EDMOND J. SAFRA CENTER FOR ETHICS AT HARVARD UNIVERSITY
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PANDEMIC RESILIENCE: GETTING IT DONE

A TTSI Technical Advice Handbook

V 1.0

JUNE 3, 2020

TTSI TECHNICAL HANDBOOK FOR STATES AND MUNICIPALITIES

By the Massachusetts Testing, Tracing, and Supported Isolation (MA TTSI) collaborative

MISSION STATEMENT

To enable a safe and progressive pathway to a pandemic-resilient, free society

By providing scaled up testing, enabling rapid contact-tracing, and instituting supported isolation

Using the collective capabilities, assets, workforce, and innovative spirit of the regional ecosystem

While continuing to monitor and respond to the needs of our communities which may be impacted by the COVID-19 pandemic in different ways.

Members of this collaborative include:

- Policy
    - Harvard Edmond J. Safra Center for Ethics
    - Harvard Global Health Institute
- Contact Tracing
    - Partners in Health
- Medical Device Manufacturing and Supply Chain
    - Massachusetts Manufacturing Emergency Response Team (M-ERT)
- Diagnostic Testing Development and Capacity Planning
    - Massachusetts Life Sciences Center
    - Ginkgo Bioworks
- Health System Care and Resource Deployment
    - Beth Israel Lahey
    - Partners HealthCare

With assistance from United States of Care.

This handbook defines TTSI programs and reviews how to:

1. **Set targets** for testing and contact tracing and make sure people have the right metrics for measuring progress on all of these
2. **Inventory sample collection modalities**; assess capacity; and fill gaps in sample collection capacity and collection kit supply
3. **Inventory testing capacity** in state and develop a supply chain support strategy and gap filling strategy for test capacity
4. **Connect test data** to contact tracing programs; and monitor progress in disease mitigation and suppression for decision-making and public communication
5. **Set up and run** contact tracing programs that successfully connect contacts to tests;
6. **Build** a program of supported isolation
7. **Inventory and assess** test funding mechanisms and fill funding gaps
8. **Run public communications programs** so that the public understands the importance of participation and how broad confidence and safety are secured this way

Because COVID response is fast changing with significant learning from week to week, we are releasing this version 1.0 as a living document in pdf form. We anticipate that it will be updated on a weekly basis.

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INTRODUCTION

What is a TTSI program? A TTSI program uses diagnostic testing (T), contact tracing (T), and supported isolation (SI), to **mitigate** or **suppress** highly infectious and dangerous diseases where the diseases have both a long incubation period and a relatively short disease course.

TTSI programs can be used to **mitigate** the disease. This means that the programs are used to help reduce prevalence of the disease alongside other non-pharmaceutical interventions such as stay-at-home orders. Mitigation does NOT bring prevalence to zero, but only slows disease spread. In the long term, it is more costly in time, testing resources and economic losses than suppression. Moreover, pursuing mitigation will make it hard to open schools, churches, and other congregate contexts without experiencing outbreaks within those organizations.

TTSI programs can also be used to **suppress** the disease. This means the programs are used at a sufficiently large scale to suppress the disease and drive prevalence to zero, providing a foundation on which to restore a vibrant economy.

TTSI programs have historically been used for diseases like tuberculosis and measles. Testing and contact tracing themselves have also historically been used for syphilis and HIV AIDS. The longer disease course of these latter diseases has meant that isolation has not been a part of the testing and tracing response to those diseases.

In TTSI programs, isolation is “supported” with pay, on an analogy to jury pay and/or income replacement for low wage workers; with residential facilities where necessary; and with access to healthcare, food provision, etc. The reasons for these supports is that these isolation programs are voluntary, not enforced by misdemeanor or criminal penalties. They are incentivized rather than enforced. The reason for this design is to ensure that our disease fighting tools are compatible with maintenance of a free society. We should all expect to contribute to and participate in isolation programs as part of the set of rights and responsibilities that define our roles as members of a free society.

Importantly, the design of TTSI programs reflects specific features of COVID as a disease. With COVID, infected individuals shed virus for roughly two weeks to one month. Moreover, roughly 50% of COVID transmission occurs when individuals are asymptomatic or pre-symptomatic. In other words, many people unwittingly pass COVID on. This is what makes the disease so highly infectious and difficult to contain.

A TTSI program is NOT a universal testing program. It is NOT a random testing program.

TTSI is instead the strategic and targeted use of diagnostic testing and contact tracing resources where they will make the greatest marginal contribution to disease suppression and drive prevalence of the disease back as close to zero as possible. While antibody testing could be folded into a TTSI program, this handbook does NOT address antibody testing.

In TTSI programs, symptomatic people or people who believe they have been exposed to the disease present at clinics or testing sites for a diagnostic test. 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.

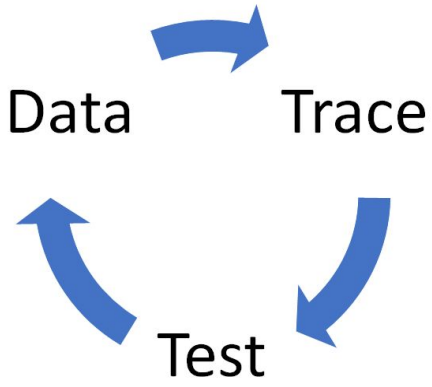
Again, **participation is voluntary** but public messaging needs to drive home the importance of contributing to the fight against COVID through acceptance of getting a test if one has been identified as a contact of an infectious person. As with the originally presenting symptomatic individual, for any contacts who test positive, their positive test result triggers a further round of contact tracing and testing. If the individual testing positive requires health treatment, they are connected to health resources. If they are asymptomatic or only mildly symptomatic, they are connected to the resources necessary for supported isolation.

TTSI programs also pursue **data-driven targeted testing of hotspots,** such as eldercare facilities, nursing homes, and correctional facilities. 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.

In addition to **diagnostic testing of chains of contacts** that start from patients who present with symptoms or individuals who have experienced exposure, 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 residential settings such as colleges and universities 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. The goal of a TTSI program is to drive disease prevalence low enough that the general public can feel a strong sense of confidence and safety in resuming ordinary workplace activities.

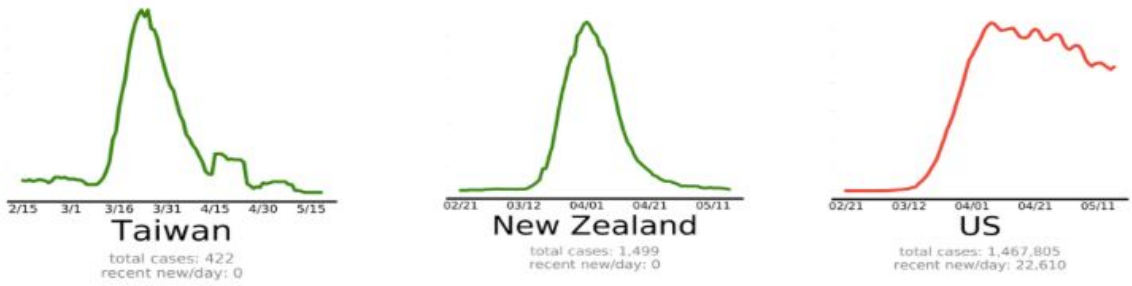
This visualization captures the TTSI process:



TTSI programs can be used to **mitigate** the disease. This means that the programs are used to help reduce prevalence of the disease alongside other non-pharmaceutical interventions such as stay-at-home orders.

TTSI programs can also be used to **suppress** the disease. This means the programs are used at a sufficiently large scale to suppress the disease, making stay-at-home orders no longer necessary, and providing a foundation on which to rebuild a vibrant economy.

Governors and state public health officials need to clearly determine whether they are pursuing a path of mitigation or suppression and need to communicate their choice of pathway to the public. The contrast between a suppression strategy and the current mitigation strategy of the U.S. is visible in these graphs:



SOURCE: https://www.endcoronavirus.org/

Additionally, given the prolonged risk of exposure and comparatively slow rate of case reduction, a mitigation strategy drastically increases the need and demand for personal protective equipment (PPE) both in and outside of healthcare facilities.

SECTION ONE: SETTING TTSI TARGETS

Step 1: Understand your baseline: Determine whether your jurisdictions are green (low prevalence), yellow (moderate prevalence), or red (high prevalence). This information should be routinely communicated to the public.

Prevalence can be best measured and communicated with two measures: **new case trend** and **active infections**. Both should be used and they should be used and communicated to the public in tandem. The active infections number will determine whether your jurisdictions are green, yellow, or red.

a. **New case trend:** 14 day rolling average of new confirmed cases, coupled with an up, down, or steady state arrow, and degree of change.

Example:

b. **Population prevalence of active infections**: (14 day rolling average of new cases x 14)/population and normalized to per 100,000, coupled with an up, down, or steady state arrow, and degree of change.
c. **Population prevalence check (for internal decision-making purposes)**: (14 day rolling average of deaths * 100)/population and normalized per 100,000.
    i. A large gap between b and c suggests testing levels are insufficient to use the case load indicator. Death-based metrics and communication should be used instead. While this death-based **prevalence** indicator is for internal purposes, jurisdictions will want to report daily and total deaths publicly.

Low prevalence/ green zone: Fewer than 10 out of every 100,000 over two weeks have COVID.

Moderate prevalence/ yellow zone: 10 to 99 out of every 100,000 over two weeks have

COVID:

High Prevalence/ red zone: 100 + out of every 100,000 over two weeks have COVID.

Step 2: Make a strategic choice: Mitigation or Suppression

If you are in a green zone, you can operate a steady-state TTSI infrastructure that delivers **maintenance** by being prepared to handle and suppress outbreaks fast, should they arise.

If your jurisdictions are yellow or red, you will need to **surge TTSI infrastructure** and you have to make a strategic choice about whether to pursue mitigation or suppression.

Mitigation = some reduction in the rate of R (the reproduction rate of the virus) through diagnostic testing and contact tracing.

Suppression = an effort to get to (near) zero prevalence.

Both mitigation and suppression require a suite of activities ranging from stay-at-home advisories to mask wearing to TTSI implementation. TTSI is a tool that can be deployed at either mitigation or suppression levels.

However, we strongly recommend jurisdictions that have the capacity to deliver suppression-level surge resources for TTSI to pursue a suppression strategy as they will be on the most efficient path toward a restored economy without future lockdowns.

Step 3: Understand Your Tools

TTSI tools consist of four categories:

- **diagnostic tests (see section 2-3)**
- **contact tracing programs (sections 4-5)**
- **supported isolation programs (section 6)**
- **funding and public communications resources (sections 7-8)**

These tools may be needed at both maintenance levels and surge levels.

Maintenance levels of TTSI resources are used in jurisdictions that are green to contain spikes and outbreaks. In green zones, the goal is to have adequate TTSI resources to stop community spread.

Surge levels of TTSI resources are needed once there is community spread. Yellow and Red Zones are both contexts with community spread. Both these zones need “surge” levels of TTSI resources to drive the disease back close to zero prevalence. Once a community has

progressed along the path to zero and returned to green zone status, the levels of testing capacity and contact tracing it needed should dramatically decline.

A **mitigation surge** targets broad and accessible testing, a test positivity rate of 10%, and for 60% of positives not coming from critical context testing to have come from contact tracing. (The positivity rate is the rate at which diagnostic tests return positive results.)

A **suppression surge** targets broad and accessible testing, a test positivity rate of 4%, and for 80% of positives not coming from critical context testing to have come from contact tracing.

> Successful suppression efforts work fast to restore jurisdictions to near-zero prevalence in a matter of 1-2 months. In other words, surge testing and tracing resources is a **temporary** need; only **maintenance** levels are permanent.

Here are the recommended levels of maintenance (green), and surge suppression TTSI resources (yellow and red):

ZONES	TTSI LEVEL	TRACING PERSONNEL NEEDED	ANTICIPATED TEST VOLUME
Green	**Maintenance**	30 contact tracers/100,000 people	10 daily tests/100,000 people
Yellow	**Suppression**	300 tracers*two-week rolling average of daily deaths	2500 tests*two-week rolling average of daily deaths + state-specific pooled testing in critical contexts
Red	**Suppression**	300 tracers*two-week rolling average of daily deaths	2500 tests*two-week rolling average of daily deaths + state-specific individual testing in critical contexts

Box 1. TTSI Resources at Maintenance and Suppression Levels

N.B.: The surge level of contact tracers needed is very substantial. Most jurisdictions will find it valuable to educate the public on how to do DIY contact tracing. This will provide an important expansion to the corps of contact tracing personnel. The volume of resources needed in red jurisdictions explains why the strategy often falls back to mitigation, yet it's important to

remember that suppression can be pursued in yellow zones even if mitigation has been chosen for red zones.

Step 4: Set Your Priorities

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.

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 state-wide testing and tracing and hotspot testing and tracing. If supported with a sufficient supply of testing capacity and contact tracers, this program should suppress the disease and drive prevalence 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 prevalence 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, 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, prevalence should be sufficiently low that organizations of this kind could rely on weekly pooled testing to catch outbreaks.

Step 5: Set Your Targets

To set your targets, you use the formulae in Box 1 above. Here is a sample targeting chart for Massachusetts built on the basis of June 1 prevalence levels:

State of Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	2,288	343	ongoing
AND				
Surge for Mitigation	10%	71,748	2,068	From May 15-indefinite
OR				
Surge for Suppression	4%	321,994	39,326	July 1 - July 31
Barnstable, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	71	11	ongoing
AND				
Surge for Suppression	4%	4,271	534	July 1 - July 31
Berkshire, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	42	6	ongoing
AND				
Surge for Suppression	4%	1,800	228	July 1 - July 31
Bristol, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	188	28	ongoing
AND				

Surge for Suppression	4%	24,086	2,947	July 1 - July 31
Essex, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	263	39	ongoing
AND				
Surge for Suppression	4%	47,500	5,779	July 1 - July 31
Franklin, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	23	4	ongoing
AND				
Surge for Suppression	4%	975	124	July 1 - July 31
Hampden, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	155	23	ongoing
AND				
Surge for Suppression	4%	19,482	2,384	July 1 - July 31
Hampshire, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	54	8	ongoing
AND				
Surge for Suppression	4%	4,048	502	July 1 - July 31
Middlesex, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	537	81	ongoing
AND				
Surge for Suppression	4%	70,257	8,592	July 1 - July 31

Norfolk, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	236	35	ongoing
AND				
Surge for Suppression	4%	25,921	3,181	July 1 - July 31
Plymouth, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	174	26	ongoing
AND				
Surge for Suppression	4%	26,096	3,184	July 1 - July 31
Suffolk, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	268	40	ongoing
AND				
Surge for Suppression	4%	60,946	7,394	July 1 - July 31
Worcester, Massachusetts				
	Positivity Rate	Tests Per Day	Tracers Needed	Timetable
Maintenance	4%	277	42	ongoing
AND				
Surge for Suppression	4%	36,611	4,476	July 1 - July 31

N.B. There is a trade-off between volume of tests and time needed for a mitigation vs. a suppression strategy. The Boston area has the highest degree of prevalence in Massachusetts. It would require a significant volume of tracing and testing to achieve suppression. The benefit to pursuing this, despite the volume of tracing and testing needed, would be the speed with which prevalence could be brought back to nearly zero.

SECTION TWO: INVENTORYING SAMPLE COLLECTION MODALITIES

To run a successful TTSI program, it is important to ensure that there are enough sample collection sites to meet the state's targets and that all of the sample collection sites are integrated with public health data systems so that key performance indicators for sample collection can be tracked.

Samples are collected in (1) traditional healthcare settings, (2) new public testing clinics, (3) at-home (still to come); and (4) in congregate living settings and businesses, schools, office, and other potential locations of routine collection.

Some sample collection modalities involve **sending samples to a lab for analysis (centralized processing).** Some involve **point-of-care processing of results.** It is important to track the volume of both kinds of tests in each jurisdiction.

Sample collection sites that send samples to a central lab for analysis introduce a challenge of the speed at which results are returned as well as questions about whether the samples are fully accessioned at the point-of-collection or in the lab. The former methodology increases lab capacity.

Point-of-care collection sites introduce a challenge for the integration of results data with your public health data systems.

Charts such as the following can assist the effort to synthesize your data:

Sample Collection Modalities for Centralized Processing					
Modality	Currently in use in state?	Number of sites	Average daily # of samples collected	Accession methodology- individual or batched	Maximum daily # of samples that could be collected
Traditional Health Care Setting					
Primary care physicians					
Clinics- Urgent Care/ CVS/ Walmart/ Rite-Aid					
Community Health Centers, including Federally Certified Health Centers					
Public Testing Sites					
Drive-thrus					
Walk-ups					
Mobile Sites					
Mobile Pop-up Sites					
At-Home Tests					
Home Collection- Mail-in Results					
Routine Testing Sites					
Businesses					
Elder Care Facilities					
Correctional Facilities					
Schools					

Sample Collection Modalities for Point of Care Processing					
Modality	Currently in use in state?	Number of sites	Average daily # of samples collected	Data integrated with Public Health Systems?	Maximum daily # of samples that could be collected
Traditional Health Care Setting					
Primary care physicians					
Clinics- Urgent Care/ CVS/ Walmart/ Rite-Aid					
Community Health Centers, including Federally Certified Health Centers					
Public Testing Sites					
Drive-thrus					
Walk-ups					
Mobile Sites					
Mobile Pop-up Sites					
At-Home Tests					
Home Collections	N				
Routine Testing Sites					
Businesses					
Elder Care Faciltiies					
Correctional Facilities					
Schools					

CASE STUDY: NEW ORLEANS TESTING STRATEGY

New Orleans was one of the first municipalities to develop a city-wide testing strategy in mid-March following confirmation from the Health Department of communal spread. The city's Phase One strategy featured a traditional testing model of a fixed location with drive through testing staffed by national Health and Human Services (HHS), Federal Emergency Management Agency (FEMA), state and local personnel.

New Orleans soon recognized limitations of the Phase One model **in reaching residents who could not access the fixed location**, who lacked a Louisiana ID or symptom criteria, or who were anxious about visiting the site.

The city quickly moved to implement Phase Two of its testing strategy by deploying mobile testing units to neighborhoods staffed by locals. These units move to areas where the virus is spreading fastest or where barriers to testing are greatest. The mobile units allow for drive through and walk-up testing, providing multiple ways for residents to access tests.

Phase Two removed Phase One ID/insurance and symptom requirements to test. Local health personnel provide on-site needs assessment and resources from the mobile units. Trained local personnel provide callbacks on test results and are having more success getting through to residents and directing them to local resources than the national callback center of Phase One.

This mobile approach has resulted in New Orleans testing site demographics generally reflecting the city's demographics. It has also allowed local officials to constantly reassess areas to identify emerging high-risk groups and testing gaps.

New Orleans' Phase Three strategy will incorporate "hyper mobile" pop-up testing at locations with the highest risk of outbreak or the highest risk individuals, including nursing homes and senior apartment buildings, homeless shelters, low-income developments, and other congregate settings. The hyper-mobile pop-up model allows for nimble and flexible test site set-up. The hiring of New Orleanians to staff these units provides cultural competence to the testing environment that helps build trust with those being tested.

Public transparency has been critical to the success of New Orleans testing strategy. The New Orleans Health Department created a testing dashboard accessible to the public through the existing municipal government communications channel used by residents to get information on emergencies and natural disasters (https://ready.nola.gov/home/).

Overall Testing Strategy

Traditional health care system testing:
Fixed location – shifting requirements – limited resources

greatest capacity to reach residents but most restrictive

increased ease of access/fewest barriers

highest risk individuals

Drive through testing

Neighborhood mobile testing

Elderly & vulnerable congregate settings

Goal: test 4-5% of population each month (500+ daily)

Over 10% of total population tested since March 9

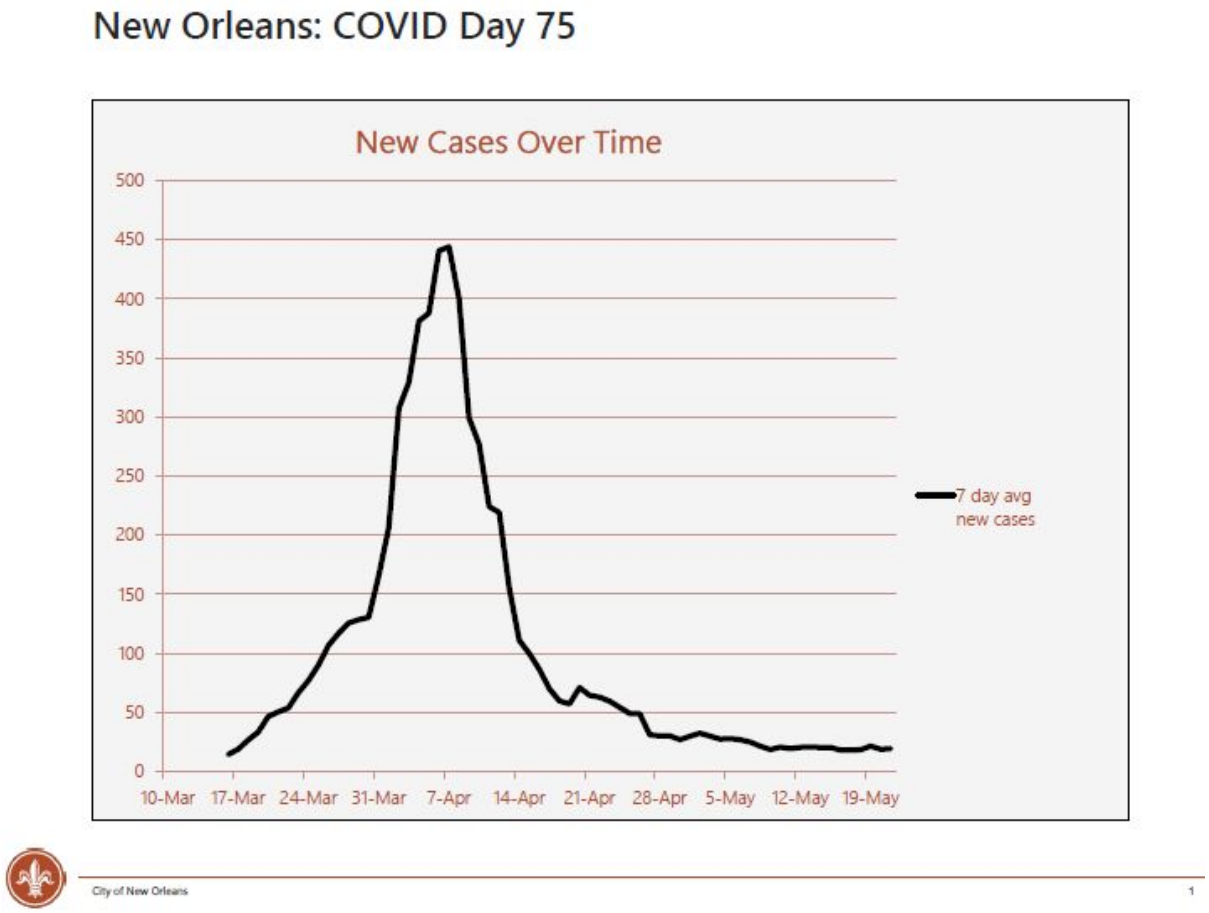
City of New Orleans 2

New Orleans Milestones: Public Transparency

Public-facing dashboard at NOLA Ready

City of New Orleans 13

The effectiveness of the city's rapid testing and tracing strategy is visible through the sharp peak in cases in late March/early April followed by a rapid decline in new cases. With the mobile testing strategy, health department officials can quickly mobilize testing resources to suppress new outbreaks (20 April in below chart).

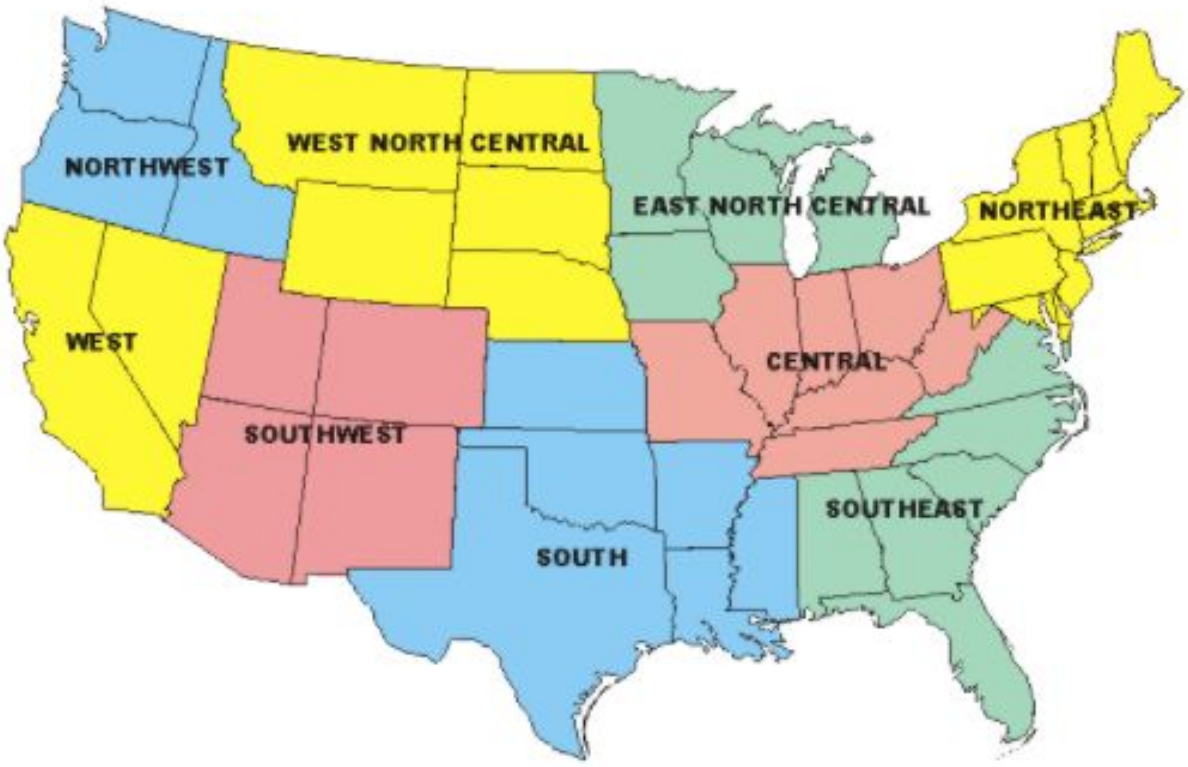


SECTION THREE: INVENTORYING OF TEST PROCESSING CAPACITY

The hardest element of establishing a TTSI program may be aligning testing capacity with sample collection volume. It is not reasonable to expect jurisdictions to conduct this inventory below the level of the state. The state should take on responsibility for securing sufficient lab capacity for all jurisdictions within it.

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

To achieve this, the state needs to inventory testing capacity available to it and to identify gaps. Importantly, this inventory process should take into account labs available regionally and not just within the state itself. While the need for 24hr turn around on test results puts a geographic limit on how far away a lab can be from a sample collection site, some regional collaboration should be possible, particularly for high density population areas within one of the regions below.



Low population density locations should expect to make much greater use of point-of-care machines.

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.

Four types of test detect the presence of viral RNA:1:

Real-Time quantitative Polymerase Chain Reaction (RT-qPCR).

Isothermal Nucleic Acid Amplification Technologies (iNAAT).

Next-Generation Sequencing (NGS)

CRISPR-based methods

Two types of test (antigen tests) use highly specific proteins called antibodies to bind viral antigens very tightly:

Enzyme-Linked ImmunoSorbent Assay (ELISA

Lateral Flow Assay (LFA)

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

SARS-CoV-2 Testing Methods						
Component Detected	*Viral RNA*				*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
Current US Tests/Day	~200,000	~5,000	0	0	0	Thousands
Projected Aug. 2020 Tests/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 Hours (Centralized) Minutes (PoC)	24-48 Hours (Centralized) Minutes (PoC)	24–48 Hours	Minutes	24–48 Hours	Minutes
Sample Type	Nasal Swab or Saliva	Nasal Swab	Nasal Swab or Saliva	Nasal Swab	Unknown	Nasal Swab
Quantifies Viral Load	Yes	No	Yes	No	Yes	No
Key Scale-Up Barrier	Reagent/Kit Availability	Reagent/Kit Availability	Logistics	Novel Technology	Assay Development	Assay Development
Regulatory Status	EUA	EUA	EUA pending	EUA	Unknown	EUA
Supply Chain Risk	Medium	High	Low	Medium	Medium	Low
Representative Companies	• LabCorp • Quest • Roche • Thermo Fisher	• Abbott • Hologic • Atila Bio	• Broad Inst. • Illumina • Hudson Alpha • Ginkgo	• Mammoth • Sherlock • Broad Inst.	• 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

In this analysis, key performance factors such as clinical accuracy and turnaround time are evaluated as well as key deployment factors such as current and future tests per day projections and supply chain risks. The availability of new or improved testing modalities will continue to be dependent on FDA authorization through their emergency guidance policies. Also, as has been experienced with PPE, the supply chain for key components (e.g. test swabs, reagents, etc) will continue to limit sample collection and processing capacity.

In order to evaluate the potential impact of thest test modalities and evaluate which option(s) are most likely to scale in order to prioritize resources and time, a qualitative-to-quantitative trade-off analysis can be performed. Note that the 2 time horizons chosen for the evaluation are Q3 2020 and Q4 2020 which yield different outcomes based on the selected evaluation factors.

For this analysis, clinical accuracy, turnaround time, and number of tests per day were evaluated; assigning a value to each factor on a 0 to 5 scale.

Note that supply chain risk was not included as we anticipate supply chain disruption in some form for each test modality. As such, supply chain risk can be mitigated by pursuing more than 1 test modality.

Test Modality			Accuracy (High = 5 Low = 1)	Turnaround Time (Minutes = 5, >48hrs = 1)	Q3 2020	Q4 2020
					Tests/Day (1M+ = 5, <5K = 1)	Tests/Day (1M+ = 5, <5K = 1)
Viral RNA	RT-qPCR	Centralized	5	2	2	3
	RT-qPCR	PoC	5	4	1	2
	iNAAT	Centralized	5	2	1	2
	iNAAT	PoC	5	4	0.5	2
	NGS	Centralized	5	2	0	4.5
	CRISPR	PoC	3	5	0	1
Viral Protein	ELISA	Centralized	1	2	0	1
	LFA	PoC	1	4	0.5	2

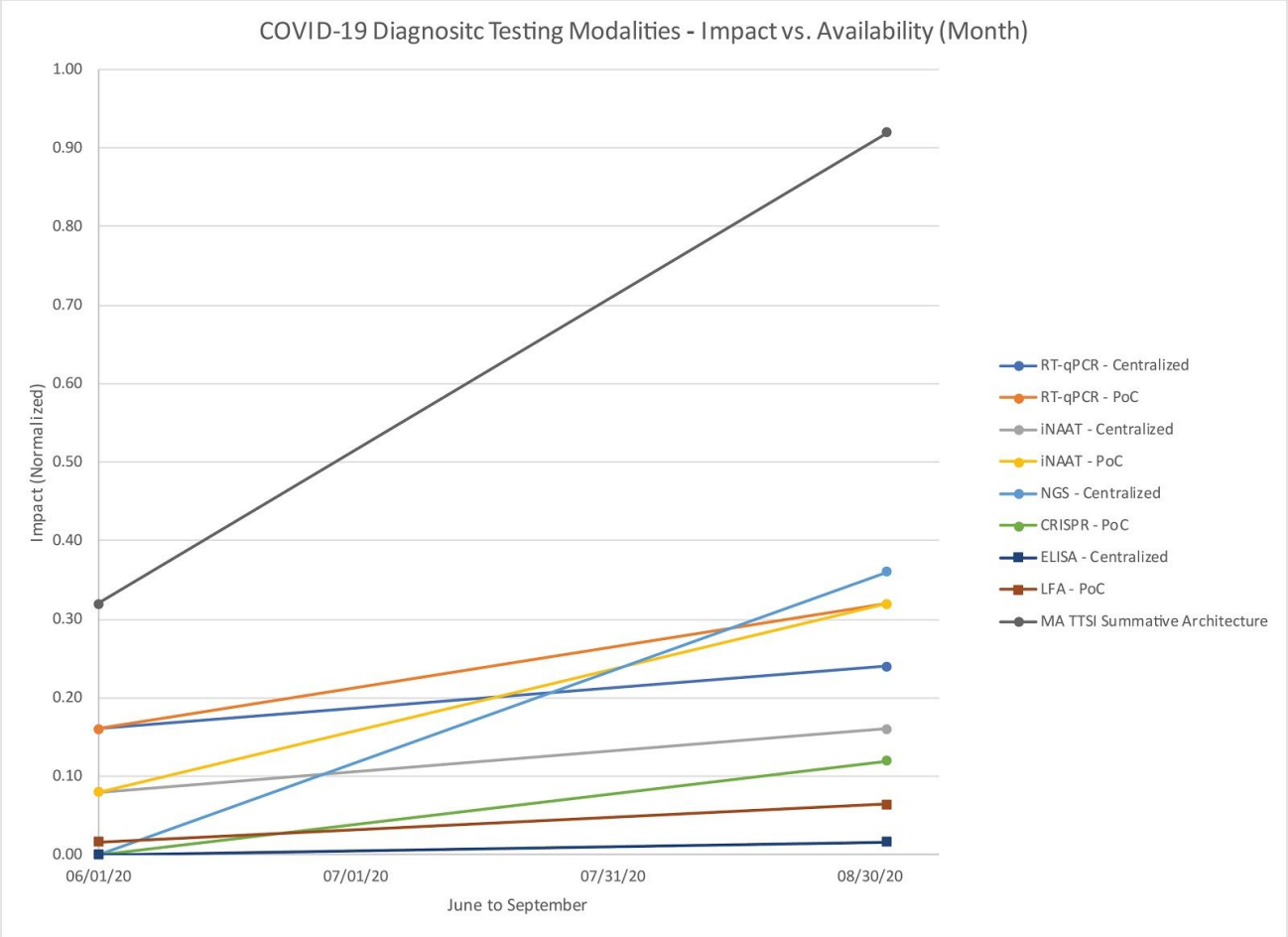
A utility function that combines multiple factors into 1 variable was created to assess the primary trade-offs we are considering when investing time and resources into scaling testing.

Impact = (Clinical Accuracy) x (Turnaround Time) x (Tests/Day)

The derived Impact value can be normalized by dividing by the highest possible product in order to provide a 0 to 1 range for comparison. The Impact value was derived for all test modalities for both Q3 2020 and Q4 2020.

Test Modalities		Q3 2020		Q4 2020	
		Month Value	Impact (Normalized) = Accuracy x Turnaround Time x Tests/Day	Month Value	Impact (Normalized)= Accuracy x Turnaround Time x Tests/Day
Viral RNA	RT-qPCR - Centralized	06/01/20	0.16	09/01/20	0.24
	RT-qPCR - PoC	06/01/20	0.16	09/01/20	0.32
	iNAAT - Centralized	06/01/20	0.08	09/01/20	0.16
	iNAAT - PoC	06/01/20	0.08	09/01/20	0.32
	NGS - Centralized	06/01/20	0.00	09/01/20	0.36
	CRISPR - PoC	06/01/20	0.00	09/01/20	0.12
Viral Protein	ELISA - Centralized	06/01/20	0.00	09/01/20	0.02
	LFA - PoC	06/01/20	0.02	09/01/20	0.06
MA TTSI Summative Architecture		06/01/20	0.32	09/01/20	0.92

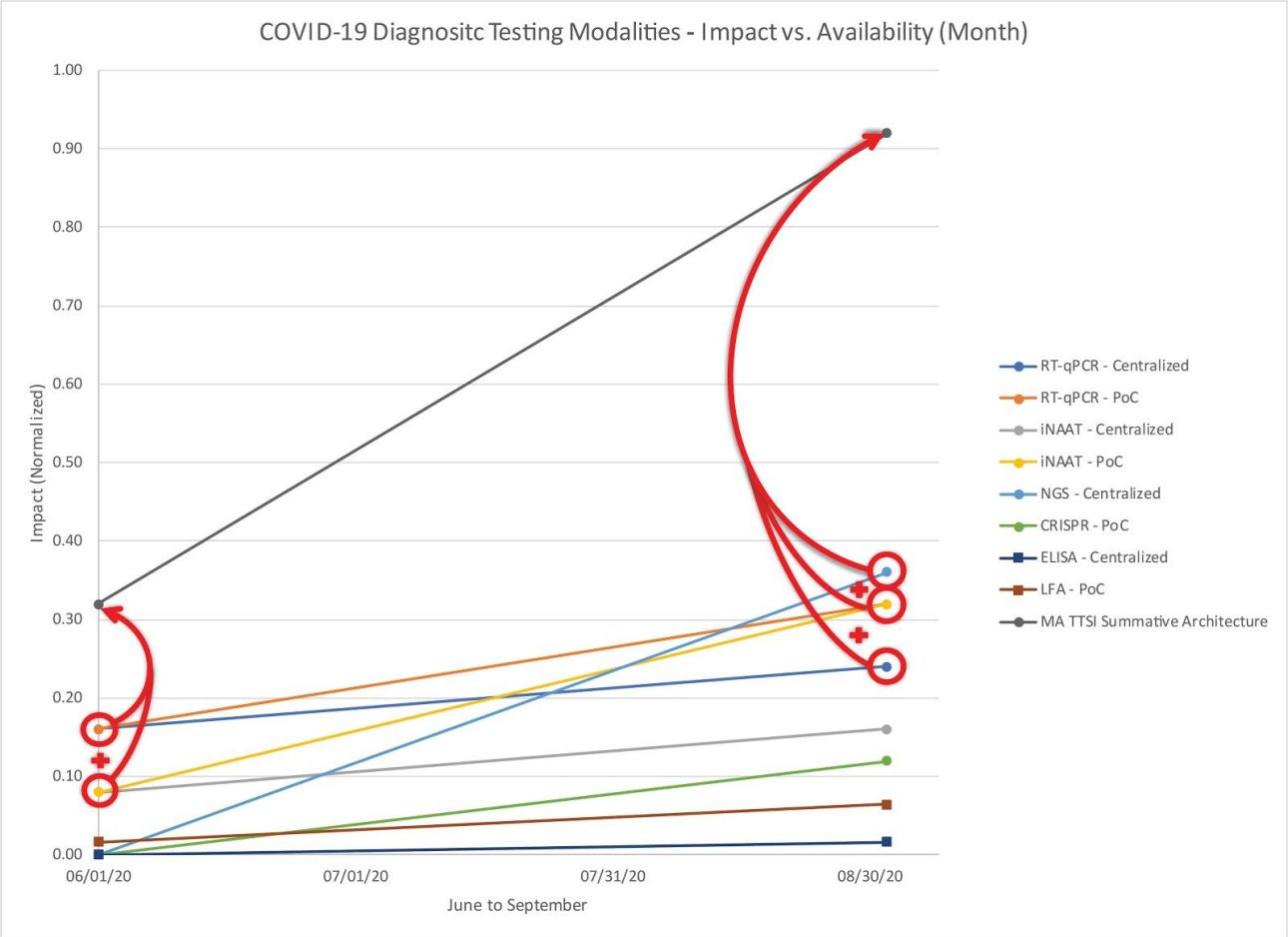
By plotting the Impact values against the initial dates of Q3 2020 and Q4 2020, an estimated rate of scaling of each test modalities' Impact can be compared visually.



As mentioned for supply chain risk, there are additional uncertainties for each of these factors. Additionally, this is a semi-quantitative analysis that injects its own level of uncertainty.

As such, mitigations to these risks also provide an opportunity to improve upon the individual Impact of each test modality.

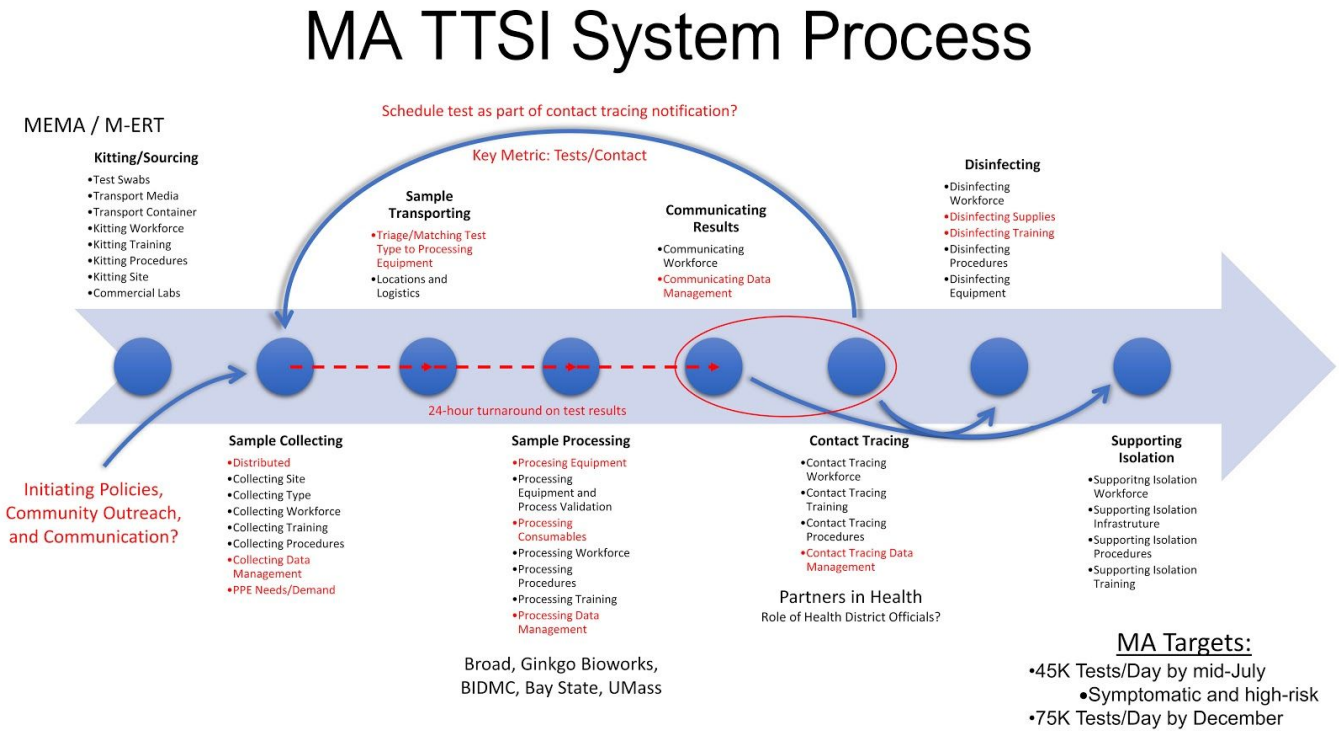
Instead of pursuing an either-or strategy of solely using 1 test modality, a greater Impact can be achieved through the summative Impact of combining multiple testing modalities into 1 strategy.



The MA TTSI Summative Architecture strategy aims to pursue multiple testing modalities in parallel to maximize Impact and reduce the risks of supply chain disruption or scaling delays.

For Q3 2020, the combination of both RT-qPCR Centralized and RT-qPCR Point of Care testing modalities provided a higher level of impact. Additional flexibility in deployment of test processing to more significantly impacted communities now becomes an option as well. Similarly, for Q4 2020, the projected availability of high-volume NGS Centralized testing further increases the strategy's Impact which also takes advantage of scaled capacity of the RT-qPCR tests.

Inventorying test processing capacity also requires inventorying the supply chain supporting testing more generally. Here is an example from Massachusetts:

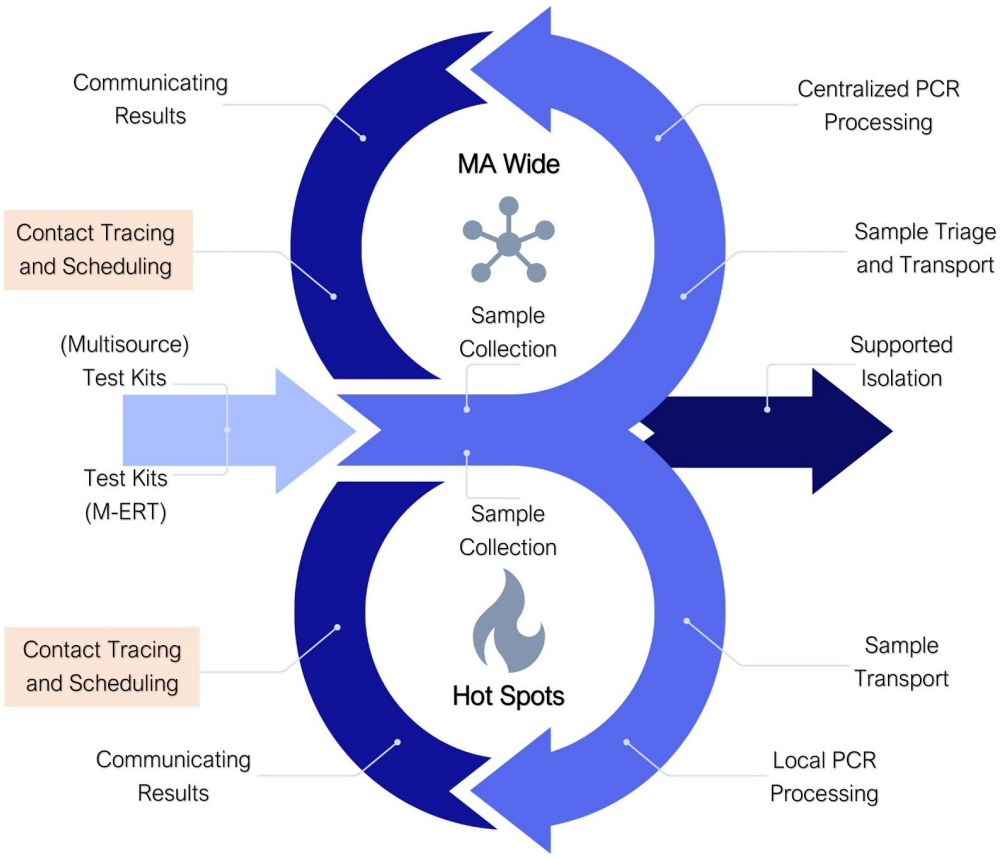


SECTION FOUR: THE TTSI SYSTEM AS A WHOLE, DATA MANAGEMENT, AND REPORTING

A TTSI system depends on a cycle of Test-Data-Trace-Test. Patient test results must flow both into state public health databases for general disease monitoring and into local jurisdiction contact tracing databases to trigger contact tracing work.

The implementation program consists of both a hotspot program and a state-wide tracing and testing program that provide feedback loops between testing, tracing, and testing of new contacts. The contact tracing organization and/or system can be the same for both the hotspot and state-wide programs.

In addition, surge capacity can flow either through centralized, regional lab processing or through point-of-care or more local lab processing. Either way, data flows and speed are fundamental to success.



Here are key metrics for assessing the operations of a TTSI system.

1. **Testing - sample collection metrics**
    a. Access: Everyone can get a free test if they want one but use insurance where available. No requirement for government ID for tests.
    b. KPI for sample collection sites (clinics etc.): % of those seeking tests which are tested and the sample arrives at a lab within 6 hours of requesting to be tested / reporting symptoms.
2. **Testing - sample analysis (labs)**
    a. Turnaround time.
    KPI for labs: % of test results returned within 24 hours of the sample arriving.
    KPI: median time to return test results.
    b. Correctness of test results
3. **Overall tracing effectiveness indicator**
    a. Ratio of new positives found by a tracer (either already isolated or were asked to get tested) to all new positives. Top level metric for local public health services, implemented through a check box by the sample collection site when someone gets a test.
4. **Additional Tracing Indicators**
    a. Number of tracers: 300 tracers x two-week rolling average of daily deaths
    b. % of identified positives who are interviewed within 24 hours of the positive test result coming back.
    c. % of identified contacts who are isolated and tested within 24 hours of the index case test result
    d. % of identified contacts who are isolated and tested within 48 hours of the index case test result.

SECTION FIVE: IMPLEMENTING CONTACT TRACING PROGRAMS

Contact tracing is a tried and true public health methodology, and there are numerous pre-existing resources on this subject.

Contact tracing programs may be run directly by departments of health, through contracts to outside vendors (like Partners in Health in Massachusetts), through community organizations recruited by public health departments (as in the NYC Knows program for HIV-AIDS), and through the development of staff capacity to do contact tracing inside private organizations from businesses to theaters. All this work can be supported by public education about DIY contact tracing. See for instance: https://www.mass.gov/info-details/learn-about-the-community-tracing-collaborative.

Because digital tracing apps are still 2-3 months away from viability, we are not including review of them in this handbook but are focusing on the urgent needs for manual contact tracing personnel.

As of May 19, 2020, the CDC has assembled voluminous resources on contact tracing, available here:

- https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf
- https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/contact-tracing-training-plan.pdf
- Contact Tracing Overview: https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contacttracing.html
- Principles of Contact Tracing: Part of a Multipronged Approach to Fight the COVID-19 Pandemic: https://www.cdc.gov/coronavirus/2019-ncov/php/principles-contact-tracing.html
- (also see PDF booklet: https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/principles-contact-tracing-booklet.pdf)
- Sample Contact Tracing Training Plan: https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/contact-tracing-training-plan.pdf
- Digital Contract Tracing Tools for COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/downloads/ digital-contact-tracing.pdf

- Preliminary Criteria for the Evaluation of Digital Contact Tracing Tools for COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/prelim-eval-criteria-digital-contact-tracing.pdf

Tools and Resources from External Partners

» Association of State and Territorial Health Officials: Making Contact: A Training for COVID-19 Contact Tracers Introductory Online Course: https://learn.astho.org/p/ContactTracer

» Johns Hopkins Bloomberg School of Public Health Center for Health Security: Review of Mobile Application Technology to Enhance Contact Tracing Capacity for COVID-19 https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-sheets/200408-contact-tracing-factsheet.pdf

» National Association of County & City Health Officials: Building COVID-19 Contact Tracing Capacity in Health Departments to Support Reopening American Society Safely: https://www.naccho.org/uploads/full-width-images/Contact-Tracing-Statement-4-16-2020.pdf

In addition to the CDC, several other entities are providing access to documentation, including Partners in Health: https://audaciousproject.org/ideas/covid-19-response/partners-in-health

We expect soon to be able to inventory the following topics across several entities:

Topic	CDC	PIH	NGA	Deloitte	Bloomberg/ Resolve	Rockefeller Fdn
Recruiting personnel						
Hiring						
Redeployment of public employees						
Activation of service personnel						
Recruitment of community organizations						
Organizational self-staffing						
Recruiting community organizations as partners						

DIY activation						
Training personnel						
Coursera MOOC						
Schools of Public Health						
Other Offerings						
Cultural Competency						
DIY Education						
Process Management & Support Tools						
Call Centers						
In-person contact						
Scripts						
Integration with Public Health System						
Relation to Testing (make appointments; do testing)						
Relation to Quarantine/Isolation						
Relation to Active Monitoring						
Relation to Compliance of Contacts with Public Health Department Orders						

Interactions between contact tracing teams and local and state public health departments						
Interactions between contact tracing teams and other service providers relevant to supported isolation						
Ethics						
Safety of contact tracing personnel						
Privacy of contacts						
Data Management						
Other Ethics Issues						

SECTION SIX: PROVIDING SUPPORTED ISOLATION

Every TTSI effort must involve the creation of a robust supported isolation network. Most people facing COVID-19 infection or exposure are able to self-isolate in their own home, but some cannot do so safely or do not have a home. Those with mild to moderate symptoms–who may be travelers, essential workers, people who live with immunocompromised individuals, people in group living settings, or without shelter–can all benefit from supported isolation.

For any effort to be successful, each isolation site must offer more than just shelter. Quality of life, including mental well-being and physical safety, must be accounted for in order to appropriately incentivize and reassure those isolating. To that end, effective supported isolation sites will include no-cost access to:

- Three meals per day that satisfy any dietary restrictions, allergies, and cultural needs.
- Hygiene products and cleaning services, such as laundry services, janitorial services, and deep-cleaning room turnover teams.
- Building security measures and staff.
- Behavioral health care, including regular check-ins; incorporation of essential mental health care may involve the hiring of additional staff, as well as offering training for those unfamiliar with working with unique adult populations. It may also be valuable to weave in telehealth services, which are expanding as reimbursement improves and behavioral health needs rise.
- Substance use disorder care, which can range from retaining the support of an on-call pharmacist to starting people on methadone, if necessary.
- Thoughtful prioritization of quality-of-life resources, including robust internet access, to make the lengthy stay more tolerable and allow people to complete the recommended length of their stay.

When establishing sites and resources for supported isolation, care must be taken to ensure that people will be able to use and access them. It is essential for the locations of the sites to be spread throughout the area served to ensure equitable access. These sites should also be connected to the population by a variety of transportation options. Connection to both transit and the sites themselves will be best managed through referrals from a centralized intake service managed by the local government or public health service.

Staying in an isolation center must also be fiscally possible; wage replacements and small cash incentives are both useful in making isolation a viable option. Workers can be further protected

with expanded paid and unpaid sick leave; New York & New Jersey adopted legislation to this effect in March, and federal action expanding family and medical leave soon followed.

A small sample of locations offering supported isolation facilities that can serve as models:

- California is offering emergency housing for sick and medically vulnerable individuals experiencing homelessness, as well as providing support to isolated individuals through volunteer efforts.
- Chicago, IL is offering access to COVID-19 Isolation Facilities for unsheltered individuals and anyone experiencing symptoms.
- King County, WA, which faced waves of COVID-19 infection before much of the U.S., built a robust network of isolation, quarantine, and recovery spaces in response.
- Massachusetts set up COVID-19 isolation facilities for homeless individuals in hotels across the state.

For additional information, see "USofCare Playbook: Isolation and Quarantine Solutions to Serve At-Risk Populations during COVID-19."

SECTION SEVEN: FUNDING TTSI

As of June 3, 2020, there are several proposals for funding state TTSI programs (eg, Rockefeller, Edmond J. Safra Center for Ethics) including block grants to states for implementation of contact tracing, collaborative networks of states, and formal interstate compacts funded by Congress for test procurement. The goal of these proposals is to increase testing capacity and foster TTSI initiatives, recognizing that these are public goods that will continue to be critically important for months to come. AEI's "Roadmap to Reopening," for example, proposes linking supplemental funding to healthcare providers to increased surge capacity and stronger partnerships with public health authorities in order to contain ongoing and future outbreaks.

Testing the Insured

The Families First Coronavirus Response Act (FFCRA) mandates that testing and related services be entirely covered by all government and private insurance plans. The CARES Act expanded the range of tests and services that insurers must cover at no cost to subscribers, including reimbursing out-of-network providers. CMS increased its reimbursement for COVID tests from $51 to $100 to support testing capacity.

Testing the Uninsured

The FFCRA allocated $1 billion to the National Disaster Medical System to reimburse medical providers for testing uninsured patients, permitting providers to bill the government directly for such services. States and local governments can seek reimbursement for eligible expenses associated with coronavirus testing through FEMA's Public Assistance program.

Contact Tracing

Local and state public health agency funds, including federal emergency response funding/CDC PHEP grants. New funding will be essential to recruiting these individuals at scale. ASTHO has requested an appropriation of $3.6 billion for a 12-month effort. Entry-level personnel could be identified from government employees in other agencies, particularly where these employees have experience working in communities, and where previous workstreams have been limited by the pandemic - including librarians, teachers and other school personnel.

CDC has designated $50 million in a cooperative agreement for an organization to support COVID-19 workforce development. It is unclear if that funding is being used to support this recruitment. To achieve the scale needed to restart and reopen most local and state

jurisdictions, more funding will be needed to support these professional positions in addition to this initial federal investment. [Source: ASTHO Guide]

Supported Isolation

Effective Supported Isolation will require provision of care packages of food, medical supplies, and PPE, assistance with internet access and other services, and/or financial support or paid leave. The FFCRA requires certain employers to provide up to two weeks of paid leave for when an employee is unable to work due to quarantine pursuant to public health orders. State authorities could work with hotels, restaurants and other food services, local internet service providers, and local businesses to provide these services.

Senator King (I-ME) is advocating appropriations in support of this element as follows:

- *Voluntary self-isolation facilities* ($4.5 billion): Some people will not be able to self-isolate in their homes because of the number of people living there or the physical structure of their dwelling. We can use idle hotels and other hospitality infrastructure to deliver this essential public service.
- *Voluntary self-isolation income support* ($30 billion): We must disincentivize infected individuals from engaging with their communities during the period of isolation. For many people, the need to earn money outweighs taking steps to protect their own health and the health of their communities. We must provide income support during the period of self-isolation to ensure maximum effectiveness.

SECTION EIGHT: PUBLIC COMMUNICATION IN SUPPORT OF TTSI

The success of a voluntary TTSI program depends on the public's understanding of their role in the mitigation and suppression of the disease. Coordinated communication efforts are essential for people to understand why they may be called by a contract tracer, when and where to get tested, who will pay for the test, and how those who test positive allow their community to stay open by entering supported isolation.

TTSI communication campaigns need to come from both state agencies and local health departments. States should develop and share with communities communication materials to support TTSI efforts, such as brochures, posters, op-eds, blogs, public service announcements and success stories, and work with media and community engagement specialists to ensure public understanding, appreciation and buy-in for contract tracing as a critical measure for stopping the spread of the disease. See below for a detailed communication strategy.

The Path to Zero Is the Path of Hope

Together to a Better Tomorrow

It's in your power to reduce the death and harm in your community.

What's Our Prevalence Level/Trend?	What's the #1 most important individual action?	What's our collective policy goal with regard to the virus?	What's our collective goal with regard to the health care system?
Red	Stay at home	Flatten the Curve	Get PPE to the Frontlines Get Ventilators Keep the Healthcare System from Getting Overwhelmed
Yellow	Wear a Mask Take the Call	Break the Chain	Enlist communities to support contact tracing

	Know Your Status Get a Test Warn Friends and Neighbors about Exposure		Train communities to do contact tracing Enroll contact tracers Support Isolation Activate all our labs
Green	Know Your Status Take the Call Get a Test Warn Friends and Neighbors about Exposure	Contain the Spike Block a Second Wave	Keep the contact tracing going Build community health

Components of a TTSI Communication and Community Engagement Strategy:

1. **Provide** your contact tracing corps and skilled contact tracers with training and material that ensure people who engage with contact tracers feel supported and protected and receive empathetic, culturally appropriate engagement in an accessible language.
2. **Determine** messages and channels for relaying messages to different audiences.

a) cases, contacts, high risk settings and health care providers.

- Support cases and contacts while in isolation and quarantine to ensure they have the information needed to stay safe and adhere to public health recommendations.
    - Share new information on the COVID-19 situation in the area.
    - Reiterate and update on health and safety recommendations.
    - Link to information sources, including official websites, press briefings and hotline.
    - Consider using email or text messages for sharing messages (or digital apps as relevant).
    - Provide fact sheets, FAQs and other educational resources

- Target messages to specific audiences, including COVID-19 cases and contacts, high-risk communities such as long-term care facilities and group homes, and health care providers and hospitals.
- Make materials available in multiple languages according to local needs.
- Send notifications to health care providers when there are changes to procedures or policies relating to provision of health care, laboratory testing, treatments, or vaccines.

b) the general public

- Communicate widely via public information campaigns, using mass media, web sites and digital media to explain contact tracing and its impact.
- Engage journalists and consider journalist briefing calls to ensure journalists understand the program and are reporting factual and timely information.
- Use mass media and digital communication campaigns to build awareness of how contact tracing is helping us all get to a better tomorrow.
- Use official health department social media handles to amplify messaging.
- Develop communications campaigns that explain the contact tracing and testing process and how personal information is protected.
- Develop a “Take the call” campaign that shows the importance of answering calls and engaging honestly with contact tracing staff in the era of spam calls.

3. **Engage** community leaders by identifying people that communities trust, such as faith and ethnic group leaders, business leaders, leaders within vulnerable populations, teachers, public officials and others. Build relationships with them, and enlist them as validators of your contact tracing messages. You can engage community leaders by:
    - Establishing a mechanism for feedback to refine messaging and tactics
    - Sharing communication plans and approaches
    - Sharing official fact sheets and other communication tools
    - Encouraging them to participate in press briefings
    - Encouraging and supporting them to share official public health notifications, recommendations and other messages with their communities. Community leaders can use existing communication channels (such as social media and email newsletters) and establish new channels
4. **Understand** risk communication principles and apply them.
    - Express empathy often. COVID-19 is scary, and spokespeople should acknowledge that. People may find it invasive to consider sharing information about who they’ve been in contact with. Be sure to empathize with the public about the downsides of contact tracing, while reminding people of the benefits to their family, neighbors, friends and communities.
    - Communication that expresses empathy, is credible, provides anticipatory guidance, promotes action, and shows respect will help build trust.

5. **Respect** confidentiality. Communication on every level needs to address and allay public concerns about privacy and confidentiality.
6. **Establish** a centralized mechanism to manage communication.
    - Depending on the size of the community and communication needs, a small team may be needed to support the various activities and coordinate with external stakeholders (e.g., community leaders, media outlets).
    - The centralized mechanism should be linked with health department staff responsible for monitoring and analyzing the epidemic science and situation. This will ensure communications are accurate and up-to-date.
7. **Evaluate** and improve communication effort. Assess what's working and what's not working to improve communication messages and strategies.

(Sources: Resolve to Save Lives, CDC, Science Friday, HGHI)

Comments, suggestions, corrections should be directed to:

globalhealth@harvard.edu with subject line TTSI Handbook.