of contacts** that start from patients who present with symptoms or individuals who have experienced exposure and **hotspot testing**, a TTSI program may be supplemented by **a limited degree of routine testing in critical contexts**, where there are highly vulnerable populations or employment contexts with national security implications. Examples of the former would be eldercare facilities, health care sites, correctional facilities, and employment contexts with assembly-line style work environments such as meat-packing plants. It may be reasonable to include other congregate settings such as schools, colleges and universities, or dense offices in such "critical context routine testing" programs. Routine testing is a highly inefficient form of testing so it should be reserved for contexts of this kind.

Priorities For Getting To Green

The following priorities for a TTSI program lead to the most efficient progress on the path to zero:

- **1. Priority 1:** Test hotspots, using mobile-labs, walk-in, and drive thru clinics as well as testing of all staff and residents in congregate living facilities with outbreaks;
- **2. Priority 2:** Encourage all symptomatics (regardless of severity of symptoms) to be tested (or to self-quarantine) and all those who have reason to think they have been exposed to the disease to come in for a test.
- **3. Priority 3:** Trace the contacts of all covid-positive individuals throughout the population. Every covid-positive individual should generate 25 additional tests.

A full suppression strategy achieves all three priorities. A mitigation strategy achieves the first two priorities but quarantines contacts without testing them and following the chain. The goal of a TTSI program is to break all the chains of transmission. Whereas mitigation seeks to flatten the curve, suppression seeks to break the chain.

For a TTSI program to succeed, these three priorities must be broadly advertised and effectively communicated along with information about where to get a test.

These three priorities, taken together, create a double-pronged program of 1) state-wide testing and tracing and 2) hotspot testing and tracing. If supported with a sufficient supply of testing capacity and contact tracers, this program should suppress the disease and drive case incidence close to zero, facilitating an open economy that can stay open and minimizing the need for private businesses to build and maintain testing programs. Once case incidence reaches green zone levels, contact tracing and testing capacity levels will fall back to maintenance levels.

In contexts that have pursued mitigation rather than suppression and continue to be in the yellow zone, it will be hard to open schools, churches, and other congregate contexts without experiencing outbreaks within those organizations. It might be tempting to envision routine testing in these contexts facilitated by a private market in diagnostic tests. However, the most efficient path to safety for individual schools and congregations is suppression in the broader community.

Resources should not be diverted to the purpose of testing in particular organizations prior to the completion of the public mission to achieve suppression in the community more broadly.

Once suppression has been achieved and a jurisdiction has returned to green, it may make sense for **schools, churches, sports leagues, and other congregate contexts** to equip themselves with testing resources to provide early warning of outbreaks in their community. In contexts where people are currently employing routine testing, the frequency for individual testing ranges from daily to every fourth day to once a week. Once in green, however, case incidence should be sufficiently low that organizations of this kind could rely on **weekly pooled testing** to catch outbreaks.

An end-to-end strategy for setting up implementation of TTSI at the state-level is available in our Technical Advice Handbook, included as an appendix.

How to Implement TTSI: Federal Level

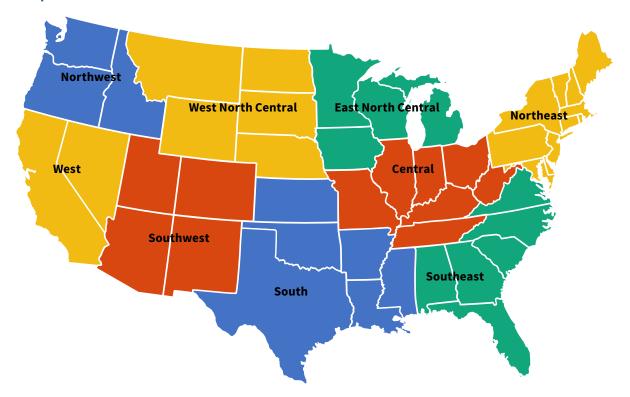
While state Departments of Health need to deliver a TTSI program, they do need logistics support from the federal government along two dimensions: 1) funds for contact tracing personnel and supported isolation and 2) a structure for regional-level procurement of tests.

The most challenging element of establishing a TTSI program may be aligning testing capacity with sample collection volume through rapid logistics and data management. It is not efficient to expect jurisdictions to conduct this inventory of testing capacity below the level of the state. The state should take on responsibility for securing sufficient lab capacity for all jurisdictions within it.

To achieve this, the state needs to inventory testing capacity available to it and to identify gaps. This inventory should account for needed point-of-care testing in low-population density locations and needed centralized labs in high population density locations with 24hr test turn-arounds. Additionally, a summative approach to looking at all available test modalities should be utilized as opposed to an either-or approach.

Importantly, this inventory process should take into account labs available regionally and not just within the state itself. Although the need for 24hr turn-around on test results puts a geographic limit on how far away a lab can be, some regional collaboration should be possible, particularly for high-density population areas within a shared geographical regions.

Ideally, the state would procure testing capacity as a participant in an interstate compact formalized and funded by Congress for procurement of tests.



States want to have visibility into capacity at the regional level flowing from all of the following testing modalities; they should not limit the horizon of their analysis to the capacity in their own state.

The chart below provides an assessment of national capacity for different diagnostic testing types.

| SARS-CoV-2 Testing Methods | | | | | | | | | |
|--------------------------------|--|--|--|-------------------------------------|--|-------------------------------|--|--|--|
| Component Detected | | Viral Protein | | | | | | | |
| Method | RT-qPCR | inaat | NGS | CRISPR | ELISA | LFA | | | |
| Clinical Accuracy | High | High | High | Medium | Unknown Medium | | | | |
| Scalable to Meet US Needs? | Maybe | Maybe | Yes | Unknown | Unknown | Yes | | | |
| CurrentUS Tests/Day | -200,000 | -5,000 | 0 | 0 | 0 | Thousands | | | |
| ProjectedAug. 2020Tests/Day | Hundreds of Thousands | Hundreds of Thousands | Millions | Unknown | Unknown | Hundreds of Thousands | | | |
| Use Case | High-volume Centralized or Point-of-Care | High-volume Centralized or Point-of-Care | High-volume Centralized | Point-of-Use | High-volume Centralized | Point-of-Use | | | |
| Turnaround Time | 24-48 Hrs (Centralized) Minutes (PoC) | 24-48 Hrs (Centralized) Minutes (PoC) | 24-48 Hours | Minutes | 24-48 Hours | Minutes | | | |
| SampleType | Nasal Swab or Saliva | Nasal Swab | Nasal Swab or Saliva | Nasal Swab | Unknown | Nasal Swab | | | |
| Quantifies ViralLoad | Yes | No | Yes | No | Yes | No | | | |
| Key Scale-Up Barrier | Reagent/ Kit Availability | Reagent/ Kit Availability | Logistics | Nosel Technology | Technology Assay Development De | | | | |
| Regulatory Status | EUA | EUA | EUA pending | EUA | EUA Unknown | | | | |
| Supply Chain Risk | Medium | High | Low | Medium | Medium | Low | | | |
| Representative Companies | LabCorp Quest Roche ThermoFisher | Abbott Hologic AtilaBio | Broadinst. Illumina HudsonAlpha Ginkgo | Mammoth Sherlock BroadInst. | LabCorp Quest Abbott Roche | Quidel ChemBio Cellex OraSure | | | |

Sources: Ginkgo Bioworks: https://www.ginkgobioworks.com/2020/05/04/how-to-deploy-millions-of-covid-19-tests-per-day/ **See also:** https://interventions.centerofci.org/pub/covid-testing-assessment/release/14

To this day, the testing market has been hampered by four problems: (1) the failure to communicate the accessibility of tests to the population broadly; (2) the absence of bulk orders and guaranteed offtake contracts that give centralized labs a market incentive for investing in ramp up; (3) the failure to establish a stable funding structure and payments process for the viral testing needed not for insurance-covered therapeutic purposes but for purposes of disease surveillance and suppression; the latter category of viral testing is not covered by insurance; and (4) intermittent and weak supply chains for both equipment and consumables. These four problems could be rectified by a Congressional statement of commitment to a TTSI program and by funded interstate compacts with the power to purchase bulk orders, with payment processes facilitated by the use of vouchers delivered to individuals for use at point of service.

Interstate compacts with a single mandate to spend \$25B on procuring tests to support suppression testing surges within their region would guarantee suppression-level purchase volumes. This is in contrast to states with cash-strapped budgets, which will have competing demands for spending and will therefore have incentives to purchase only mitigation volumes, which is more costly in the long-run. This is a classic state "collective-action" problem that can be remedied by interstate compacts. The opportunity to win off-take contracts from interstate compacts will also create a market incentive for rapid expansion of testing capacity and testing modalities beyond conventional PCR testing. We will see more innovation in next generation sequencing mega-labs that can process million tests per day or CRISPR point-of-use tests—technologies that can produce rapid test results for any novel disease in a future pandemic.

Interstate compacts also offer efficiency advantages over state contracting, such as economies of scale, regional oversight & expertise, and reduced transaction costs.

FUNDING TTSI

In support of the efforts of state, tribal, and local leaders, Congress needs to make substantial investment in TTSI infrastructure. We recommend investments in local and country public health offices, contact tracing personnel, voluntary self-isolation facilities, income support for voluntary self-isolation, investment in test kits and test processing, investment in point-of-care testing machines, and investment in mega-labs.

- \$1 billion for IT infrastructure upgrade—the model is Germany which made this a critical early step in activating its pandemic response.
- **\$4.5 billion** in additional annual mandatory funding for local, state, tribal, and territorial core public health infrastructure, in addition to existing annual discretionary appropriations. The contact tracing surge can only be as successful as the public health infrastructure that supports it. By building the core public health infrastructure of localities, states, tribal governments, and territories the nation will be better prepared for the next threat (NACCHO 2020).
- \$3.6 billion for 100,000 contact tracers as a year-long corps (numbers are based on a study published by Johns Hopkins University).
- \$5.4 billion for 600,000 contact tracers for a suppression surge.
- \$4.5 billion for self-isolation facilities

"In order to prevent infection spread, we will need to offer individuals the opportunity to self-isolate for up to two weeks if they are unable to do so in their homes. There is substantial evidence that providing a voluntary option to safely isolate will help to dramatically reduce spread of infection to one's family and therefore the spread of infection overall. We believe 14 percent of infected individuals and exposed contacts will need such an option. Hotels are largely sitting idle at present and can provide local options for such voluntary self-isolation sites. Utilizing otherwise vacant hotels over the course of 18 months will both maximize the ability to contain COVID-19 and also provide a much-needed stimulus for the hospitality industry across the country as hotels deliver an essential public service. The total funding is estimated to be \$4.5 billion."

^{1.} Extract from "Bipartisan Public Health Leaders Letter to Congress" submitted by Andy Slavitt, Scott Gottlieb, Larry Brilliant, Atul Gawande, et al. to The Honorable Nancy Pelosi, The Honorable Kevin McCarthy, The Honorable Mitch McConnell, and The Honorable Chuck Schumer, April 27, 2020.

• \$30 billion for income support for those in isolation

"A key ingredient in maximizing the ability to contain COVID-19 is the ability to offer income support to individuals for whom loss of income during 14 days of voluntary self-isolation represents a prohibitive barrier to being able to self-isolate. We estimate 40 percent of individuals will need a measure of income support in order to be able to afford to voluntarily self-isolate. Paying these individuals a stipend of \$50 per day (analogous to federal jury duty) will greatly increase the success of containment efforts and the ability to maintain an expanded measure of openness in the economy. We estimate this income support will require approximately \$30 billion in funding over the course of 18 months."

• \$25 billion for test procurement

Funding for tests (kits, handling, processing) is calculated as \$4 billion for one month's worth of test kits @ \$25/kit, or \$24 billion over six months. Some portion of that could be paid by private insurance. In addition, employers should be asked to take on the testing required to operate in high-risk industries. This also requires addressing the need for liability protection (a matter of both federal and state law). If OSHA put out detailed guidelines and employers followed them, there could perhaps be a no-fault fund that could pay out for harms. In addition, we anticipate the need for an additional \$1 billion for capital investment in testing labs.

We recommend investment in surge capacity in commercial and academic labs (capable of achieving processing levels of 200,000 tests a day), via a Defense Production Act "Title III" style investment in 5 to 10 regional labs, at a cost of \$50 to \$100 million each.⁴ For labs to pivot to delivering this surge capacity, they need capital for equipment to rapidly support build-out. Additionally, to expand operational capacity to the required numbers, these providers will need working capital for the supply chain. Dedicated purchasing contracts, also known as "guaranteed off-take" agreements for specific quantities of tests that meet certain criteria are a powerful way to create the private working capital liquidity to fund expansion. The funding program could be structured with full pre-purchase contracts being awarded on the basis of a rapid DARPA-style application process, but with milestones to unlock tranches of funding. The target level of cost per test should be \$25 per test. We recommend an investment of \$500 million in total for this program.

WHY WE NEED TO FUND TTSI

With a TTSI package of \$75 billion, the nation's governors would be equipped to deliver a suppression strategy and the nation as a whole would benefit. Each month of collective national quarantine cost \$150-\$300 billion, in addition to compounding social costs of unemployment and social unrest. Our phased reopening in conditions where case incidence remains high ensures a long and slow recovery, not a V-shaped recovery. Achieving suppression would accelerate recovery. This investment would quickly pay for itself.

WHO

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^{2.} As we recommended in our Roadmap, supported isolation also requires job protection, so covid positive individuals can get their jobs back after isolation. For unemployed people, they will need exemption from job search requirements in order to be able to continue to receive unemployment insurance.

^{3.} Ibid.

^{4.} See US Dept. of Energy, "Title III of the Defense Production Act.