# Reopening the United States

Developed by TeamHealth Emerging Infectious Disease Task Force Updated May 5, 2020



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## **INTRODUCTION**

Due to the many unknowns related to the current COVID-19 pandemic, determining the right timing and approach to opening America again has proven to be quite challenging. Because of the lack of testing capacity and a continued lack of adequate knowledge regarding SARS-CoV2 infectivity, we do not have insight into the true population still at risk as we begin reopening. While most states have managed COVID-19 patient critical care surges during this initial wave, a handful were overwhelmed. Additionally, it is likely that our hospitals were able to handle the demand to some degree because it was blunted due to social distancing. Another potential factor is that the SARS-CoV2 virus likely has a lower overall case fatality rate than initially feared. The role that each of these factors had in the evolution of the pandemic and the future of the pandemic remains to be fully defined.

## THE WHITE HOUSE FRAMEWORK

## THREE PHASES

The White House framework for reopening America involves three phases that are each gated by 14-day cycles of declining incidence and prevalence of disease and lack of evidence of recurrence. Each phase has guidance for individuals, employers and special employers along with progressive loosening of social distancing measures. There is acknowledgement that special considerations are necessary for vulnerable populations. They define vulnerable populations as: 1) elderly individuals and 2) individuals with serious underlying health conditions, including high blood pressure, chronic lung disease, diabetes, obesity, asthma, and those whose immune system is compromised such as by chemotherapy for cancer and other conditions requiring such therapy.

		-	-	-
	Category	Phase 1	Phase 2	Phase 3
	Vulnerable individuals	Shelter in Place	Shelter in Place	Resume public interactions with distancing
Individuals	All individuals in public	Maximize physical distance	Maximize physical distance	Consider avoiding crowds
	Group socializing	Avoid groups of > 10 people	Avoid groups of > 50 people	Consider avoiding crowds
	Travel	Minimize non-essential travel	Non-essential travel can resume	No restrictions
	Telework	Encourage	Encourage	
	Return to work in phases	If possible	N/A	
Employers	Common areas	Closed	Closed	Resume Unrestricted Staffing
	Travel	Minimize non-essential travel	Non-essential travel can resume	
	Vulnerable populations	Special accommodations	Special accommodations	
	Schools, Daycare, Camp	Closed	Reopen	Open
	Senior Living	No visitors, strict worker hygiene	No visitors, strict worker hygiene	Resume visits with diligent hygiene
Special	Large Venues	Strict physical distancing	Moderate physical distancing	Resume with limited physical distancing
Employers	Elective Surgeries	Can resume	Can resume	Resume
	Gyms	Open with distancing and sanitation	Open with distancing and sanitation	Open with sanitation protocols
	Bars	Closed	Open with diminished standing	Open

Each phase is gated by a 14-day period of declining disease incidence and absence of re-emergence

Source: https://www.whitehouse.gov/openingamerica/

## GATING CRITERIA

There are three gating criteria: 1) symptoms, 2) cases and 3) hospitals. The gating criteria for symptoms include: 1) downward trajectory of influenza-like illness (ILI) and 2) downward trajectory of COVID-like syndromic cases, both over a 14-day period. Similarly, the gating criteria for cases reflects a similar decrease over a 14-day period of: 1) documented COVID-19 cases and 2) positive tests as a percent of total tests. The hospital criteria include: 1) the ability to treat all patients without crisis care and 2) a robust testing program in place for all at-risk healthcare workers (HCW), including emerging antibody testing.



Source: https://www.whitehouse.gov/openingamerica/

## THREE COUNTRIES OPENING UP

As of April 23, several countries had announced or had already begun to move towards reopening. Several states in the United States have also announced plans to start gradual reopening.

#### CHINA

China ended its lockdown on April 5, two months after their peak number of daily new cases and six weeks after their peak number of active cases.





Daily Cases

## Active Cases in China



## DENMARK

Denmark reopened schools the week of April 13, two weeks after their peak daily rate of new cases and two weeks after their peak in active cases.

## Daily New Cases in Denmark



## Active Cases in Denmark



## AUSTRIA

Austria began opening small business the week of April 13, one month after their peak in daily new cases and three weeks after their peak in active cases.





## Active Cases in Austria



## WHERE IS THE UNITED STATES BASED ON THE WHITE HOUSE FRAMEWORK?

#### **SYMPTOMS**

Although the Centers for Disease Control and Prevention (CDC) data is lagging by two weeks, ILI and COVID-like symptoms are both trending lower over the 14 and 15 weeks of the year, corresponding to March 29 through April 11.

### Updated April 17, 2020



Likewise, daily numbers of new cases have been declining for three weeks, since the peak on April 4 (data as of May 5). Note intermittent spikes in cases are likely related to surges in testing availability as opposed to resurgence in COVID-19 cases.

# Daily New Cases in the United States



Daily New Cases

Source: https://www.worldometers.info/coronavirus/country/us/

Thus, both symptom criteria are already met nationally. It is important to acknowledge that these criteria likely vary based on state and even local geography, thus it is important to contextualize this data based on your local market.



## CASES

The current number of active cases is still on the rise in the United States, thus we have failed to meet this criteria. Based on an imperfect lockdown starting March 20 and a peak in active cases on April 4, we likely have two weeks before we will see the total active cases begin to decline.

# Active Cases in the United States



Active Cases

The good news, however, is that all but five states have hit their peak demand for healthcare resources, and only New York, New Jersey and Connecticut had demands that exceeded their capacity.



## PERCENT POSITIVE TESTS

The CDC tracks percent positive COVID-19 tests. However, their data lags by one to two weeks at any given point in time. The most recent data published by the CDC shows percent positive COVID-19 tests declining over the last week overall but increasing in the 5-50 age groups.



U.S. State and Local Public Health Laboratories Reporting to CDC: Number of Specimens Tested and Percent Positive for SARS-CoV-2

Source: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

This is in contrast to the COVID Tracking Project data, updated daily, which shows decreasing rate of positive tests over the past four weeks with numbers of tests sharply increasing over the past two weeks. This picture is very encouraging.



Figure 4: US Daily Tests



Figure 5: US Positive % of Daily Tests



Source: The COVID Tracking Project

Source: https://covidtracking.com/data/us-daily

Source: The COVID Tracking Project

Thus, one of two cases criteria are met nationally. However, since this is an "or" category, the United States passes the cases test. It is important to acknowledge that these criteria likely vary based on state and even local geography, thus it is important to contextualize this data based on your local market.



Source: https://www.whitehouse.gov/openingamerica/

## STATES REOPENING

As of May 5, many states have taken steps towards reopening, despite not meeting the above outlined criteria. Georgia was one of the first states to announce reopening, though not yet arriving at its peak in active cases. While these early moves to reopen the economy are understandable, the actions must be weighed against the risk of resurgence of COVID-19 cases which would overwhelm the healthcare system. Many healthcare systems have improved their supplies of personal protective equipment (PPE), but the future need is uncertain, especially in the event of a second wave that exceeds the demands of wave one.



## HOSPITALS

In order to understand hospital preparedness, we must understand both the capacity to effectively care for patients and the ability to protect hospital staff and patients through reliable PPE. The first category, "treat all patients without crisis care," was largely accomplished through wave one of the pandemic. As previously mentioned, only New York, New Jersey and Connecticut saw hospital demand that exceeded bed capacity, according to the Institute for Heath Metrics and Evaluation (IHME). If the success was, indeed, a result of social distancing, there is the potential that there is still large at-risk population susceptible to the disease and when social distancing is relaxed, we will see a resurgence in COVID-19 cases. This assertion is supported by the largest population-based study of SARS-COV-2 antibodies in the United States being administered in New York state. This study suggests, in aggregate 12.2% of the population has had COVID-19 disease but that the incidence varies regionally based on population density, correlating with urban, suburban and rural locations. Of note, in the global epicenter of the pandemic, New York City, the percent of people testing positive for antibodies is 20%, indicating that 80% of the population is still at risk, even in the hardest hit location in the country.

Denien	%
Region	Positive
Capital District	2.2%
Central NY	1.9%
Finger Lakes	2.6%
Hudson Valley	3.0%
Long Island	11.4%
Mohawk Valley	2.7%
North Country	1.2%
NYC	19.9%
Southern Tier	2.4%
Westchester/Rockland	13.8%
Western NY	6.0%
Updated 5/2/20	

The second category, "Robust testing program..." has been insufficient to date, and there is no clear indication of when testing will be available to meet the needs of the country to identify and isolate COVID-19 cases. In a recent survey of TeamHealth Facility Medical Directors (FMDs), 55% indicated that they did not have sufficient testing capacity to identify COVID-19 patients. The lack of available testing, backlogs of available testing and the long turn-around times for test results created a situation during the initial epidemiologic curve where we were unable to effectively identify and isolate COVID-19 cases. As a result, the disease was able to spread much more pervasively. Newer antibody tests have the ability to detect acute or previous infection, providing valuable information as to the true incidence of disease and the potential of immunity in a 10-minute bedside test. These tests, however, have not been approved by the Food and Drug Administration (FDA), even for emergency use, due to wide variations in sensitivity and specificity and lack of clarity of the significance of the presence of IgG as it relates to true short and long-term immunity. The ideal test is a bedside polymerase chain reaction (PCR) test able to detect the presence of the virus which should have the highest correlation to infectivity. While historically we have failed in the area of testing, there is promise in the near future that testing will not be a constraint to our combating the disease.

The following is a list of tests with FDA Emergency Use Authorizations (EUA) in development as of April 4, 2020. Note that four of these tests can be performed in under one hour.

# DIAGNOSTICS

Vasudev Bailey, PhD Zoe Guttendorf 🎔 @vasudevbailey 🛛 @zoeguttendorf

Product Company Test Type Result Time (hr) **Approval Status** 1. RealTime SARS-CoV-2 Abbott 4-6 PCR 2. ID NOW COVID-19 test Abbott FDA - EUA Isothermal amp. - PoC AvellinoCoV2 Avellino Labs PCR 24-48 4. Real-Time Fluorescent RT-PCR kit 🖮 BGI PCR BioMérieux - BioFire Defense 5. BIOFIRE COVID-19 test PCR 🚾 CDC 24-72 6. 2019-nCoV Real-Time RT-PCR Dx Panel PCR d Cepheid FDA - EUA Xpert Xpress SARS-CoV-2 test PCR-PoC <1 😔 DiaSorin Molecular 8. Simplexa COVID-19 Direct PCR GenMark Diagnostics 9. ePlex SARS-CoV-2 Test PCR 10. Panther Fusion SARS-CoV-2 Assay - Hologic PCR S LabCorp FDA - FUA 11. Covid-19 RT-PCR test PCR 24 Luminex Molecular Diagnostics FDA - EUA 12. NxTAG CoV Extended Panel Assay PCR 13. Accula SARS-CoV-2 test 🧠 Mesa Biotech PCR-PoC PerkinElmer 14. New Coronavirus RT-PCR Test 4-6 PCR 😁 Primerdesign 15. COVID-19 genesig Real-Time PCR assay PCR 2 Quest 96-120 Quest SARS-CoV-2 rRT-PCR PCR 🖸 Quidel 17. Lyra SARS-CoV-2 Assay 4-6 PCR Roche 18. cobas SARS-CoV-2 Test 24 PCR **Thermo Fisher** FDA - EUA 19. TaqPath COVID-19 Combo Kit PCR 4 🙈 Wadsworth Center, NY State 20. NY SARS-CoV-2 Real-time RT-PCR 24-72 PCR Dept of Public Health (CDC)

Source: https://www.visualcapitalist.com/every-vaccine-treatment-covid-19-so-far/



Source: <u>https://www.whitehouse.gov/openingamerica/</u>

## THE FLATTEN, FIGHT, FUTURE FRAMEWORK BY BOSTON CONSULTING GROUP (BCG)

According to BCG's Flatten, Fight, Future framework, the COVID-19 pandemic will have three phases. The first phase is the "Flatten" phase, in which the primary risk is that the initial wave of disease overwhelms healthcare resources. The key in this phase is to flatten the curve through social distancing so that the healthcare system is able to expand resources and grow capacity. In addition to providing time for the healthcare system to prepare, it is argued to save lives by preventing oversaturation of the healthcare system which would result in increased morbidity and mortality. The "Flatten" phase is expected to last 7 to 14 weeks and will vary based on geography and state politics.



Source: https://www.bcg.com/en-us/publications/2020/covid-scenario-planning-winning-the-future-series.aspx

The end of the "Flatten" phase and the beginning of the "Fight" phase is signaled by a reduction in disease burden, which enables relaxing of social distancing. The "Fight" phase will require constant vigilance in terms of identifying new cases, broad-based testing and public health measures to isolate new cases to prevent a resurgence. As such, the "Fight" phase could encompass several "outbreaks" or clusters of disease that require reverting to some partial or complete social

distancing measures. This could result in a number of new waves in a few different patterns. The first is a series of peaks and valleys of varying amplitudes and durations, the second is a fall peak that is more severe than the first wave (as a result of the large population of remaining susceptible individuals due to social distancing), and the slow burn, a result of progressive development of short term herd immunity which effectively limits the further spread of disease.



The "Fight" phase continues until there is such a significant population of immune individuals that the virus can no longer spread. There are three ways to achieve this "herd immunity":

- 1. An effective vaccine is developed
- 2. An effective treatment is developed
- 3. Enough people acquire the disease and recover, developing antibodies

Most experts agree that the development and distribution of a vaccine is at least one year out. On April 21, the National Institutes of Health (NIH) released their consensus guidelines regarding effective therapies for COVID-19, concluding the following:

- 1. The COVID-19 Treatment Guidelines Panel (the Panel) does not recommend the use of any agents for pre-exposure prophylaxis (PrEP) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outside of the setting of a clinical trial (AIII).
- 2. The Panel does not recommend the use of any agents for post-exposure prophylaxis (PEP) against SARS-CoV-2 infection outside of the setting of a clinical trial (AIII).
- 3. The Panel recommends no additional laboratory testing and no specific treatment for persons with suspected or confirmed asymptomatic or pre-symptomatic SARS-CoV-2 infection (AIII).
- 4. At present, no drug has been proven to be safe and effective for treating COVID-19. There is insufficient data to recommend either for or against the use of any antiviral or immunomodulatory therapy in patients with COVID-19 who have mild, moderate, severe or critical illness (AIII).

On May 1, the Food and Drug Administration (FDA) issued an <u>Emergency Use Authorization (EUA) for remdesivir</u>, an antiviral drug used for the human immunodeficiency virus (HIV) based on the Gilead trial that demonstrated a <u>reduction in hospitalization</u> from 15 to 11 days and a reduction in mortality from 12% to 8% that approached statistical significance. While this is not a "magic bullet" any intervention that will reduce duration of hospitalization and reduce mortality should be considered a significant step in the right direction.

The problem with developing natural immunity is that it is unclear how long immunity lasts against the coronavirus. Because SARS-COV-2 is a new virus, this fact is not known. However, it is known that other coronaviruses do not impact lifelong immunity. Studies form the SARS outbreak in 2003 showed that 12% of individuals had no antibodies after one year and 50% had no antibodies after three years. HCW with mild to moderate MERS-CoV infection had no antiviral binding 18 months after recovery.<sup>1</sup>

The "Fight" phase is expected to last between 12 to 24 months, and our success in this phase depends on multiple factors. Because each state controls the decision to reopen, there will be some variability in the timing of reopening. If a state reopens too soon, there is the risk that there will be a local recurrence of disease. The deployment of testing, surveillance and containment strategies will be important to prevent recurrence. The healthcare and public response infrastructure must be sufficient to support testing, tracing and isolation of positive cases.

The development and deployment of a vaccine is the most logical pathway out of this pandemic. Until this is achieved, coordination of monitoring and data sharing to achieve real-time course corrections will be crucial. Translating local successful interventions into scaled national programs will be important and can be facilitated though artificial intelligence. Tailoring the ultimate course for the high-risk and low-risk populations could accelerate the national recovery, shifting from "Flatten and

Fight" to "Protect and Provide." This would essentially translate into letting the disease run its course in the low-risk population and protecting and providing social resources to the high-risk population and to the healthcare system to support expansion of healthcare resources and ongoing preparedness.

## THE CASE FOR PROTECT AND PROVIDE

A key requirement of "Protect and Provide" strategy is the clear delineation of high-risk and low-risk populations. Fortunately, since the beginning of the pandemic in China, data has consistently shown very low risk in younger individuals. It has also shown to adversely affect elderly individuals and those with preexisting medical conditions, including high blood pressure, chronic lung disease, diabetes, obesity, asthma, and those whose immune system is compromised such as by chemotherapy for cancer and other conditions requiring such therapy.

While tracking patients with comorbidities may be complicated, analyzing data on age and mortality related to COVID-19 is relatively easy, and the data is quite abundant. However, there are inconsistencies in data being reported from common tracking sites, like Worldometers and IHME. This is presumably due to the greater accuracy required by the CDC in terms of processing death certificates or a backlog due to human resource or other limitations. As such, the CDC data typically lags 7 to 14 days on any given reported measure. CDC data as of April 23 shows the following age and case fatality rate (CFR) distribution:

Age group	Population	COVID-19 Deaths	COVID POS Tests	Reported Case Fatality Rate (CFR)
Total 0-24	103,856,244	20	10,868	0.18%
Total 24-44	86,975,662	490	207,833	0.24%
Total 45-64	83,904,335	3,691	212,099	1.74%
65–74 years	30,492,316	3,829	61,917	6.18%
75 and over	21,938,877	9,689	69,429	13.96%

## THE PROBLEM(S) WITH REPORTING CASE FATALITY RATE (CFR, i.e. MORTALITY)

It is difficult to interpret CFR data coming from the CDC and other data sources. This is because there are so many confounding variables that could increase or decrease the perceived CFR of COVID-19.

- 1. Because we are only taking a snapshot in time, we could underestimate the CFR because although many cases are diagnosed, a small fraction have recovered. Also, the duration of illness is long enough that we do not yet know the outcome of a majority of the cases. For example, as of April 26, there are 987,160 cases and 55,413 deaths in the United States. If you only considered these two numbers, you would incorrectly assume a mortality rate of 5.6%. The reason for this is that only 118,871 cases have recovered and 868,289 are still in the active phase of illness. Likewise, if we take the 55,413 deaths and divide this by the total recovered or deceased (total completed cases is 174,284), you would incorrectly conclude the CFR is 3.2%.
- 2. The overall mortality rate of the general population may also be higher than can be explained by COVID-19 deaths alone. Some <u>COVID-19 deaths could be underreported</u> due to lack of testing for coronavirus particularly early in the pandemic. Some people may die at home of COVID-19 remaining undiagnosed. Other people may die from other illnesses like stroke or heart attacks due to a fear of going to the emergency department (ED) and being exposed to COVID-19 or from the emotional stress impacts of the pandemic on their chronic illnesses.
- 3. If we are only testing patients with moderate to severe illness because we have not had widespread testing available, there would presumably be more cases in the population that are uncounted, effectively increasing the CFR because there are fewer total cases counted (the denominator).
- 4. By antibody testing a random cross section of the population and looking for IgG, we can better understand the true incidence of disease. Because IgG is indicative of prior disease and recovery, it would tell us how many people have been infected since the onset of the pandemic. We would likely find more cases, increasing the denominator and effectively lowering the CFR.

Although it is difficult to arrive at an exact mortality figure, one important conclusion we could draw from the raw CDC data is that the relative risk of the above age 65 population relative to the under age 45 population is 9.44% / 0.21% or 45. In other words, if two people were to contract the COVID-19 disease, one over 65 years and the other under 45 years, the over-65 person would have a 45-fold higher risk of dying.

Perhaps the most important issue with the reported data is the lack of testing and thus the failure to report the total number of cases in the denominator of the CFR calculation. There have been <u>reports from Dr. Robert Redfield of the CDC</u> that the percent of asymptomatic COVID-19 patients may be as high as 25%. In March, Iceland tested more than 10,000 people and <u>found that 50% were asymptomatic</u>. A recent study of Marion Correctional Institution in north central Ohio found 2,028 positive tests out of 2,300 prisoners tested. Of those testing positive, <u>close to 95% were asymptomatic</u>. While the absolute number and percent of positive asymptomatic patients is unclear, counties and states have begun to attempt to answer that question.

<u>There have been three local studies</u> to date characterizing the presence of antibodies as a surrogate for incidence of disease and others underway in Michigan and by organizations such as the CDC and NIH.

- Santa Clara County 50 out of 3,330 volunteers tested positive (1.5%). After correcting for false positives, they estimated antibodies between 2.5 to 4% of the population with potentially 48,000 to 81,000 cases in a county with the population of 1.9 million. That county had reported only 1,946 positive test results. This indicates an estimated true incidence of 32 times the testing positivity rate.
- Los Angeles Out of 863 adults tested, 4.1% had antibodies to the virus, suggesting a 2.8% to 5.6% incidence of infection. This translates into 221,000 to 442,000 out of the 10 million people had been exposed vs. 8,000 recorded. This indicates an estimated true incidence of 41 times the testing positivity rate.
- 3. New York State New York began a <u>statewide antibody study</u> on April 20 and has collected around 15,000 samples from 40 locations in 19 counties across the state through May 1. In New York City, about 20% of randomly sampled people had antibodies against the coronavirus. The incidence across the state was 12.2%. If the actual infection rate among the entire population is similar to the early sample infection rate they found of 12.2%, it would change the death rate of the state. <u>New York is reporting 19,645 COVID-19 deaths</u>, and if 2.4 million people were infected, that would mean the case fatality rate would be 0.8%. As of May 4, New York had 321,192 reported positive cases. This indicates an <u>estimated true incidence of 13.1 times the testing positivity rate</u>.

While it is challenging to calculate the true CFR from this extrapolated data, we can conclude that the true CFR is likely lower than reflected in the reported data. Because New York has the most conservative picture in terms of incidence in the population relative to positive tests and because they have excellent public health data, their data may be helpful to determine at-risk populations. The following is the distribution of deaths based on age range in New York City:

	Underlying Conditions				
Age	Present	Absent	Unknown	Total Deaths	% of Total
0-17	5	0	0	5	0.04%
18-44	381	10	91	482	4.08%
45-64	2,225	52	372	2,649	22.41%
65-74	2,065	5	840	2,910	24.62%
>75	3,819	1	1,952	5,772	48.84%

Source: https://www1.nyc.gov/site/doh/covid/covid-19-data.page

This data demonstrates that 73.5% of the mortality is represented in the over 65 population. The New York City data is consistent with national CDC data, which reports this percent as 76.3%:

Population	NYC COVID-19 Deaths	NYC % Total Deaths	USA COVID-19 Deaths	USA Percent Total Deaths
103,856,244	5	0.04%	20	0.11%
86,975,662	482	4.08%	490	2.77%
83,904,335	2,649	22.41%	3,691	20.83%
30,492,316	2,910	24.62%	3,829	21.61%
21,938,877	5,772	48.84%	9,689	54.68%

Source: https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm

## This data shows that 76% of the total deaths related to COVID-19 are coming from 16% of the total population.

Regardless of where the numbers ultimately fall, the most significant point is that patients over the age of 65 are 45 times more likely to die of the disease than patients under 45 years of age. Thus, instead of locking down the entire country, we should focus our efforts on the over age 65 population to "Protect and Provide," opening the economy and providing the resources to support the healthcare system to treat those with the disease and remain vigilant in case of a recurrent widespread outbreak.

## PROTECT THE VULNERABLE POPULATION

In the context of lack of treatment or vaccine, the only alternatives are containment and social distancing (source control). This is best achieved, as outlined above, through defining, protecting and providing for vulnerable populations, development of broad-based testing capabilities and implementation of a coordinated surveillance and monitoring program.

## THE GENERAL POPULATION

Based on the "Protect and Provide" framework, the under 65 population should return to work as soon as feasible (i.e. phase 1) with practical considerations to social distancing in the workplace and commercial areas. The main consideration in this population should be prompt addressing of symptomatic individuals and protection of vulnerable coworkers. Examples would include:

- Self-screening and isolation if symptomatic workers should screen for symptoms and fever temperature prior to reporting for work. If symptoms arise at work, patients should be sent home. All symptomatic individuals should be tested for COVID-19.
- 2. All employees should exercise strict hand hygiene.
- **3.** To the degree possible, relationships should be established with known testing providers in order to establish reliable reporting and follow-up mechanisms.
- 4. Vulnerable should wear masks when not at their workstation, in group meetings and common places until there are no active cases of COVID-19 in the local community or region.
- 5. For future surges in COVID-19, vulnerable people should return to social distancing immediately upon the detection of a rise of cases in the local community. For the non-vulnerable population, strict social distancing should be implemented only when it is projected that healthcare and intensive care unit (ICU) resources will be overwhelmed in a given locale.

## THE VULNERABLE POPULATION

Vulnerable populations are defined as: 1) elderly individuals and 2) individuals with serious underlying health conditions, including high blood pressure, chronic lung disease, diabetes, obesity, asthma, and those whose immune system is compromised such as by chemotherapy for cancer and other conditions requiring such therapy. This population should maintain social distancing until phase three as outlined by the White House, and they should immediately return to social distancing with any return of COVID-19 to the community. This includes:

- 1. Maintain social distancing with the exception of essential activities (i.e. grocery shopping).
- 2. Vulnerable should wear masks when in public and exercise strict hand hygiene.
- 3. No visitors should be allowed to nursing homes and assisted living facilities. All workers in these facilities should be screened for symptoms and fever prior to coming to work, and any symptomatic workers should be tested immediately. If a worker is found to be positive, all workers and residents should be tested.
- 4. Vulnerable individuals should limit group activities.
- 5. There should be liberal routine screening testing of the asymptomatic in group settings and symptomatic others.
- 6. Vulnerable populations should limit contact with the under age 65 population. Vulnerable should wear masks and exercise strict hand hygiene when interaction is necessary.
- 7. Government should support the elderly through financial aid, social support and healthcare systems to expand capacity.

## CONTAINMENT

Containment requires very low disease prevalence and high resources for tracing purposes (people and tests). The resources required for tracing and monitoring quarantined individuals has overwhelmed the local and state health departments who are not resourced for large spikes in activity. During surges in activity, the government should work with the private sector to execute in collaboration with local health departments and the CDC. This can be accomplished through local healthcare systems, telehealth and advanced surveillance methods like cell phone tracing. In order for containment to be effective, we must be able to support widespread testing with real-time results, and we must be able to support the healthcare system to care for patients and prevent further spread of disease.

A broad-based testing strategy must be available in anticipation of recurrent cluster outbreaks and implementation of isolation measures for infected individuals.

- Tests should be available in all healthcare delivery locations, including pharmacies and first responders. This includes EDs, hospital points of entry for admittance or outpatient procedures, urgent care centers, pharmacies, emergency medical service (EMS) locations, nursing homes and assisted living facilities.
- 2. All HCW should be screened daily for ILI symptoms and fever upon presentation to workplace. Any symptomatic individuals should be immediately tested.
- 3. All post-acute residents should be screened daily for symptoms. Any symptomatic individuals should be immediately tested. Routine surveillance testing should be performed to screen for asymptomatic outbreaks.
- 4. All patients entering the hospital for admission or outpatient procedures should be tested with the possible exception of lab and radiology in lieu of expanded precautions (i.e. mask patient, mask technician and forced hand hygiene).
- 5. Symptomatic ED patients should be tested, and HCW should mask symptomatic patients and wear masks and eye protection in all encounters with symptomatic individuals. All patients admitted from the ED should have any initial bedside screening test followed by confirmatory PCR test.
- 6. All HCW should be tested initially, and routine screening programs should be implemented to screen for asymptomatic individuals. This program should be implemented in all hospitals, nursing homes, assisted living facilities, urgent care facilities and outpatient surgery centers.
- 7. Frequency of surveillance testing needed is unclear and should be based on prevalence of the disease at any given point of time in the local community.

The model above was proposed to TeamHealth's FMDs, who were asked if their organization had the testing capacity to carry out the protocol described above, and 52% indicated that they did not have the capacity today. Of those who did have the capacity, only 44% indicated they could sustain that level of testing for over a month.

The following is a model proposed by the Duke Center for Public Health<sup>2</sup> that includes test and treat infrastructure, syndromic surveillance, serologic testing and rapid response in order to achieve long-terms sustained containment:

- 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 (HCW, 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

In order to support the healthcare system to care for patients and prevent further spread of disease, healthcare systems must be provided support in the form of PPE, serologic and PCR testing, equipment and human resources. It is important to emphasize that the healthcare system should be supported to maintain a constant state of readiness in terms of capacity for cluster outbreaks as opposed to capacity for the bare minimum or average anticipated outbreak until there is no longer a clear and present danger. The most relevant risk to healthcare can be defined in terms of exposure to HCW and saturation of inpatient, ICU, ventilator and human resources. The most significant risk to patients is when inpatient and ICU resources fail to meet the demand of patients presenting for care. In these situations, mortality increases significantly over baseline.

## RESOURCES

PPE must be readily available to all HCW. This includes sufficient standard precautions must be stocked with a reliable supply chain. The following are PPE recommendations until COVID-19 is no longer a clear and present threat as indicated by the development of a vaccine or viable treatment or the absence of COVID-19 in the local community as measured by the CDC and local or state health departments.

- 1. Proper hand hygiene is top priority as is liberal use of alcohol-based hand sanitizer.
- 2. All ILI and CLI patients and family members entering any aspect of the facility should be masked.
- 3. HCW caring for ILI and CLI patients should wear surgical masks and eye protection
- 4. Expanded precautions, including gowns, gloves, N-95 masks and face shields, should be used on any patients undergoing aerosolizing procedure such as endotracheal intubation or bronchoscopy.
- 5. For service lines in the hospital providing procedures, such as endoscopy, cardiac catheterization, surgical services and anesthesia, a documented negative COVID-19 test should be in place for all elective procedures. This can be accomplished with a rapid, bedside PCR test in under one hour as a part of routine pre-admission testing.
- 6. All positive COVID-19 patients and untested emergent or urgent patients should be treated as if COVID-19 positive with expanded PPE.

Patients with ILI and CLI symptoms should be considered positive until definitively proven otherwise.

As previously indicated, rapid testing should be immediately performed on all suspected patients. Ideally this is a bedside PCR test. The value of serology tests is unclear at this time, but due to the false negative rate of up to 70% and the fact that they will not turn positive until seven days after infection, these tests are not sensitive enough to reliably prevent infection in healthcare facilities. If a bedside serology test is the only available rapid test, PCR testing should be used to confirm the results prior to determining the patient is negative for COVID-19 disease. Highly suspicious cases (i.e. x-ray, CT or lab findings) should use high level protection regardless of test result.

In our study of TeamHealth FMDs, 22.1% ran out of some element of PPE. 12.4% ran out of N-95 respirators, 6.9% ran out of surgical masks, 15.2% ran out of gowns and 9.2% ran out of eye protection. Only 77.9% of FMDs reported not running out of one or more elements of PPE. The supply chain failed for a number of reasons: 1) China was hit first, wiping out 80% of the global production, 2) health systems, states and even the federal government were competing with each other, often through bidding wars, and 3) PPE was sourced internationally through an impaired air transport system and overwhelmed customs process. Moving forward, the PPE supply chain should be maintained through public/private partnership with the government supporting increased reserve quantities within the supply chain to prevent obsolescence. In order to maintain the most reliable supply chain and mitigate against the impact of another global pandemic, investments should be made in PPE sourced in the United States to prevent supply chain issues.

ICU and ventilator resources have proven to be the most important elements of pandemic preparedness through the "Flatten" phase of the pandemic. The severe nature of the sickest patients and the prolonged ventilator support and inpatient care required drive the potential saturation of healthcare resources. As previously mentioned, only New York, New Jersey, and Connecticut experienced demand surges in excess of their capacity. This may be different in local markets that have experienced cluster outbreaks. However, it does appear that the planning required to address this first wave of COVID-19 has identified areas for expansion of ICU capacity and quantified the need for ventilators. Local facilities should hardwire this expansion into their disaster preparedness response. Thus, vigilance and monitoring of healthcare capacity will always play an important role until a vaccine or treatment has been developed. The government should support healthcare systems to bridge the gap between ventilators. The government should support production of low-cost ventilators and supply them to hospitals to circulate into their existing ventilator pool for maintenance purposes. It should be noted, however, that the ultimate impact of social distancing on demand for healthcare resources remains unclear. If it did significantly flatten the demand for healthcare resources, there is an almost certainty that the remaining population of people who have not been exceeds the population that have been exposed and have recovered.

Human resources have also been challenged during the first wave of the pandemic. However, due to reduced operating room volumes, anesthesiologists, general surgeons and surgical specialists were effectively able to support ICU, inpatient and ED care. During social distancing, ED volumes showed declines of up to 50% while declines in surgical and ED volumes temporarily reduced the inpatient demand for hospitalists by up to 20%. This inpatient demand returned during peak COVID-19 periods, in some cases exceeding pre-COVID-19 demand. Thus, shifting of resources was shown to effectively compensate for the dramatic rise in demand during COVID-19 peaks. Instead of augmenting human resources, support should be provided to cross train and provide the mechanism for reimbursement when caregivers provide care in other areas of the healthcare system, some of which is either not currently reimbursable or is not reimbursable at a lower rate due to type of procedure, demand for procedures or achievable efficiency.

## SUMMARY

The COVID-19 pandemic has been an unprecedented global challenge. As we pass through the first wave of the pandemic, most experts agree there will be future waves of disease until we find a suitable treatment or vaccine. Due to the severe impact of this pandemic on the healthcare system, social distancing measures were implemented in order to flatten the curve, providing time needed to prepare the healthcare system by expanding intensive care resources and attaining sustainable levels of PPE. As we pass through the "Flatten" phase, we enter a period where we need to maintain vigilance and caution, protecting and providing for the most vulnerable and allowing the least vulnerable to reopen the nation. This will require widespread testing availability, surveillance systems, public health resources, and most importantly, engagement of all Americans.

## REFERENCES

- <u>National Academies of Sciences, Engineering, and Medicine 2020. Rapid Expert Consultation on SARS-COV-2 Viral</u> <u>Shedding and Antibody Response for the COVID-19 Pandemic (April 8, 2020). Washington, DC: The National Academies</u> <u>Press. https://doi.org/10.17226/25774.</u>
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