NORTH AMERICAN OBSERVATORY on Health Systems and Policies

North American COVID-19 Policy Response Monitor: United States

December 23, 2020

What is the North American COVID-19 Policy Response Monitor?

The North American COVID-19 policy monitor has been designed to collect and organize up-to-date information on how jurisdictions are responding to the crisis. It summarizes responses of health systems as well as wider public health initiatives. The North American policy monitor is an offshoot of the international COVID-19 Health System Response Monitor (HSRM), a joint undertaking of the WHO Regional Office for Europe, the European Commission and the European Observatory on Health Systems and Policies.

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List of Acronyms and Abbreviations

APIs	Application programming interfaces
CARES	*Coronavirus Aid, Relief, and Economic Security Act*
CDC	Centers for Disease Control
CHIP	Children's Health Insurance Program
CISA	Cybersecurity and Infrastructure Security Agency
CMS	Centers for Medicaid and Medicaid Services
COBRA	*Consolidated Omnibus Budget Reconciliation Act*
DPA	*Defense Production Act*
HHS	Department of Health and Human Services
ED	Emergency department
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FFCRA	*Families First Coronavirus Response Act*
ICU	intensive care unit
LTC	long-term care
LTCF	long-term care facility
NGA	National Governors Association
NP	Nurse practitioner
OSHA	Occupational Safety and Health Administration
WHO	World Health Organization

1. Preventing Transmission

This section includes information on key public health measures that aim to prevent the further spread of the disease. It details how jurisdictions are advising the general public and people who (might) have the disease to prevent further spread, as well as measures in place to test and identify cases, trace contacts, and monitor the scale of the outbreak.

1.1 Health communication

The federal government's response to COVID-19 began in early January with the creation of a 2019-nCoV Incident Management System [1.1.1] and a Centers for Disease Control (CDC) media briefing on the novel coronavirus [1.1.2]. In the weeks following, the White House established a "Coronavirus Task Force" [1.1.3] and the Department of Health and Human Services (HHS) declared a public health emergency [1.1.4]. Official communication about hand hygiene and respiratory etiquette was issued soon thereafter in late January/early February 2020 [1.1.5]. Communication on physical distancing, though originally limited to at-risk populations or avoiding those who were sick, gradually expanded to include more widespread physical distancing (maintaining greater than six feet distance, etc.). In March 2020, the Coronavirus Task Force and CDC released two documents detailing mitigation and prevention strategies for both communities and individuals, including reiterating hand hygiene recommendations and respiratory etiquette and strengthening physical distancing [1.1.6-1.1.8]. In mid-April 2020, the White House released a three-phase plan titled "Guidelines for Opening Up America Again" that provides guidance to states and local authorities on how to ease physical distancing measures in a manner that mitigates risk of additional waves and protects vulnerable populations [1.1.9] (also see section 1.2.) On May 15, the White House announced "Operation Warp Speed", a public-private initiative intended to expedite the development of COVID-19 vaccines, therapeutics, and diagnostics [1.1.10]. In late May, the CDC published a press release acknowledging that more than 100,000 Americans had passed away due to COVID-19 related mortality [1.1.11].

The Coronavirus Task Force and CDC have held periodic briefings (previously daily until late April 2020) and webinars to disseminate updates on outbreak severity and government responses. Official health communication regarding COVID-19 is regularly published on the CDC website (https://www.cdc.gov/coronavirus) as well as distributed through social media. The CDC website is updated daily, including total number of cases and testing (though it now relies on states for this information). A dedicated government webpage (https://www.coronavirus.gov/) has also been created to share updates from the Task Force and answer frequently asked questions. Other federal government agencies and state health departments have further maintained their own channels of COVID-19 related communication, though the CDC and .gov website remain the primary sources.

With the approval of two vaccines and start of mass vaccination efforts in December, HHS has started rolling out a national education campaign ("Tell Me More") [1.1.12]. The first set of videos discusses topics like vaccine safety, vaccine production, and why vaccines will be an important tool in ending the pandemic. The video campaign features top scientists and officials, including Dr. Anthony Fauci, the head of the National Institute of Allergy and Infectious Diseases, and U.S. Food and Drug Administration (FDA) Commissioner Stephen Hahn [1.1.13].

The "Tell Me More" campaign is set to be followed by a radio campaign ("Slow the Spread") and radio, print, digital, and social media ads focused on scientific messaging for the public. The "Building Vaccine Confidence" campaign, however, remains in the planning stages as of December 9th. A new website (https://combatcovid.hhs.gov/) was also created focusing on COVID-19 vaccine and treatment clinical trials [1.1.14].

1.2 Physical distancing and wearing masks

Initially, physical distancing was advised for those isolating due to a positive test result, being in contact with a confirmed case, or returning from travel to a high-risk area. Starting in late February 2020, the federal government began to implement more widespread physical distancing measures, such as recommendations to avoid close contact with those who were sick. In early March 2020, the CCDC advised that those over 60 or with underlying chronic health conditions should avoid face-to-face contact as much as possible [1.2.1].

On March 15, 2020, the CDC provided guidance on mass gatherings, including limiting the number of people to 50 or less [1.2.2]. A day later, the President released national guidelines that implemented a 15-day voluntary national shutdown, limited mass gatherings to 10 or less people, and advised against discretionary travel. The federal government further recommended that schools, restaurants (for dine-in), gyms, and other indoor or outdoor venues where the public congregate should be closed in states with evidence of community transmission [1.2.3]. On March 29, 2020, this shutdown was extended through April 30. As of late April, no national stay at home mandate has been instituted [1.2.4]. Due to the significant number of asymptomatic cases in early April, the CDC increased physical distancing recommendations, advising that Americans wear cloth face coverings in public places with limited physical distancing capabilities (e.g. grocery stores) [1.2.5].

Since there has not been a national lockdown, individual states (and cities) have taken additional measures to prevent or curb community spread. As of March 31, 2020, 29 states had issued stay at home orders. Similarly, a number of states (including the District of Columbia) have implemented other physical distancing measures: 30 have closed all non-essential businesses, 39 have prohibited either all gatherings or those with greater than 10 people, 44 have closed restaurants/bars with the exception of takeout/delivery, and 47 have mandated statewide school closures. As of April 24, 2020, 42 states had stay at home orders, while 8 states had eased physical distancing measures (e.g., reopening certain businesses) [1.2.6].

In mid-April, the White House released guidelines for state governors and local authorities to reopen the country. The recommended criteria for transitioning out of shutdown was downward trajectory of reported influenza-like and COVID-like cases for two weeks, downward trajectory of documented cases or positive tests as a percent of total tests for two weeks, and for hospitals to treat all patients without crisis care and have stringent testing programs in place for at-risk healthcare personnel. States should also have certain capabilities including screening, testing, and surveillance sites and adequate personal protective equipment (PPE) and medical equipment supplies. Individuals throughout all phases were advised to practice good hygiene and stay home when sick; employers likewise would be expected to implement new policies to preserve physical distancing, monitor their workforce, and perform contract tracing. The plan then laid out specific guidelines by phase [1.2.7]:

- *Phase 1:* vulnerable individuals (elderly or those with serious underlying health conditions) should shelter in place, public gatherings limited to 10 or less, minimized non-essential travel, return to work in phases with telework encouraged when possible, and other guidelines for specific employers (e.g. schools/youth activities remain closed, visits to senior care facilities or hospitals are prohibited, elective surgeries can resume).
- *Phase 2 (notable changes from Phase 1):* public gatherings limited to 50 or less, non-essential travel can resume, and other guidelines for specific employers (e.g. schools/youth activities can reopen, bars can reopen).
- *Phase 3 (notable changes from Phase 2):* vulnerable individuals can resume public interactions, unrestricted staffing of workplaces, and other guidelines for specific employers (e.g. visits to senior care facilities or hospitals can resume, large venues can operate with limited physical distancing).

Recommendations for businesses included closing break rooms. Restaurants were encouraged to use disposable menus and plates, and schools were asked to have lunches in classrooms rather than cafeterias [1.2.8].

Three coalitions of states, one on the east coast, one on the west coast (including Colorado and Nevada), and one in the south, formed to coordinate reopening [1.2.9]. The east and west coast states are working together to share information and meet benchmarks before relaxing physical distancing orders. The western coalition agree that physical distancing should stay in place until there is a good system for testing, tracking and isolating individuals exposed or with symptoms. The states also agree that reopening requires sufficient hospital capacity and protective gear, and a plan for protecting vulnerable populations, such as those in nursing homes [1.2.10].

On the other hand, some states in the southern coalition, such as Georgia, Florida, and Texas, began phase 1 reopening in late April or early May [1.2.11]**.** Public health experts and scientists emphasize that there are three key elements to a safe and successful reopening of society: 1) mass testing to identify those who are infected; 2) contact tracing to find and isolate people who may have caught COVID-19 from known cases; and 3) sufficient PPE to shield healthcare workers from the infected [1.2.12]. These conditions did not exist in any state in the U.S., much less those that were beginning to reopen. In fact, Georgia, Florida and Texas lagged in physical distancing and testing compared to the rest of the country. Georgia, for instance, was 42nd in testing in the country at the time of beginning reopening [1.2.13]. In July, Dr. Deborah Birx, the White House Coronavirus Task Force coordinator, highlighted that this early and accelerated reopening by Southern states led to the current surge in the South compared to regions in the North that were harder hit earlier on [1.2.14].

As of June 8, all states (including D.C.) had begun lifting some social distancing measures. 35 states had either completely removed or eased their shelter-in-place orders, 46 allowed some or all non-essential businesses to reopen, 36 states decreased or removed bans on gathering, and 42 states permitted restaurants to resume dine-in service with reduced capacity, increasing capacity over time [1.2.6]. Covid Exit Strategy, a non-partisan group of public health experts, has been tracking states' progress in meeting the White House reopening criteria [1.2.15]. Only 4 states – New York, New Jersey, Connecticut, and South Dakota – were "trending better" as of June 8, while nearly 40% of states were "trending poorly" towards

a safe reopening based on their case growth rate, testing capacity, and intensive care unit (ICU) utilization. It should be noted that states have been oscillating between different categories [1.2.15].

As of July 13, in response to a surge in cases, some states began to pare back reopening plans. 26 states are still proceeding with reopening and 7 have reopened fully (stay-at-home order and large gathering ban lifted, non-essential business open, restaurants open to full capacity) but 7 have paused reopening and 11 have added new restrictions [1.2.6]. Though certain states have reopened to some degree, the majority of these states continue to have certain restrictions (e.g. capacity constraints, social distancing measures, masking policies) [1.2.16].

Only 4 states (New York, New Jersey, Connecticut, and Maine) were "trending better", while the plurality of states were facing uncontrolled spread [1.2.15]. Admiral Brett Giroir, the Assistant Secretary for Health and White House Coronavirus Testing Czar, stated that renewing or adding new lockdowns should be a consideration in hotspot areas [1.2.17]. The statement comes in the setting of increasing evidence that lockdown orders reduce mortality and curb growth in hospitalizations [1.2.18], and is in stark contrast to earlier messages to not lockdown again.

During late summer and early fall, cases began to dip and the U.S. proceeded with increased reopening. Some schools and many universities reopened for either partial or complete in-person learning. The majority of states did not have an order preventing school reopening [1.2.19], though reopenings have followed a patchwork pattern. In an August 2020 nationally representative survey of 477 school districts, 49% planned to open for in-person learning full-time [1.2.20]. However, schools have had to close or alter their plans depending on the number of cases in the local community, positive cases in the school, etc. [1.2.21]. Colleges and universities also struggled with resuming in-person learning, including issues with getting students to comply with social distancing, inadequate quarantine housing, and limited COVID-19 testing capacity [1.2.22].

In the fall, a record spike in cases, particularly in Midwestern states, led most states to again reintroduce mitigation measures [1.2.23]. As of December 18, 39 states have added new restrictions and an additional 4 have paused reopening. 34 states have also instituted some type of large gathering ban prohibiting all gatherings or gatherings of less than 10, 25, or 50 people. 16 states have closed bars and another 19 have new service limits in place [1.2.6].

As noted above, earlier recommendations regarding physical distancing at both the national and state level singled out vulnerable individuals. During March 2020, the CDC issued a number of guidelines for other special facilities and populations. The CDC created a preparedness checklist for long-term care facilities (LTCFs) and nursing homes, and recommended drastic changes such as visitation restrictions (including on volunteers and non-essential healthcare personnel) and active screening of residents and healthcare personnel (March 2020) [1.2.24]. Similarly, the CDC issued guidance for correctional and detention facilities on topics including physical distancing and medical isolation [1.2.25]. A "No Sail Order" was further issued by the CDC for all cruise ships [1.2.26]. In mid-April, the CDC published interim safety guidance for critical infrastructure workers (e.g. law enforcement, janitorial staff, workers in certain industries like food/agriculture or transportation) that may have been exposed to a positive case [1.2.27].

Given the growing number of states easing social distancing restrictions, the CDC released new guidance for reopening safely. In mid-May, the CDC published one-page guidelines for reopening businesses,

restaurants and bars, schools, camps, child care, and mass transit [1.2.28-1.2.33]. A week later, the CDC released a more detailed roadmap outlining additional strategies for reopening these public places like spacing desks six feet apart in classrooms [1.2.34]. Additional CDC guidelines were released on June 12 [1.2.35]. The new guidelines focus on social distancing and call for maintaining a distance of 6 feet from others whenever possible, wearing face coverings in public, and washing hands. The new guidelines include specific recommendations for visiting libraries, hotels, banks, nail salons, gyms, restaurants and bars, and attending gatherings at someone's home or in public spaces.

Politicization of the issue has led to divisive stances on masking policies but there have been growing calls from both sides of the political aisle to increase mask wearing [1.2.37]. Major healthcare associations – the American Medical Association, the American Hospital Association, and the American Nurses Association – published a public letter in July urging Americans to wear masks and socially distance [1.2.38]. In cases where state governments have refused to institute such policies, local governments and even businesses are stepping in [1.2.39]. However, businesses are growing increasingly tired of having to establish and enforce these policies on their own [1.2.40]. The Retail Industry Leaders Association, for instance, wrote a letter to the National Governors Association urging for a uniform approach to public health guidelines and stressing the importance of masking policies [1.2.41].

Universal masking policies gained more popularity with the summer surge in cases. Although there was no federal mandate, 25 states mandated masks or face coverings in public as of July 13 [1.2.36]. With a new surge of cases in the fall, even more states have issued mask mandates: 38 states have a mask mandate as of December 17 [1.2.42]. This is partly due to many Republican governors and/or legislatures beginning to reverse their initial opposition to mandates [1.2.43]. The CDC has also been promoting universal face mask use during the most recent wave in cases [1.2.44].

As states teeter between relaxing and imposing physical distancing restrictions, it is important to note the impact of earlier lockdowns and other stringent public health measures. Several studies have highlighted the success of these interventions in decreasing transmission and mortality [1.2.18, 1.2.45, 1.2.46]. Likewise, as stay-at-home orders are lifted and businesses and restaurants reopen, research showing that physical distancing and wearing masks reduces transmission [1.2.47] buttresses mandates for these policies.

1.3 Isolation and quarantine

At the start of the pandemic, isolation was limited to travelers returning from the Hubei province in China, who were forced to quarantine for 14 days [1.3.1]. Mandatory quarantine was similarly required for passengers associated with cruise ship outbreaks, most notably the Grand Princess. In March 2020, the CDC recommended that travelers from all countries with widespread transmission or those returning from cruise ships should voluntarily self-isolate for 14 days [1.3.2].

As community spread exponentially increased during late March, government recommendations began to change. All Americans, regardless of exposure, were asked to participate in the voluntary national shutdown to prevent further spread. Those who were sick were advised to self-isolate and stay home, unless in need of medical care. Household members of someone who tested positive or those who came into contact with someone who was infected were also instructed to self-quarantine starting in March [1.3.3]. With these new changes, the CDC issued additional guidance on home care and self-isolation:

proper ventilation, isolating to a separate room, not sharing household items, etc. [1.3.4]. Home quarantine was advised to be discontinued only when risk of transmission to others is low and in consultation with a healthcare provider.

Moreover, as noted in Section 1.2 Physical distancing, separate recommendations on medical isolation and clinical care were given to long-term care (LTC) and correctional facilities.

In late May, the CDC released new guidance about when individuals who are positive or are presumed to be positive can stop self-isolating. The CDC recommended that symptomatic individuals could resume contact after 3 days with no fever, symptom improvement, and 10 days post-symptom onset. Individuals that are tested a second time could similarly resume contact after fever and symptoms subside and the patient tests negative twice in a row. Asymptomatic individuals were advised to wait 10 days (assuming no symptoms arise) or to be tested negative twice in a row [1.3.5].

In December, the CDC revised its guidelines to state that asymptomatic individuals who have been exposed can either quarantine for 10 days, or 7 days with a negative test (assuming no subsequent symptom development) [1.3.6].

1.4 Monitoring and surveillance

The U.S. has adopted a similar definition to that of the WHO definition, defining COVID-19 as a new coronavirus disease that has not been previously identified [1.4.1]. The main symptoms included in the case definition are fever, cough, and shortness of breath, though this has changed over the course of the pandemic to account for a wider range of symptoms [1.4.2]. In late April, the CDC explicitly added signs and symptoms such as muscle pain and new loss of taste or smell.

Starting on January 17, 2020, flights from Wuhan, China were directed to three airports (JFK, SFO, and LAX[1]) where passengers were screened [1.4.3]. In the months since then, screening expanded to thirteen airports in total [1.4.4]. Initially, probable cases were those who were symptomatic ("flu-like" symptoms) and had relevant recent travel history (originally China, but grew to include Italy, Iran, Japan, and South Korea) or been exposed to a confirmed case. In early March 2020, the CDC allowed final testing decisions to be made by states and local providers [1.4.5], though guidance on testing priorities was provided including targeting symptomatic patients, high-risk populations, and healthcare workers. The details of this guidance are described in Section 1.5 Testing.

As part of identifying probable cases, contact tracing was touted as an essential component of the federal government's strategy to containing the coronavirus. However, given extensive community spread, certain municipalities initially had to move away from containment strategies such as contact tracing towards mitigation strategies. In late April, many states have been increasing their contact training capacity (e.g., training and deploying more contact tracers, creating online apps) in preparation for an eventual reopening phase [1.4.6-1.4.8]. Some states are opting to hire contact tracers from communities that have been disproportionately affected (e.g., racial and ethnic minorities) to allowed for tailored approaches and greater community collaboration [1.4.9]. Also in April, Apple and Google announced that they will work jointly to develop an opt-in exposure notification system that would allow smartphone

[1] John F. Kennedy (JFK) International Airport in New York; San Francisco International Airport (SFO) in California; and Los Angeles International Airport (LAX) in California.

users to know whether they have been in contact with a positive case based on Bluetooth technology [1.4.10]. In May, the tech companies released application programming interfaces (APIs) that will allow contact tracing apps from state public health authorities to work cross-platform. In the next few months, Apple and Google plan to implement this contact tracing technology at the operating system level, allowing users to opt in without having to download an app [1.4.11].

However, as of July 13, no state public health departments have released apps that use the Apple and Google APIs [1.4.12]. Contact tracing capacity has increased [1.4.13], but tracing capacity is still severely lacking. Subpar tracing capabilities have contributed to the inadequate response to spikes in the number of cases [1.4.14]. Moreover, research has shown that the new hotspots in the U.S. are areas that failed to build up tracing capacity and key public health tools. However, even states with adequate capacity face challenges, including getting the public to cooperate and answer calls from tracers [1.4.15]

Contact tracing efforts increased in the fall, but continue to face challenges. The U.S. contact tracing workforce reached 50,000 in October, but remains short of initial recommendations [1.4.16]. More states are adopting digital contact tracing apps, but uptake by individuals remains limited due to privacy and other concerns [1.4.17].

With regards to surveillance, the CDC originally used the existing influenza surveillance system to track COVID-19 cases. On February 14, 2020, the CDC announced that it would start testing those with flu-like symptoms for COVID-19 at five public health laboratories as part of an influenza-based community surveillance system that would be rolled out nationwide [1.4.18]. Following the passage of a USD$2 trillion emergency stimulus bill in late March directed towards COVID-19 relief, at least USD$500 million was set aside for development of a surveillance and data collection system. The CDC is expected to revamp the existing public health surveillance and analytics infrastructure and will report on this within the next month [1.4.19]. Further, two billing codes have been created to allow for tracking of new COVID-19 cases and billing for testing [1.4.20].

Beginning in April, the CDC started publishing a weekly surveillance summary of COVID-19 activity "COVIDView" that details key trends and indicators with regards to outpatient visits, emergency department (ED) visits, hospitalizations and deaths, and laboratory data. COVIDView also describes the CDC's updated surveillance system which is comprised of four components [1.4.21]:

- Virologic Surveillance: weekly reporting from all laboratories on the total number of respiratory specimens tested for SARS-CoV-2 and positive cases;
- Outpatient and Emergency Department Illness Surveillance: uses two syndromic surveillance systems (U.S. Outpatient Influenza-like Illness Surveillance Network and National Syndromic Surveillance Program) to monitor trends in outpatient and ED visits that may be related to COVID-19 and better account for mild/moderate cases;
- Hospitalization Surveillance: tracks laboratory-confirmed COVID-19-associated hospitalization rates through the COVID-19-Associated Hospitalization Surveillance Network (which covers ~10% of the U.S. population);
- Mortality Surveillance: death certificate data collected from state vital statistics offices by the National Center for Health Statistics.

The CDC added national- and state-level mortality and hospitalization forecast models in mid-May. The ensemble models incorporate different assumptions from individual models about social distancing and public health interventions to predict mortality and new hospitalizations [1.4.22]. The CDC also started conducting serology surveillance to better understand the incidence of COVID-19 in the general population. The CDC is using large-scale geographic surveys, community-level surveys, and surveys targeted toward specific populations (e.g. healthcare workers) to assess seroprevalence [1.4.23].

LTCFs, which have been disproportionately affected, are also included in most monitoring and surveillance efforts. Nursing home deaths account for more than 40% of deaths in some states [1.4.24]. As of mid-April, 36 states reported coronavirus cases and deaths in LTCFs, though variations in the type of data and definition of a LTCF exist from state to state. 47 states are now reporting on LTCFs as of early June [1.4.25]. The Centers for Medicaid and Medicaid Services (CMS) has proposed greater reporting requirements for nursing homes, though this would not impact long-term care facilities that are not part of Medicare or Medicaid programs. Additionally, current numbers of cases and deaths in these facilities are likely underestimated due to these variations in reporting as well as death certificates listing incorrectly listing non-COVID 19 causes of death [1.4.26]. On May 1, CMS approved a final rule requiring federally-funded nursing homes to report COVID-19 data on a weekly basis starting by May 31 [1.4.27]. CMS data showed that nearly 32,000 resident deaths occurred in nursing homes by May 31 [1.4.28]. CMS previously announced new monetary penalties for nursing homes and states that fail to report data or with poor infection control [1.4.24]. The total deaths at long-term care facilities is likely much higher when accounting for non-federally funded nursing homes as noted by other sources [1.4.29]. Some states are creating special post-hospital facilities to avoid exacerbating ongoing infection control issues in nursing homes [1.4.30]. Misaligned incentives for long-term care facilities are leading to other issues. Given that these facilities can receive at least $600 per day from Medicare for caring for sicker patients for a short period of time, some facilities are taking on more profitable COVID patients and evicting existing residents [1.4.31]. The recent fall/winter surge in cases has affected nursing homes heavily. During the week of November 15, more than 16,000 cases were reported in nursing homes and mortality appeared to be approaching spring 2020 levels [1.4.32].

1.5 Testing

At the beginning of the outbreak, the CDC recommended testing those who were symptomatic and had recently travelled to China or been exposed to a confirmed case. As the disease continued to spread, testing criteria was expanded in late February to include those with travel history to Italy, Iran, Japan, and South Korea as well as those with respiratory failure requiring hospitalization regardless of travel history. On March 4, 2020, the CDC deferred testing criteria to physician discretion. The tiered priorities of testing are (as of March 24, 2020 [1.5.1]):

- *Priority 1:* Hospitalized patients and symptomatic healthcare workers
- *Priority 2:* Symptomatic patients in long-term care facilities, symptomatic patients 65 years of age and older, symptomatic patients with underlying conditions, and symptomatic first responders
- *Priority 3:* Symptomatic critical infrastructure workers, other symptomatic individuals, health care workers and first responders, individuals with mild symptoms in communities experiencing high COVID-19 hospitalizations

- *Non-priority:* Asymptomatic individuals

As noted above, despite this guidance on testing priorities, all testing decisions are at the discretion of individual providers and local/state health departments. The federal government has taken steps to assist Americans in determining whether they need to be tested or require care. Apple, in partnership with the Coronavirus Task Force and HHS, released a screening tool in March that allows Americans to assess whether they need to seek care for COVID-19 symptoms [1.5.2]. The CDC has also implemented a coronavirus self-checker on their website. In mid-April, the CDC changed the period of exposure risk for an individual with suspected COVID-19 from onset of symptoms to 48 hours prior to symptom onset [1.5.3].

All testing was initially conducted at the CDC. State and local public health laboratories were subsequently awarded Emergency Use Authorization (EUA) by the FDA on February 4, 2020 [1.5.3, 1.5.4]. Private labs were granted the authority to start testing later that month [1.5.5]. More recently, new COVID-19 testing and treatment centers have been set up, though this varies from state to state. These include drive-through testing locations through the federal or state government, health systems, and private retailers, though all are currently not open to the general public. As of April 21, over 600 drive-thru testing sites were available nationwide [1.5.6].

With the involvement of both the public and private sectors and advent of new tests, testing has gone up – on average, about one to two million people are being tested weekly as of late April [1.5.7]. As testing capacity increases, certain states have started testing a wider range of individuals – e.g. asymptomatic first responders, health care workers, and essential employees [1.5.8]. Despite the increase in the number of conducted tests, delays have been noted in test reporting. Supply shortages and issues are notably to blame (see Section 2.1). The U.S. also has yet to hit the testing capacity benchmark prescribed by the World Health Organization (WHO), which recommends a positive rate around 10% [1.5.9]. Introducing more point-of-care tests, increasing testing center availability, and decreasing testing delays will be critical to ensuring that adequate laboratory testing capacity exists and that those in need can get access to appropriate care in a timely manner [1.5.10].

As of June 10, testing capacity and demand continues to increase. On average, three to four million people are being tested weekly [1.5.7]. However, issues with test reporting have been noted. In mid-May, it was discovered that the CDC and several states were combining viral and antibody test results, despite the tests being used for different purposes [1.5.11]. Public health experts have also lamented the incompleteness of testing data. In early June, HHS announced that labs would be required to report on race, ethnicity, and sex as part of testing data submission given growing evidence of the significant impact on racial and ethnic minorities. These requirements will allow for more complete surveillance and interpretation of testing results [1.5.12].

Continuing to increase testing capacity will be important for safely reopening businesses, schools, and other public places. An analysis by Castlight Health in mid-May found that most states have the capacity to test 1% of their population weekly, but testing sites were disproportionately distributed within individual states. More than 50% of counties did not have a testing site, especially in rural areas. More than half of counties with a testing site also failed to meet that minimum threshold. The expansion of testing sites by retailers like CVS and Walmart may address this gap [1.5.13]. In late May, the FDA also

issued new guidance and recommendations intended to help accelerate the development and EUA approval of at-home coronavirus tests [1.5.14]. Increased testing supply further allows for more post-mortem COVID-19 testing and facilitates accurate measurement of COVID-related mortality [1.5.15]. Additionally, while the CDC is conducting serology surveillance, the agency has cautioned using seroprevalence as a guide for knowing when to reopen [1.5.16].

As the U.S. continues to face spikes in cases in June/July, testing issues are beginning to resurface. Cases are outpacing testing capacity once again [1.5.17]. Given the high demand and low supply of tests, some cities are restricting who can get tested [1.5.18]. Recent statements by health policy experts and government officials have also highlighted the lack of adequate testing. Based on antibody testing conducted by the CDC, Dr. Robert Redfield, Director of the CDC, said that the number of total cases may be ten times as high as the total confirmed cases in the U.S. [1.5.19]. Former FDA Commissioner Scott Gottlieb similarly echoed that the U.S. is probably only diagnosing one in ten infections and emphasized the need for more testing [1.5.20]. Delays in test result reporting are hindering the ability of health departments to adequately respond [1.5.21]. The federal government also announced its intention to shut down testing sites [1.5.22]. This comes in the face of increasing research on disparities in testing site accessibility, including less testing sites in communities of color [1.5.23]. Despite these struggles, the U.S. continues to pursue a decentralized testing strategy. HHS released state testing plans from May and June, and will offer feedback to states in July about their July-December testing plans based on their May and June plans [1.5.24].

As of December 20, nearly 2 million tests are conducted daily on average [1.5.7]. Yet, despite increased testing availability, the U.S. continues to face issues with access, reporting delays, and restrictions on who can get tested [1.5.25]. The FDA's approval of the first over-the-counter, fully at-home COVID-19 test in mid-December offers hope for alleviating some of these issues [1.5.26].

2. Ensuring sufficient physical infrastructure and workforce capacity

Infrastructure and workforce capacity are crucial for dealing with the COVID-19 outbreak, as there may be both a surge in demand and a decreased availability of health workers. This section considers the physical infrastructure available in the jurisdiction and where there are shortages, it describes any measures being implemented or planned to address them. It also considers the health workforce, including what jurisdictions are doing to maintain or enhance capacity, the responsibilities and skill-mix of the workforce, and any initiatives to train, protect or otherwise support health workers.

2.1 Physical infrastructure

As COVID-19 hit the U.S. in January, and infections accelerated throughout February, the existing supply of physical resources needed to test and treat the cases quickly fell behind demands. Many hospitals and other healthcare organizations in the U.S. stock inventory very leanly, resulting in a short supply of equipment and medical supplies needed for the pandemic. Hospital beds in the U.S., which has one of the lowest hospital bed/population ratios among OECD countries [2.1.1; 2.1.2], started filling up quickly.

Ramping up production and distribution of testing supplies, medical equipment and supplies, including PPE, and expanding bed capacity for COVID-19 cases proceeded slowly in February. The slow development

and distribution of tests throughout February (see below), along with delayed use of physical isolation (see Section 1.2), contributed to an explosive growth in COVID-19 cases in March and April, which created an even greater strain on the infrastructure needed for treating the virus [2.1.3].

COVID-19 Testing Supplies

Testing for COVID-19 got off to a slow start in the U.S. due to initial problems with testing supplies [2.1.4]. The first commercial coronavirus test was approved on March 13, 2020, and the first serological antibody test to assess previous infection and potential immunity was approved on April 3. In total, 48 in-vitro diagnostic tests have received EUA for COVID-19 testing as of April 24. On April 20, FDA approved its first COVID-19 test with home collection of specimens; however, no test can currently be processed at home [2.1.5]. The efficacy of these tests is unknown – healthcare experts caution that up to one-third of patients with coronavirus may test negative [2.1.6]. In addition to developing effective rapid diagnostic testing, accurate serologic testing capabilities for surveillance and identification of potential immunity is needed for safely reopening the country [2.1.7]. Other testing supplies also remain an issue – reagents are often only compatible with testing equipment made by the same commercial manufacturer [2.1.8], and swab production only ramped up in late April. Johns Hopkins researchers claim that the U.S. needs a massive expansion of rapid diagnostic tests as well as development of new technologies dedicated to case identification and contact tracing [2.1.9].

Prominent health policy experts, physicians, and state governors cite testing capacity needs ranging from 370,000 to tens of millions of tests daily [2.1.10; 2.1.11]. The federal government has left the states in charge of testing strategy, so public health efforts to reach populations in need of testing, such as people going back to work in close quarters, those who believe they have been exposed or found to be exposed through contact tracing, food industry workers, and essential workers with high public contact such as grocery workers, have not been promoted on a national level. State efforts vary. Some states invite anyone who wishes to be tested to go for a test, others continue the same restrictive testing policies they had when testing supplies were low.

By late May, testing supplies were meeting or exceeding demand. However, the numbers of people being tested remained low, indicating that supplies were not necessarily adequate, but rather that demand was not where it should be [2.1.10; 2.1.11]. As of June 12, close to 600,000 people nationally were tested a day, indicating that the low end of testing capacity had been reached [2.1.12]. However, some states were still having difficulty acquiring testing kits and supplies, such as swabs. States continued to appeal to the federal government to help reduce supply shortages and coordinate purchases and distribution [2.1.13].

In July, testing increased to around 4 million diagnostic tests per week, but the surge in cases in many states and the expansion of populations being tested (more of the population in general, prisons, nursing homes, workplaces) outpaced testing capacity [2.1.14]. Commercial labs continued to have trouble getting adequate stocks of reagents, pipettes, and other testing components, and some were considering limiting testing to high risk populations. Some states claimed that federal distribution of testing supplies has created disruptions and added work. According to Washington state's health secretary, federal test supplies sent to that state were "badly packaged, unlabeled, incompatible with the state's equipment or otherwise unusable" [2.1.14]. Testing bottlenecks are leading to long wait times for results. These testing supply problems are limiting testing capacity just when the need for testing is at its greatest.

Hospital bed capacity, medical equipment and supplies

As the U.S. experienced growing COVID-19 cases in late March and April, shortages of hospital beds, medical equipment and supplies grew. Hospital bed shortages were uneven because bed capacity and the population at-risk for needing these beds varies from state to state [2.1.15]. Furthermore, initial epicenters such as the states of Washington, California, and New York, and urban centers such as New York City and Chicago, also required higher numbers of beds. Hospital shortages also existed in some areas for ventilators and protective equipment, such as gloves, gowns and masks [2.1.5]. In late March nearly a third of facilities were almost out of face masks, 13% were out of face shields, and about 25% were completely or nearly out of gowns [2.1.16] In a late March national survey, 91% of the mayors of U.S. cities reported that their cities had inadequate supplies of face masks and 88% said they didn't have enough PPE for their medical and first responder personnel [2.1.16]. Throughout March, as shortages of supplies and protective equipment were observed in COVID-19 epicenters, some staff in these areas publicly appealed for more gear so that the public would understand the severity of the problem and support policy efforts to alleviate the shortages [2.1.17].

To deal with shortages of medical equipment and supplies, several measures have been taken. Initially, the U.S. safety net of medical-equipment supplies—the Strategic National Stockpile—was tapped to fill shortages. However, the stockpile ran low by the end of March. Additionally, distribution of the supplies was uneven, with some states, such as Florida receiving all that they asked for, and others, such as New York and New Jersey, receiving only a small amount of what they asked for [2.1.17].

In mid-March the Federal Emergency Management Agency (FEMA) was put in charge of procuring and distributing resources for states, federal agencies and the private sector. As of mid-April, FEMA had distributed $5.5.billion in emergency assistance, including PPE, ventilators, testing samples, and construction of federal medical stations [2.1.18; 2.1.19]. On May 15 FEMA reported that the agency had distributed "billions of essential resources and protective equipment…throughout the nation," and that together FEMA, the Department of HHS, and the private sector have "coordinated the delivery of more than 97 million respirators, 133.7 million surgical masks, 10.5 million face shields, 22.4 million surgical gowns, 989 million gloves, 10,600 ventilators and 8,450 federal medical station beds." [2.1.20].

Federal emergency acts (see Section 5) have included funding and policies designed to reduce supply shortages. The *Coronavirus Aid, Relief, and Economic Security Act* (CARES Act), passed by Congress at the end of March, provided USD$179 billion provision for public services, with targeted funding for producing and purchasing ventilators and masks. The *Heroes Act*, which has passed the House of Representatives but is not expected to pass the Republican-controlled Senate, would mandate the sufficient use of the *Defense Production Act* for increased production of PPE and other medical supplies [2.1.21]. In response to complaints about the uneven distribution of equipment and supplies by the federal government, it would also create a federal Medical Supplies Response Coordinator, who would oversee the manufacture and distribution of medical equipment and supplies, including PPE.

Many states engaged in contingency planning to relieve shortages of hospital beds and ventilators. Hospital bed capacity was improved by reducing or stopping elective surgeries and expanding beds into other medical facilities such as surgical centers and inpatient rehabilitation hospitals, and non-medical facilities such as gymnasiums, hotels, dormitories and convention centers. Hospital bed expansion into

non-medical facilities was not possible until a late March Center for Medicare and Medicaid ruling that allows hospitals to set up beds in non-medical facilities.

Key to reducing shortages of medical equipment and supplies has been engaging the manufacturing sector in the production of needed items. Automakers such as General Motors and Ford Motor Company were commissioned, through the *Defense Production Act* (see Section 5), to address the shortage of ventilators by collaborating with ventilator companies and using a simplified design to produce tens of thousands of ventilators. Manufacturers also began voluntarily to produce more protective gear. By late March, production of tests, ventilators, medical supplies, PPE and other needed equipment was underway.

In addition to new manufacture of items, industries, such as auto, have donated masks out of their supply. Community members and organizations are sewing homemade masks to donate to hospitals. Some places are obtaining masks and other protective equipment from China. The media has reported some cases where providers are using Twitter and other social media to plead for more protective gear [2.1.22].

As the production of ventilators and PPE revved up, in late April, distribution of the items and the costs of obtaining the items became an issue. States found themselves having to independently search for products and compete with each other and the federal government to procure them. As the state bidding war heated up, price gouging occurred [2.1.23]. To address these issues, the National Governors Association (NGA) created a Coronavirus Resource website [2.1.24]. The NGA is also considering a multi-state consortium to create a monopsony in buying the goods [2.1.23].

These efforts of the federal and state governments, private companies, and individuals, combined with a fall in hospital resource use in late April, alleviated the shortage of hospital beds and ventilators somewhat in May [2.1.25]. However, shortages of PPE remained [2.1.26].

As several states reopened in May and June, and the number of cases in those states surged over the summer, having sufficient ICU beds once again became an issue. Four states (Florida, Texas, Arizona, and California) had record numbers of new cases each day and approached bed capacity. In Arizona and Florida, ICU beds were at capacity in early July [2.1.27; 2.1.28].

The fall surge has created extreme shortages of ICU and general hospital beds in many states, particularly the hard-hit Midwest. According to the New York Times, as of December 9, more than a third of Americans live in areas where hospitals are critically short of intensive care beds, while one-tenth live in an area where ICUs are completely full or have less than 5% of beds available [2.1.29].

Despite attempts to increase supplies of PPE, shortages have continued throughout the pandemic. In early May, 87% of nurses had to reuse PPE designed to be single-use, and 72% worked with exposed skin or clothing while treating COVID-19 patients [2.1.30]. As of mid-September, hospitals, nursing homes, and doctor's offices still had to decontaminate and reuse masks and gloves and obtain equipment through unconventional markets [2.1.31]. In November, only 16.5% of nurses in hospitals reported having universal PPE in EDs, over 80% said they had to reuse single-use PPE, and about 20% said their employer limits the use of N95 respirator masks [2.1.32]. December shortages reveal similar rationing of disposable gloves and gowns and reusing of N95 masks [2.1.33]. Nursing homes have had severe PPE shortages [2.1.34], with 46% having only one-week's supply of at least one type of PPE in the summer and 1 in 5 dangerously low in one or more items, like gloves and hand sanitizer, in October [2.1.35].

2.2 Workforce

The initial healthcare workforce supply going into the pandemic was on the low side in the U.S. The U.S. has fewer practicing physicians per capita than several other high-income countries [2.2.1, 2.2.2]. The supply of nurses in the U.S. is around the median of other high-income countries [2.2.1, 2.2.2], but only 60% of nurses work in hospitals, and within hospitals the staff working in patient care, is lower than several other OECD countries [2.2.3]. Even before the pandemic, staffing was not optimal in the eyes of nurses [2.2.4, 2.2.5].

As the pandemic progressed, the supply of both these professionals, as well as many other healthcare workers, became inadequate to meet the surge in demand for healthcare from COVID-19 patients in settings such as critical care and emergency rooms, and in pandemic epicenters [2.2.6]. One analysis found that even if ICU beds in epicenters could be doubled or tripled, there would not be enough nurses to staff them, as only 15% of hospital-employed nurses (which is 60% of the nurse workforce), work in critical care units [2.2.7]. Furthermore, even if ICU staffing could be bolstered by transferring non-ICU personnel in medical-surgical, pediatric, neonatal, and other departments to ICUs, those areas would continue to need staff.

LTCF have also suffered staffing shortages. In May 2020, nearly 2,000 LTCFs reported shortages of nurses [2.2.8].

Several strategies were implemented to alleviate the shortages of physicians and nurses. In order to be able to increase professionals in shortage areas, licensing laws have been liberalized to allow a professional with a license in one state to be able to work across state lines. Additionally, former physicians and nurses are being asked to rejoin the workforce, and salaries for professionals capable of working in crisis settings have risen in some places. Governors of some states such as New York and Michigan have used social media, as for example Twitter, to call for health professionals to come help their state. The use of telehealth to diagnose, triage and treat the milder cases is increasing, and provisions in the *CARES Act* support the expansion and strengthening of telehealth systems (see Section 4 – Financing healthcare for more details). To address staff shortages in ICUs, nurses are being moved from other hospital departments to the ICU to work under the supervision of ICU nurses. Non-nursing personnel are being used in clinical care where possible. In general, hospitals are adopting flexible assignments of the healthcare workforce.

Some ways to improve the physician shortage face barriers. Increasing the use of nurse practitioners (NPs) as independent practitioners would help, but this can only occur in the 22 states that allow NPs to have full scope of practice. In the other 28 states NPs are bound to a collaborative role where physicians must oversee NP's work. The American Association of Nurse Practitioners has called on state governors to waive practice restrictions.

In late April, as the number of new cases started to flatten in many areas, and as testing of the population increased, workforce requirements shifted from professional healthcare providers in acute-care settings to public health workers who can carry out testing, contact tracing, isolating the sick, and quarantining those exposed. A plan developed by researchers at Johns Hopkins calls for a surge in public health workers to accomplish these tasks [2.2.9]. The plan is to place these workers in areas of greatest need, managed through state and local public health agencies. Contact tracing, in particular will take a large number of

workers--approximately 100,000 (paid or volunteer) [2.2.9]. At this time, however, health departments in many states are struggling to build contact tracing to a sufficient level. To build up this workforce researchers state that congress will need to distribute sizeable emergency funding to state and regional health departments.

An important aspect of improving the supply of healthcare workers is keeping workers healthy. Central to that includes adequate staffing, supplies, and protective gear, and ongoing testing of the workforce. Measures to increase staffing through expanding supply are described above in this section while those to improve supplies and PPE are discussed in section 2.1. As described above, PPE shortages have continued throughout the pandemic. Testing of the workforce has also been inadequate. For example, as of May 10 only 16% of nurses had been tested [2.2.10].

PPE lapses and inadequate testing may have contributed to the 1.3 times higher infection rates among healthcare workers and the deaths of nearly 1,700 U.S. healthcare workers from COVID-19 by September 2020 [2.2.11]. A section of the Heroes Act would mandate the Occupational Safety and Health Administration (OSHA) to enact measures to ensure that employers protect workers during the COVID-19 pandemic, but this act has yet to be passed by the Senate [2.2.12].

Despite actions to improve staffing, acute care staffing shortages appeared again with surges in the Southern states in the summer and Midwestern and other states in the fall. As of November 19, hospitals in 25 states were critically short of clinicians and other staff [2.2.13]. One out of five nursing homes have had staffing shortages since May [2.2.14]. Healthcare worker shortages were probably exacerbated due to continued PPE shortages and testing difficulties which led to reduced staffing from workers out sick and deaths.

As of December 2020, many healthcare workers were exhausted and burned out [2.2.15]. A July survey reported that around eight per cent of doctors had closed their offices and another four per cent planned to within the next year [2.2.15]. Nurse job turnover rates are high and nurses are leaving the profession [2.2.15]. Strikes have broken out over inadequate PPE, unsafe working conditions and understaffing in Southern California, Houston, Illinois, Northern California and Pennsylvania [2.2.15; 2.2.16]. Even public health workers in states such as Kansas are leaving the profession in response to harassment by the public [2.2.17].

3. Providing health services effectively

This section describes approaches for service delivery planning and patient pathways for suspected COVID-19 cases. It also considers efforts by jurisdictions to maintain other essential services during periods of excessive demand for health services.

3.1 Planning services

The American Hospital Association reports metrics for community and federal hospitals in the United States; in 2018, the U.S. had 5,198 community hospitals and 209 federal hospitals. Community hospitals had 792,417 beds, 3,532 EDs, and 96,500 ICU beds, of which 23,000 were neonatal and 5,100 pediatric. Less than 68,400 ICU beds of all types were available for the adult population, according to 2018 survey

[3.1.1] While the U.S. has approximately 62,000 full-featured ventilators (with 10,000 – 20,000 more in the National Stockpile) in the country, the limiting factor will most likely not be ventilators, but respiratory therapists and critical care staff. Given these numbers, a shortage of hospital beds, ICU beds, and ventilators may occur [3.1.2]

During the March 31 press briefing, the Coronavirus Task Force announced an expected 100,000 - 240,000 deaths from COVID-19 in the upcoming months [3.1.3]. As of April 9, the model used for this estimate has been revised to around 60,000 deaths, with peak resource use projected for April 11. As of July 17, with over 130,000 registered deaths, the model projects 224,089 COVID-19 deaths by November 1, 2020 [3.1.4] and estimates the second resource use peak to fall in the beginning of August.

According to the University of Washington model, the demand for hospital resource use peaked on April 15 and has been declining since [3.1.4]. As of June 9, the model predicts the need for 24,882 hospital beds, 7,453 ICU beds and 6673 invasive ventilators, while projecting the total of 145,728 deaths from COVID-19 by August 4, 2020, However, these estimates could be substantially higher depending upon how quickly the states reopen and reduce measures of physical isolation. As of July 17, after over two months of decline in both mortality and hospital resource use, the estimates are on the rise again, projecting the demand for over 6,200 ICU beds and 5,100 invasive ventilators by August 1. However, given the surge in new cased in the first half of July, the uncertainly of these estimates has increased as well. Longer term projections are even less certain and more grim as CDC anticipates confluence of COVID-19 and seasonal influenza to produce the “most difficult time in American public health” [3.1.5].

In the attempt to facilitate the delivery of care, on March 23, the CMS approved a waiver granting 13 states a substantial regulatory relief, including relaxing rules regarding virtual visits, which aim to broaden availability of telehealth care delivery and modalities [3.1.6]. The Office of Inspector General curbed co-pay and collection of deductibles for telehealth programs, including 80 additional services that were not payable prior to March 30 [3.1.7]. As of June 10, 38 states have taken mandatory action expanding access to telehealth services through private insurers including new requirements for coverage, waiving cost-sharing, reimbursement parity, and expanded options for delivery of telehealth services [3.1.8].

3.2 Managing cases

The CDC has instructed members of the public with general questions about COVID-19 to call their state health department’s main daytime telephone number [3.2.1] or contact the CDC at www.cdc.gov/cdc-info or 1-800-CDC-INFO (800-232-4636). Hotlines for COVID-19 support are experiencing a substantial surge, however the uptick in calls to nurse and triage lines is also attributable to the lesser availability of medical personnel.

There is no national triage plan for COVID-19 patients, but multiple states have been re-examining their own triage strategies, including provisions specific to the expanding epidemic. On March 28, the National Academy of Sciences, Engineering and Medicine issued a document articulating the guiding principles for Crisis Standards of Care decision-making at all levels [3.2.2], while American College of Emergency Physicians issued a national strategic plan for ED management of outbreaks of COVID-19 [3.2.3]. Guidelines for rationing scarce resources differ by state, but as of April 2, the government has not released official recommendation for resource distribution.

On March 6, the *Coronavirus Preparedness and Response Supplemental Appropriation Act* of 2020 (HB 6074) was signed into law, increasing access to telehealth at the federal level [3.2.4]. On March 17, the CMS issued a set of recommendations, allowing patients to be seen via live video conference in their homes, regardless of geographic location. HHS announced that it will waive penalties for using non-HIPAA compliant videoconferencing software [3.2.5]. In response to these legislative actions aimed to increase availability of telemental health services, American Psychiatric Association has issued Practical Guidance for COVID-19 [3.2.6; 3.2.7]. As of July 17, 49 states have modified requirements for telehealth in response to COVID-19 [3.2.8].

In the second pandemic wave in summer 2020, states experiencing the greatest surge of new cases, such as Arizona and Texas, adapted crisis standards of care that offered greater flexibility to allocate resources based on current needs of the patients [3.2.9]. However, these new standards of care potentially introduced discriminatory denial of life-saving health care [3.2.10].

3.3 Maintaining essential services

On March 18, the CMS issued a set of recommendations [3.3.1] for adult elective surgery and procedures, providing a framework for hospitals and clinicians to implement during the COVID-19 response. The decisions about nonessential procedures are to be made at the local level, considering such factors as patient risk, availability of beds, staff, PPE, and the urgency of the procedure. A month later, on April 17, The American College of Surgeons released guidance for local resumption of elective surgery [3.3.2] and elective case triage for surgical care [3.3.3].

The CDC has issued a framework for the provision of non-COVID-19 clinical care [3.3.4]. Providers are urged to determine the essential services that can continue, to screen patients for symptoms of exposure to COVID-19, and ensure mask wearing and hand hygiene. The CDC distinguishes three levels of potential harm for patients (highly likely, less likely, unlikely) and provides examples of symptoms and clinical decisions. CDC recommendations are updated regularly.

The CDC also issued a COVID-19 preparedness checklist for Nursing Homes and other long-term care settings [3.3.5], identifying key areas that long-term care facilities should consider in their COVID-19 planning. The checklist offers a guide for developing a comprehensive COVID-19 response plan, including rapid identification and management of ill residents, considerations for visitors and consultant staff, supplies and resources, sick leave policies, education, training, surge capacity planning, and post-mortem care. A similar set of strategies was issued by CDC to inform the response of all LTCFs [3.3.6]

The American Medical Association released a set of resources for navigating mental health effects of COVID-19, particularly targeting frontline medical workers [3.3.7]. The US Department of Veterans Affairs has issued a similar guide for the general public [3.3.8]. As part of the *Coronavirus Aid, Relief, and Economic Security Act* (CARES), Division B, USD$425 million have been appropriated to Substance Abuse and Mental Health services Administration to address mental heath needs of Americans [3.3.9].

As the first pandemic wave lessened in May-June, routine outpatient visits, routine dental care, and elective procedures started back up. Routine care and elective surgeries continued throughout the second pandemic wave in the summer [3.3.10]. However, by the end of November, the third pandemic

wave had hospitals again at maximum capacity, and many have enacted volume restrictions, rescheduled cases, or stopped scheduling cases [3.3.11]

4. Paying for services

Adequate funding for health is important to manage the excess demands on the health system. This section considers how jurisdictions are paying for COVID-19 services. The subsection on health financing describes how much is spent on health services, where that money comes from, and the distribution of health spending across different service areas. The section also describes who is covered for COVID-19 testing and treatment, whether there are any notable gaps (in population coverage and service coverage), and how much people pay (if at all) for those services out-of-pocket.

4.1 Health financing

During March 2020, Congress passed three major legislative initiatives to address the escalating COVID-19 outbreak. On March 6, the President signed the *Coronavirus Preparedness and Response Supplemental Appropriations Ac*t, 2020, an USD$8.3 supplemental spending bill intended to provide funding to states, localities, territories, and tribes to assist with COVID-19 preparedness and response. The bill allocated USD$2.2 billion to the CDC [4.1.1], which soon thereafter informed State Health Officers that over USD$560 million would be distributed to states and local jurisdictions [4.1.2]. HHS later announced that it would be providing USD$100 million from the bill's funding to support the National Special Pathogens Treatment System, a national infectious diseases training and treatment network used for Ebola and other special pathogens [4.1.3]. On March 18, a second bill, the *Families First Coronavirus Response Act* (FFCRA), was signed into law. This act addressed key healthcare-related issues including insurance coverage of coronavirus testing as well as other benefits like paid sick leave, nutrition assistance, and unemployment [4.1.4], and explicitly provides USD$3.5 billion in payouts for benefits [4.1.5]. Most recently, Congress passed the *Coronavirus Aid, Relief, and Economic Security "CARES" Act* on March 25. This USD$2 trillion relief package includes a variety of components including more than USD$150 billion for the healthcare system (hospitals, research, treatment, and stockpiling vital equipment like ventilators) and an additional USD$150 billion for state and local governments [4.1.6, 4.1.7]. Furthermore, the President previously declared a national emergency on the 13, freeing up USD$50 billion in additional funding under the *Stafford Act* [4.1.8].

In addition to these funds, the declaration of a national emergency provided HHS with the authority to bolster the response effort by waiving a number of regulations including Medicare's three-day hospital stay requirement prior to nursing home transfer, state licensures requirements for providers, and provisions for telehealth [4.1.5]. However, no payment incentives are in place for providers of COVID-19 patients. Along with other flexibilities discussed above (e.g. telehealth), the CMS has increased flexibilities for providers including decreasing barriers for clinicians to be hired from the community or other states and providing temporary relief from paperwork, reporting and audit requirements [4.1.9].

Aforementioned legislation has also increased resources for addressing health system capacity constraints. The federal government has partnered with major retailers such as Walmart to implement drive-through testing capabilities, though the number of sites remains limited. Payment details are not known, but funding these partnerships were cited as another potential reason for invoking the *Stafford*

Act. Moreover, HHS has provided funding to private labs to develop more diagnostic tests as a means of increasing testing capacity and reducing delays [4.1.10].

In mid-April, the *Paycheck Protection Program and Health Care Enhancement Act* was passed by Congress. Though the majority of the bill is targeted to supporting the emergency loan program for small businesses, USD$75 billion are allotted to hospitals and USD$25 billion are designated to increase testing [4.1.11]. In total, hospitals and other healthcare providers have been given USD $175 billion to offset lost revenue from elective surgeries and cancelled procedures and any higher incurred costs during the crisis. Hospitals can also opt to receive advance payments from Medicare, though these payments must be repaid [4.1.12].

Despite these legislative actions, administration of coronavirus relief funding allocated to HHS has been slow. As of early June, nearly USD$100 billion had yet to be paid to healthcare providers. The majority of distributed funds has also gone to providers and health systems serving Medicare patients [4.1.13]. Medicaid providers, however, had been left waiting. The National Association of Medicaid Directors, several Medicaid directors, and other advocates had stressed the need for funding the federal program for low-income Americans [4.1.14]. On June 9, HHS finally announced its plans for distributing funds to Medicaid agencies. USD$15 billion will be given to providers serving Medicaid or Children's Health Insurance Program (CHIP) patients who have yet to receive funds and USD$10 billion will be allocated to safety-net hospitals. HHS is still working on developing an allocation plan for dentists [4.1.15].

As testing capacity has increased, the latest testing struggle has centered around who is responsible for financing these tests. Despite the FFCRA and CARES Acts requiring that testing be covered with no co-pays for patients, a lack of a uniform policy and conflicting state/local guidance has led to standoffs on coronavirus testing payments. Some large employers or employers with self-funded health plans are refusing to pay for testing [4.1.16]. Similarly, testing nursing home workers is essential for protecting one of America's most vulnerable populations, though nursing homes and insurers have been unclear about who should foot the bill [4.1.17]. Additional federal guidance will increase accessibility to necessary testing. Guidance from the HHS and the Department of Labor in July continues to affirm limits on testing coverage. Testing is only covered for diagnostic purposes (i.e., no reimbursement for surveillance testing of asymptomatic individuals or individuals returning to work) and when recommended by a healthcare provider based on a clinical assessment [4.1.18]. Some insurers have also added restrictions such as the need to be symptomatic [4.1.19].

CMS released data in June on Medicare spending on treatments for hospitalized COVID-19 patients. From January to mid-May, Medicare spent a total of USD$1.9 billion or roughly $23,100 per hospitalized patient [4.1.20]. Congress has resumed ongoing discussions on a new coronavirus relief bill following its July 4 recess, and there is interest in passing a bill before their summer recess.

After months of Congressional gridlock and inaction, Congress agreed to a USD$900 billion stimulus package on December 20. The package includes provisions for the healthcare system, including USD$30 billion for vaccine procurement and distribution and relief funding for healthcare providers and hospitals, as well as supports for individuals and small businesses (e.g., stimulus checks) [4.1.21].

4.2 Entitlement and coverage

Through the *Families First Coronavirus Response Act*, co-payments for COVID-19 testing for Americans with all types of insurance (e.g., private, Medicare, Medicaid, etc.) were waived [4.2.1]. Additionally, the bill allowed for coverage of uninsured individuals by state Medicaid programs. To account for these additional coverage expenses, the federal government announced it would cover a larger portion of Medicaid expenditures and provided USD$1.3 billion for the provision of health care services and testing [4.2.2].

In addition to paying for diagnostic testing, certain insurers have waived cost-sharing requirements for other COVID-19 related services. Some private insurers have opted to waive co-pays and deductibles for inpatient admissions, telehealth services, and treatment. Others have removed barriers to care like prior authorization and out-of-network requirements [4.2.3]. The federal government has also allowed for Medicare beneficiaries to receive telehealth services for both COVID-19 and non-COVID-19 related needs. Most co-payments for inpatient and outpatient services for COVID-19 will be waived, with some exceptions (post-acute care for extended days in a skilled nursing facility, 20% co-insurance for certain outpatient services covered under part B, etc. [4.2.4].

Despite these increased benefits, there is currently no federal requirement for insurers to waive cost-sharing associated with COVID-19 treatment. Several health policy experts have lamented the fact that protections are not built in against surprise billing, especially during a pandemic such as COVID-19, though no action has been taken to date [4.2.5, 4.2.6].

Uninsured individuals may also be at risk of encountering similar excessive medical charges or other barriers in care. States that did not expand Medicaid under the *Affordable Care Act*, for instance, may face challenges in providing testing and treatment for their uninsured. In these non-expansion states, more than 2 million uninsured adults fall into a coverage gap due to having incomes above Medicaid eligibility limits but below the lower limit for Marketplace premium tax credits. Expanding comprehensive coverage to the uninsured or reimbursing clinicians for expanded services and any potential uncompensated costs related to COVID-19 could alleviate this issue [4.2.7, 4.2.8].

In mid-April, HHS announced that it will reimburse claims to health care providers and facilities for testing and treatment of uninsured individuals with a primary COVID-19 diagnosis seen on or after February 4, 2020 [4.2.9]. Claims will generally be reimbursed at Medicare rates. An online portal for submission of reimbursement claims was launched on April 27 [4.2.10]. However, the Kaiser Family Foundation has raised concerns about the reimbursement program. As of October 2020, reimbursement has been limited for the uninsured. There are also disparities in access to care and less protection from large medical bills for the uninsured compared to those with insurance. Some notable limitations include the requirement of a primary diagnosis of COVID-19 (which may prevent coverage for some COVID-19 patients like those who subsequently develop sepsis), optional participation of providers, and the lack of guaranteed reimbursement for providers [4.2.22].

New reports released in May estimated that nearly 27 million may have lost their employer-sponsored health insurance coverage [4.2.11]. The *Consolidated Omnibus Budget Reconciliation Act* (COBRA) allows employees to stay on their employer coverage in situations such as a losing a job. The federal government extended the enrollment timeline for COBRA, allowing Americans to wait 60 days after the coronavirus

national emergency ends rather than within 60 days of notice [4.2.12]. Aside from COBRA, the other options for those losing coverage include enrolling in Medicaid/CHIP or a subsidized plan on the *Affordable Care Act* exchanges, although eligibility varies by state [4.2.11]. CMS also provided further guidance on the aforementioned new Medicaid eligibility group designed to cover testing for the uninsured. The document provides states with implementation requirements regarding eligibility and enrollment, claims and data reporting, and benefits coordination [4.2.13].

New research published by FamiliesUSA in July showed that 5.4 million workers lost their employer-sponsored health insurance between February and May. Southern states, which currently face the worst outbreaks in the country, have been the hardest hit by coverage losses [4.2.14]. In response to losses in employer-based coverage, enrollment in ACA Exchange and Medicaid plans has increased. The number of unemployed persons who enrolled in ACA plans was up 46% compared to 2019 [4.2.15]. Increases in Medicaid enrollment have also accelerated, potentially rising faster than ACA coverage [4.2.16].

Though HHS had appeared to waive surprise medical billing practices for COVID-19 patients, patients may still receive such bills for using out-of-network labs or providers due to loopholes [4.2.17]. The federal government also seems to have relinquished its "march-in rights" in contracts with vaccine and therapeutics manufacturers. While the federal government has never used this tool and manufacturers have stated their intention to make therapies affordable, it would theoretically allow the government to step in if manufacturers charge exorbitant prices or fail to produce enough [4.2.18, 4.2.19].

December 2020 findings from the Bureau of Labor Statistics highlight that more than 50% of businesses instructed their employees to not work at some point during the pandemic. 51% of these companies continued paying wages for some workers, but only 42% continued paying health insurance premiums [4.2.20]. Industries that were most economically impacted were the least likely to pay these health care expenses for their employees. This data is another indication of the fragility of the employer-based insurance system and how the economic impacts of COVID-19 may have severely impacted American's access to care during the pandemic [4.2.21].

5. Governance

The governance of the health system with regard to COVID-19 relates to pandemic response plans and the steering of the health system to ensure its continued functioning. It includes emergency response mechanisms, as well as how information is being communicated, and the regulation of health service provision to patients affected by the virus.

5.1 Pandemic response plans

Two pandemic response plans were in place in the U.S. prior to the COVID-19 outbreak and one other plan had been developed but not activated. **Homeland security** developed a pandemic plan - the ***National Strategy for Pandemic Influenza***—in 2005-2006 *[5.1.1].* This plan has not been updated. The strategy outlines plans for detecting and responding to a pandemic. It provides for antiviral vaccine research and surveillance for viral disease in animals and humans. It requires participation & coordination at all governmental levels (national, state, local) and all sections of society. In the event of a pandemic it calls

for: 1) containment measures; 2) prioritizing resources to areas with greatest impact (as for example, the federal government coordinates the distribution of needed supplies rather than having states go it alone and bid against each other as they face shortages); 3) providing technical assistance and support to state and local communities; and 4) taking leadership in communicating with the public to reduce exposure and transmission. This latter could include modeling physical distancing in messages. It is clear that the U.S. lagged in implementing these plans, and in some cases has yet to implement the measure. For example, as described in the sections above, the country had a late containment response, resources have not been prioritized to areas in need, states and local communities have been told to try to find supplies on their own, and messages coming out of the federal government have been conflicting and inconsistent.

The **Department of Health and Human Services (HHS)** issued its own ***Pandemic Influenza Plan*** in 2005 and updated versions in 2009 and 2017. This plan aims to "prevent, control, and mitigate the effects of influenza viruses that pose high risk to humans." However, the HHS plans lacked information on how to identify, characterize, and develop medical countermeasures against a novel pathogen such as SARS-CoV-2 *[5.1.2].* Key domains of the plan are:

1. Surveillance, Epidemiology, and Laboratory Activities
2. Community Mitigation Measures
3. Medical Countermeasures
4. Healthcare System Preparedness and Response Activities
5. Communications and Public Outreach
6. Scientific Infrastructure and Preparedness
7. Domestic and International Response Policy, Incident Management, and Global Partnerships and Capacity Building

In 2016 the **National Security Council** developed a ***Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents*** *[5.1.3].* However, these guidelines were never fully approved by the current administration and were not immediately followed in the current pandemic [5.1.3]. The playbook has strategies for dealing with a pandemic (detecting outbreaks, securing resources and funding, having a unified federal strategy, and making use of the *Defense Production Act*), and lists early steps to take in the event of an emerging pandemic. Recommendations included securing sufficient PPE early on.

The playbook also recommends when to activate the ***Defense Production Act (DPA)***, which authorizes the president to compel manufacturers to produce equipment and supplies for the sake of national defense that takes priority over all other orders. The President used the DPA toward the end of March to direct manufacturers to make ventilators, and at the end of April to keep meat packing plants whose workers have been affected by the virus open [5.1.4; 5.1.5]. The act also allows the president to distribute materials, although to date, the president has preferred to focus distribution efforts using market forces.

5.2 Emergency legislation

Several emergency acts have been activated with regard to the COVID-19 outbreak. The first was to declare a public health emergency under the ***Public Health Service Act*** on January 31. This act enables the secretary of HHS to declare a public health emergency for significant outbreaks of infectious diseases,

which was declared on that date. HHS has since issued additional policies to support response efforts of the health care community [5.2.1].

The COVID-19 outbreak was declared a national emergency through the ***National Emergencies Act*** on March 13. The act allows the president to waive some federal regulatory requirements and activate existing emergency rulings. For example, the act suspended entry of foreign nationals who were in areas affected by COVID-19, and established policies to acquire PPE, testing, and other equipment [5.2.1; 5.2.2].

A third national emergency ruling, through the ***Disaster Relief and Emergency Assistance Act*** (*Stafford Act*), placed FEMA at the head of the federal COVID-19 emergency response. FEMA can take actions in support of the U.S. Department of Health and Human Services, provide assistance to the states, local governments, and private non-profit organizations, and provide federal financial assistance from the President's Disaster Relief Fund [5.2.1; 5.2.3]. For FEMA actions see section 2.1.

As also described in the 4.1 Health Financing section, the U.S. government enacted several other broad emergency acts in March and April 2020 and is considering a fifth act. The first, the ***Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020***, enacted on March 6, funded domestic and global efforts to detect and contain COVID-19 [5.2.4]. The second, the ***Families First Coronavirus Response Act (FFCA)*** "funded detection and diagnosis of Covid-19, paid sick leave, nutrition services for school-age children and the elderly, and unemployment benefits." [5.2.5]. Building upon the prior two, the third emergency legislation was the ***CARES Act***, which expanded unemployment benefits, business support, tax credits, and funding for hospitals, public services, and equipment such as PPE and ventilators. The fourth, the ***Paycheck Protection Program and Health Care Enhancement Act,*** enacted in mid-April, mostly provides loans to small business, but allocates some funds to hospitals and testing [5.2.6]. According to the Commonwealth Fund President David Blumenthal, M.D., the first three bills did not do enough to address the needs of healthcare workers, as for example, providing for protective equipment, and future bills need to address this need [5.2.7]. The act is currently under congressional consideration. It passed the House of Representatives in May and will move to the Senate for consideration in August, although it is not expected to pass the Senate in its current form. The act provides funds to pay and protect (PPE) first responders, essential workers, teachers, and healthcare workers. It funds testing supplies and contact tracing. Additional unemployment benefits would be provided, as well as health insurance protection for furloughed individuals. It also would protect healthcare workers by enforcing workplace safety through OSHA rules.

None of these acts nationalized any healthcare sectors or suppliers. Rather, the strategy has been to create public-private partnerships to increase the manufacture and distribution of supplies and equipment, and to expand testing. In late March, much of the supply procurement and distribution effort was handed over to medical supply companies. According to some state governors, such as New York State's Andrew Cuomo, this has not resulted in supplies going where they are most needed, but where there are market and business ties. Hospitals with existing supply contracts receive supplies whether or not they need them, while hospitals without existing supply contracts that need the supplies may not get them [5.2.10]. Likewise, the public-private Airbridge project flies supplies to private companies that are only required to sell around half of the supplies to COVID-19 hotspots. The rest can be sold to whomever the companies want.

5.3 National Response Leadership

Leadership of the COVID-19 response initially was shared between the federal and state governments, and an ad hoc private sector group, with the exact roles, authorities and responsibilities unclear and shifting, and the federal government role fading over time. Even early on, there were instances where the federal government should have taken the lead (as instructed by the several pandemic response plans and emergency laws described above), but the responsibilities shifted to the states. A major example is that testing supplies, ventilators and PPE should have been procured and distributed by the federal government [5.3.1, 5.3.2, 5.3.3], but the states were largely left on their own. In contrast, at one point the president claimed complete authority to make decisions regarding lifting of physical distancing and reopening the economy, but when faced by state opposition, he gave all authority to them.

To advise the response efforts at the federal level on January 29 the President formed the Coronavirus Task Force. Vice President Mike Pence is the Chair. Members include Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, Dr. Deborah Birx, U.S. Global Aids Coordinator, Dr. Jerome Adams, the Director of the Department of Health and Human Services, Dr. Alex Azar, the Surgeon General of the U.S., Dr. Robert Redfield, from the CDC, and other government officials and economists [5.3.4]. On May 15, as the U.S. began reopening, the task force was expanded to include members with expertise in vaccines and therapeutics and worker safety. These members include the Secretary of Agriculture, Secretary of Labor, and the Director of the Center for Biologics Evaluation and Research [5.3.5].

Initially, this task force served in both an advisory and communication capacity regarding ways to reduce the spread of the virus. While little is known about the advisory role of the task force, (which is behind the scenes), its role in communication was more public. Dr. Fauci was the main public spokesperson for medical and scientific information regarding dealing with the outbreak (physical distancing, etc.), while Dr. Birx communicated research efforts and findings. In addition to frequent public appearances by Dr. Fauci and other scientists and health experts on this task force, President Trump and other non-scientists in his administration also made public announcements, which often contradicted those of the task force leaders.

Increasingly, the Trump Administration openly disagreed with the scientists on the committee, and by late April, the Task Force met with the President infrequently and made few public briefings. President Trump made it clear that the U.S. had entered a new phase where his administration's emphasis would be on economic issues rather than the nation's health. Although the task force still exists as of December, it has very little public presence and some conservative lawmakers are calling for it to disband because Dr.'s Fauci and Birx contradict the President [5.3.6].

An ad hoc task force headed by President Trump's advisor, Jared Kushner, and composed of heads of private industry, was also formed to work alongside government officials to deal with logistical and technical issues. The objectives of the group was to work with FEMA and HHS to expand testing access, spur industry production of needed medical supplies, and find ways to distribute supplies, but little has been reported about the actual activities of this group.

By June and July, governmental leadership devolved nearly completely to the states and local governments, where the National Governors Association played an active role of coordinating state

governments. No federal plan existed to respond to the resurgence of cases that was occurring in many states, particularly Arizona, Florida and Texas. Each of the affected states made their own response decisions, some slowing or reversing reopening, others leaving such decisions to local authorities (counties or cities) or continuing the reopening and making it difficult for local authorities to do otherwise. For example, as of July 15 Florida's governor DeSantis had not issued a state-wide mandate to wear masks in public, despite a large surge in cases in that state in June and July, but local authorities issued mask mandates. The Georgia governor barred mask mandates but local authorities defied the ban. On July 16 the governor sued the Atlanta mayor to try to stop her from mandating the wearing of masks [5.3.7].

Official public discussions by the Trump administration about the pandemic declined since April-May, but when they occurred the messages were likely to contradict and marginalize public health officials and guidelines [5.3.8; 5.3.9]. Instead of using official messaging channels, President Trump tweeted his messages to his followers. The administration downplayed the seriousness of the pandemic, put a positive spin on the situation in the U.S., and attempted to steer public focus onto other issues [5.3.8; 5.3.9]. President Trump personally set examples that contradicted public health guidance (e.g., held indoor rallies where masks were discouraged and refused to wear a mask), and politicized the response to the pandemic by stating that those who wear masks are criticizing or are against him [5.3.8]. Correspondingly, Trump followers refused to wear masks and socially distance. In early July, President Trump declared the rise in COVID-19 cases to be a result of expanded testing, stated that testing should slow down, and threatened to pull funding to states needing federal support for testing [5.3.10].

One area in which President Trump has tried to assert leadership has been to demand that public schools reopen fully face-to-face in August. Face-to-face school reopening has been a controversial issue, with local school systems voicing concern about doing so, and public health officials trying to establish guidelines to safe reopening. In July, Trump declared the CDC guidelines (see below) to be too strict and threatened to defund public schools that do not reopen fully face-to-face [5.3.9].

Throughout the pandemic the CDC--the nation's premier public health organization with a mission of guiding the public through a pandemic--has not played a strong leadership role outside of having a representative on the task force and providing information on their website regarding the nature of the virus and how to mitigate spread [5.3.11]. During a pandemic it would be natural for the CDC to take a strong advisory and communication lead, which would include issuing guidelines and having a strong public presence. Instead, the CDC has had few public appearances and its guidance appears to be vetted through the White House. In one of the few public appearances by Dr. Redfield, director of the CDC and member of the task force, his advice was repeatedly contradicted by President Trump [5.3.12]. In another example, the CDC's initial detailed guideline for reopening was delayed for two weeks while a shorter version was released in mid-May and then a more detailed version was published on the CDC website on May 20 [5.3.13]. It has been noted that the May 20 version does not provide guidelines on reopening for churches. Other differences with the initial guidelines may exist.

Another example of the marginalized leadership status of the CDC relates to public school reopening guidelines. On July 1, the CDC came out with school reopening guidelines (mentioned above) [5.3.14]. The guidelines recommended that schools collaborate with state and local health officials to determine how classes should be taught in the fall, taking into account the situation in the local community. The CDC guidelines also outlined the risks of different teaching configurations, from virtual to partial to full face-

to-face. Schools should be guided "by what is feasible, practical, acceptable, and tailored to the needs of each community." A general, and daily/weekly readiness assessment checklist was provided in the guideline. President Trump felt that the guidance was "too tough and expensive," and directed the CDC to create different guidelines [5.3.15].

In September, administration officials in HHS bypassed the CDC's scientific review process and published testing guidelines on the CDC website that claimed that people who have been exposed to COVID-19 do not need testing if they are asymptomatic. This was quickly corrected by CDC scientists. In October, the administration installed two officials without public health backgrounds at the CDC to monitor CDC officials and try to control CDC information releases [5.3.16]. In December, a House Panel subcommittee investigation reported initial findings that the Trump administration tried to block or change more than a dozen government reports on the spread of the virus [5.3.17]. The subcommittee found evidence of a "political pressure campaign" to "bully" professionals at the CDC. The subcommittee believed that the effort intended to underplay virus effects in an attempt to promote "herd immunity."

Similar political interference has further been noted at other government agencies with a prominent role in the COVID-19 response, such as the FDA. Earlier political pressure by the Trump Administration to rush vaccine approval by Election Day led to public concern about the safety and efficacy of COVID-19 vaccines and may cripple the mass vaccination efforts that started in December [5.3.18]. Political interference has also extended to COVID-19 treatments, including the nonevidence-based emergency approval of hydroxychloroquine and misrepresentations of the efficacy of convalescent plasma [5.3.19].

In November, President-Elect Joe Biden created a COVID-19 Task Force consisting of 13 physicians, scientists, and public health experts. The COVID-19 Task Force is co-led by Dr. David Kessler, a former FDA Commissioner, Dr. Marcella Nunez-Smith, a Yale physician and prominent health equity advocate, and Dr. Vivek Murthy, a former U.S. Surgeon General under President Obama and the current nominee for that role [5.3.20]. President-Elect Biden has also made several key appointments and nominations targeted toward leading the COVID-19 response including: Ronald Klain (former Ebola Czar) as White House Chief of Staff; Dr. Anthony Fauci (current Director of the National Institute of Allergy and Infectious Diseases) as Chief Medical Advisor on COVID-19; and Dr. Rochelle Walensky (current Chief of Infectious Diseases at Massachusetts General Hospital) as CDC Director [5.3.21]. The appointment of these experts and the proposed Biden COVID-19 response plan suggest the potential for a scientifically-informed response that will include improved public communication and a greater focus on addressing health inequities [5.3.22].

The CDC's role also includes surveillance coordination, communications, international reporting, and testing, which is discussed in Section 5.5. As shown below, the CDC is being side-lined in these areas as well.

5.4 Fast Track procedures for regulation and licensing of medical devices

The FDA issued guidance in March 2020 to increase availability and access to essential medical devices such as ventilators. These changes included [5.4.1; 5.4.2]:

- Relaxing premarket review requirements to ease regulatory burden and ramp up medical device production.

- Allowing manufacturers to add production lines or alternative sites (e.g. non-medical device manufacturers like automobile manufacturers) to increase ventilator manufacturing capability.
- Allowing hospitals and providers to use ventilators and medical devices intended for other environments (e.g. ventilators in ambulances, devices for sleep apnea, etc.).
- Encouraging both domestic and foreign manufacturers to pursue emergency use authorization to distribute ventilators.

5.5 Surveillance coordination, communications, international reporting and testing

The lead body for surveillance should be the CDC, which has the best infrastructure for these activities. From the beginning of the pandemic the CDC used the existing network of local and regional public health agencies and laboratories and academic partners to carry out surveillance of COVID-19 in the U.S. Johns Hopkins University has played a major role in this network. The system uses a number of data sources, including influenza, viral respiratory disease, and syndromic surveillance, case reporting, commercial lab reporting, and other systems [5.5.1; 5.5.2]. Section 1.4 addresses additional details with regard to the CDC surveillance system.

Although the CDC should be the major source of COVID-19 scientific and public health communication, it has played a less visible role, mostly posting information on its website [5.5.2]. Instead, a major source of COVID-19 scientific and public health communication in March and April was the Coronavirus Task Force (on which the CDC has a member). Task Force members Drs Fauci and Birx initially made daily briefings and press conferences alongside the President that updated the public on the state of the pandemic, what is currently known about the disease, and recommendations for preventing its spread. However, their public presence, particularly with the President, diminished since late April so the nation has received less official communication since then.

Universities, foundations and journals are also providing online information. Johns Hopkins University runs a Coronavirus Resource Center online that provides data on the number of cases world-wide, information about the disease and how to prevent it [5.5.3]. Other universities, such as Harvard, University of Colorado, and the University of Pennsylvania have similar websites. Health policy organizations such as the Commonwealth Fund and Kaiser Family Foundation, conduct their own research studies and collect information about the situation, which they post on their websites [5.5.4; 5.5.5]. Finally, journals such as Health Affairs, devote pages of their journal and online blog to COVID-19 issues [5.5.6]

The CDC has responsibility for international reporting and communication [5.5.7]. Throughout the pandemic, the CDC has worked closely with the WHO and other global organizations and country administrations to collectively prepare for and respond to COVID-19.

Although the CDC should be the lead body for surveillance coordination, communications, international reporting and testing, its role in these activities is increasingly being reduced by the Trump administration. On July 14, the Trump administration ordered hospitals to bypass the CDC in their surveillance reporting and to send all information to the Department of Health and Human Services, an agency more aligned with the administration [5.3.8]. Public health experts are fearful that the data will be altered for political gain [5.3.8].

Another problem with U.S. COVID-19 surveillance and communication is the validity and reliability of data on the amount of testing, positive cases, and deaths. For example, reporting the percentage of positive cases over time is problematic, as the percentage of people being tested is increasing, thus changing the denominator for these calculations. The determination of COVID-19 morality has also been an issue. Initially, COVID-19 deaths were counted as such only if there were confirmatory testing evidence. This definition was expanded in April to include presumed or probable COVID-19 deaths, the determination of which is left to the clinician or coroner with some guidelines. It is also not known how vigilant state and local governments are in collecting data.

Another surveillance and communication issue is data transparency. It is not known how open states are in publishing the data being collected or in reporting to governmental and academic data collection and warehousing agencies. Further, the publicizing of COVID-19 statistics appears to be on the decline and has been eclipsed by protests against police brutality and systemic racism. One example is the removal of the head of the Florida COVID-19 dashboard and the disappearance of data from the website in mid-May when the state began reopening.

6. Measures in other sectors

Many measures beyond the immediate scope of the health system are being taken to prevent further spread of the virus. This section contains information on many of these areas, including border and travel restrictions and economic and fiscal measures, among others.

6.1 Borders

Canada and Mexico issued a joint initiative with the U.S. to temporarily restrict all non-essential travel, effective March 21 and in place for 30 days, subject to renewal [6.1.1]. All travel from Europe, except for returning U.S. Citizens and permanent residents, was suspended starting on March 14 for a period of 30 days, subject to renewal. On April 8, U.S. Embassies and consulates suspended routine visa services [6.1.2].

As of July 13, The US-Canada border remains closed to non-essential travel until July 21, however recent exemptions (e.g. immediate family members, workers, students, and refugees) increased the land border traffic from about 115,000 crossings in late April to about 175,000 in late July [6.1.3]. While the Public Health Agency of Canada has added on-site employees at 36 points of entry to help the Canadian Border Service agents screen the incoming visitors, 81% of Canadians would like the border with the US to remain closed to nonessential travel for the foreseeable future [6.1.4]. Similar travel restrictions have been implemented on the US-Mexico border; Homeland Security has extended the joint initiative first implemented on March 21 (renewed every 30 days) to continue to prohibit non-essential travel, with the current expiration date of July 22 [6.1.6].

As of July 17, The State Department is keeping in effect its March 31st advisory to US Citizens to avoid all international travel [6.1.7]. However, while some countries are starting to open their borders, many prohibit entry to American tourists. On July 1, the European Union opened its borders to non-essential travelers from a select list of countries in which the pandemic was considered to be under control, however the United States was not part of this list.

6.2 Mobility

A nationwide lockdown is difficult due to the country's federalist state system, however multiple states issued their own stay-at-home orders in March and April. The CDC issued travel recommendations within the country, advising people to stay at home as much as possible, especially if the trip is not essential (grocery shopping, food delivery, banking, healthcare are considered essential) [6.2.1]. For the essential travel outside of one's local area, Cybersecurity and Infrastructure Security Agency (CISA) issued a guideline (last update April 17), identifying essential critical infrastructure workers (e.g. health, law enforcement, energy, transport, etc.) [6.2.2].

As of June 10, within country travel restrictions have been eased or lifted in 14 states, original quarantine mandate remains in place in 11 states, and 26 states issued no action to restrict travel [6.2.3].

In a move widely perceived to increase pressure on education systems to open college campuses for face-to-face classes, President Trump issued a directive on July 7 to revoke visas of international students whose schools opt for online-only instruction during the fall semester [6.2.4]. This left many students from countries that suspended air travel with the U.S. (e.g., India) without the means to comply with this policy and facing deportation. This directive follows on the heels of June 22 executive order by President Trump [6.2.5] calling for a temporary suspension of H1B work visas, directing the administration towards merit-based immigration.

With certain states exhibiting sharp increases in confirmed cases in the first half of July (e.g., Arizona, Texas, Florida), many states started issuing travel guidance for out-of-state visitors, typically requiring a 14-day self-quarantine for incoming visitors and mandatory testing upon arrival [6.2.6]. States like New York, New Jersey, and Connecticut, who, for the first time since March started registering zero new cases per day, launched enforcement operations at airports to help ensure travelers are following the quarantine restrictions [6.2.7]. As of July 3, 17 states have coronavirus-related restrictions in place [6.2.8].

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