COVID-19 Second Wave Public Health Policy Recommendations

June 2020

Wendy Chavkin MD, MPH

Professor Emérita of Public Health and Obstetrics-Gynecology of the Heilbrunn Department of Population and Family Health, Columbia University Medical Center, New York

Karen Nelson, MD, MPH Former Senior Vice President, Maimonides Medical Center, Brooklyn, New York

Laurel Swerdlow, MPH Health Policy Analyst, Oregon

Supported by Scholars Strategy Network



HEILBRUNN DEPARTMENT OF Population & Family Health

COVID-19 Second Wave Public Health Policy Recommendations: Executive Summary

After varying levels of success containing the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or coronavirus disease 2019 (COVID-19), governments throughout the world now seek public health policies that will enable them to lift stay-at-home orders while continuing to curb infection. Short of a vaccine, no one strategy will prevent a second "surge" of new infections: successful containment relies on implementation of several different interventions at once, and the approach must be adjusted based on the prevalence of infection.

Recommendations will certainly focus on continued hand hygiene measures, social distancing practices, use of personal protective equipment (PPE) and robust contact tracing programs, along with hospital-level policies needed to triage care to critically ill patients and protect staff and patients from infection. Any policies and programs implemented to curb disease spread will require ongoing analysis and review as technologies progress and the pandemic evolves. Policies aimed at protecting the general population will differ from those aimed at early diagnosis of disease or those established to gather epidemiologic data for planning. To that end, policymakers must stay up to date and communicate clearly with the public about the latest technology available and be transparent about how different programs and policies will prevent the transmission of COVID-19 and end the pandemic.

Testing and Contact Tracing

Testing

- Molecular tests (also known as Diagnostic or Antigen tests) detect active infection. If and when molecular testing becomes sophisticated enough to provide rapid, and highly sensitive and specific results, these tests could be used to identify most contagious individuals before they enter densely populated areas, such as workplaces, theaters, or airplanes.
- Serologic tests (also known as Antibody tests) detect past infection. These tests help us better understand disease prevalence--the proportion of individuals who have previously been infected by COVID-19. We do not know the proportion of those infected by COVID-19 who develop antibodies. Nor do we know whether or which antibodies or antibody levels indicate protection from future infection, nor for how long. Once we learn more about the therapeutic value of antibodies, antibody testing could have important ramifications for individuals as well as society.

Contact Tracing

- **Contact tracing** is the long-standing public health process of identifying with whom an infected person had contact, telling those people that they have been exposed, explaining that they may be contagious, and offering resources for testing, treatment and self-isolation to prevent further transmission.
- **Manual contact tracing,** the traditional version of the program, relies on personal interaction with contacts and is slow and expensive but highly effective in containing disease transmission early in a pandemic or when disease prevalence is low.

- **Digital contact tracing,** which uses GPS data or Bluetooth technology to track possible exposure, is new and experimental, and raises concerns about privacy.
- **Proximity tracing**, one kind of digital contact tracing that uses Bluetooth technology, currently has two notable limitations: it requires most of the population to participate in order to be effective, and it focuses on proximity regardless of duration of the contact.

Enforcement

- Messages for individuals and the population at large need to emphasize care, love and social responsibility, as opposed to punishment and deprivation. Mandatory isolation policies compromise the efficacy of test and trace programs and are counterproductive.
- Concerns have been expressed about the possible spread of COVID-19 from the current demonstrations against racial injustice occurring throughout the world. In fact, protesting outdoors rather than assembling indoors, using PPE and physical distancing will significantly reduce the chance of exposure. Risk mitigation need not be conceptualized as an all-or-nothing proposition.

Symptom Screening

 Symptom screenings before entering densely populated areas do not protect others from exposure, as we know that the majority of cases are highly contagious for several days before they become symptomatic, and some remain mildly symptomatic or asymptomatic throughout the course of the disease.

Healthcare Delivery Policy Recommendations

- Services that can be delayed: At the height of a pandemic, services should not be delayed if clinicians and patients consider them urgent and hospitals have the capacity to perform them. Medical evidence should underlie these decisions, which should not be driven by political controversy nor profit-making interests, as transpired during the initial surge of the COVID-19 pandemic.
- **Visitation**: Limitations on visitation may be necessary at the height of the surge in order to protect staff and patients from infection. Policies that limit patient visitors need to be continually re-evaluated in terms of hospital capacity, stage of the pandemic and unanticipated consequences of such policies, such as avoidance of needed care.
- **Telehealth**: Health systems throughout the United States have rapidly pivoted to provision of non-emergent services via telemedicine. In order to be sustainable, insurance plans will need to adjust reimbursement rates for telehealth services so that there is equity with payments for office-based care. It will also be necessary to establish clinical outcomes and measure patient and clinician satisfaction in order to assess the effectiveness of telehealth compared to usual office-based care.

The rise in cases in those states that have relaxed precautions underscore the necessity of learning quickly from our own and others' recent experiences so that we can be intelligently and effectively prepared.

COVID-19 Second Wave Public Health Policy Recommendations

Introduction

After varying levels of success containing the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or coronavirus disease 2019 (COVID-19), governments throughout the world now seek public health policies that will enable them to lift stay-at-home orders while continuing to curb infection. Previous pandemics have had waves of infection, and communities that prematurely loosened restrictions before effectively flattening the curve of infection were especially at risk for a second wave of cases several weeks later, as we are now seeing around the world and at home in states that have re-opened early. ¹ As the virus has already caused more than 119,000 domestic fatalities, containment continues to be an urgent issue.²

State governments are looking to the experiences of other countries, especially those that were more successful in containing the first surge of COVID-19 cases, as well as to experiences with past infectious disease epidemics to design containment strategies in order to mitigate a second wave of COVID-19 cases and deaths. Recommendations will certainly focus on continued hand hygiene measures, social distancing practices, use of personal protective equipment (PPE) and robust contact tracing programs, along with hospital-level policies needed to triage care to critically ill patients and protect staff and patients from infection. Any policies and programs implemented to curb disease spread will require ongoing analysis and review as technologies progress, the surge abates and the pandemic evolves.

The first part of this document provides public health evidence related to COVID-19 testing and contact tracing policies, which will be key components in preventing a second wave of cases. The second part focuses on policies related to the provision of health care services through various stages of the pandemic.

Part 1: Testing and Contact Tracing

Testing for SARS-CoV-2 began in early January 2020, when researchers in China first sequenced the virus. Since that time, COVID-19 tests have been rapidly evolving and improving in quality, making it critical for policymakers to stay up-to-date on the latest technologies available.

SARS-CoV-2 is a virus transmitted by respiratory droplets. Most people will begin shedding the virus 5 days after being exposed, although it can incubate without symptoms or viral shedding for up to two weeks, and can start to replicate and damage cells during that fourteen-day period. COVID-19 is particularly hard to contain because some people have very mild symptoms that they don't even recognize as illness (e.g. low-grade fever or dry cough), and people appear to be most infectious in the 24 to 48 hours *prior* to symptom onset, when they are still asymptomatic. So, for example, if people are exposed to COVID-19 on Day 1, they could be asymptomatic and test negative for the disease for up to 14 days. If the virus begins to

replicate on Day 5 in this hypothetical example, they will be asymptomatic, unknowingly shedding the virus and spreading the disease on Days 3 and 4.

Cohort studies conducted in March 2020 estimate that 50-90% of patients whose diagnostic tests were positive for COVID-19 had been asymptomatic when tested. ^{3, 4, 5} There are now estimates that up to 45% of people remain entirely asymptomatic throughout the course of their illness.⁶ Researchers are still studying how much virus asymptomatic people shed, and whether or not they can easily transmit disease.

<u>Molecular tests</u>. Molecular tests (also referred to as "diagnostic" or "antigen" tests) reveal the presence of a pathogen, either by identifying its genetic material (ribonucleic acid or RNA), or by identifying unique markers of the pathogen itself. COVID-19 molecular tests generally require a nasopharyngeal or throat swab, which samples the respiratory tract where the virus usually first infects an individual.⁷

Reverse transcript polymerase chain reaction (RT-PCR, or simply **PCR**) tests identify and quantify the presence of virus in the sample by detecting and amplifying specific RNA sequences of SARS-CoV-2. These tests may be **qualitative**, offering a positive/negative result (similar to a pregnancy test), or **quantitative**, requiring further interpretation to determine the viral load and presumed degree of infectivity. As compared to other tests on the market, PCR tests are currently considered to have the highest analytic **sensitivity**—the rate at which the test correctly captures all true positives—and **specificity**—the rate at which the test correctly captures all true negatives. Unfortunately, these tests require 2-4 hours to conduct, specialized equipment, and trained personnel to analyze the results.

In contrast to PCR tests, **rapid antigen tests** avoid the lengthy RNA extraction and amplification process by instead detecting easy-to-find surface markers on the outside of the virus.⁷ Rapid antigen tests provide results within 15-30 minutes, but speed comes at a cost: at this time, rapid antigen tests are generally less sensitive and less specific than their PCR counterparts.

Molecular tests are currently the best option for detecting COVID-19 within the first two weeks of exposure. However, approximately 11-12 days after symptom onset (or 16-17 days after exposure in asymptomatic cases), the body begins to develop antibodies to the disease and it becomes harder to detect the virus using PCR testing. PCR testing is recommended, and is most likely to be positive, in the most highly infectious, pre-symptomatic and early symptomatic phases of infection.

<u>Serologic tests</u>. Serologic tests (also referred to as "antibody" or "blood-based" tests) assess antibody production to a particular pathogen and are used to identify whether people have been exposed to that pathogen. By approximately Day 12 after symptom onset of COVID-19 (or Day 16 after exposure in asymptomatic people), the body has begun developing an immune response, which includes production of three types of antibodies: IgA and IgM, followed shortly thereafter by IgG. Because antibodies result from the body's immune response to exposure and do not detect the virus itself, such testing reveals prior infection, but cannot be used to diagnose current infection.⁸

The enzyme-linked immunosorbent assay (**ELISA**) serologic test identifies IgG or IgM antibodies. It can be qualitative or quantitative, and generally requires 2-5 hours of laboratory time. There is also a rapid version (rapid diagnostic test or **RDT**, also referred to as a "lateral flow assay") which similarly detects IgG and IgM antibodies, and provides a qualitative result within 10-30 minutes via a small, portable device that can be used at point of care. Unfortunately, like rapid antigen tests, RDTs have lower sensitivity and specificity than their ELISA lab-based counterparts.

Both ELISAs and RDTs provide antibody titers—they quantify the number of IgG and/or IgM antibodies in a sample. They do not provide information as to whether or not those antibodies could successfully fight COVID-19. **Neutralization assays** test whether or not the patient's antibodies are actually active and effective against the virus in blocking viral replication.⁹ Unfortunately, these tests require expensive technology and highly trained personnel for operation, and are generally only used in research labs.

Serology testing of large populations, especially given the high rate of asymptomatic infection, will help us better understand **prevalence** (the proportion of people who have been infected with SARS-CoV-2), patterns of spread and risk factors for infection, and improve estimates of the case-fatality ratio. Serosurveys must focus on vulnerable and marginalized communities in order to better understand how and why these communities carry a disproportionate disease burden.¹⁰ Some companies are marketing participatory syndromic-surveillance tools which capture data on reported symptoms using mobile technology such as phone apps or internet-based questionnaires.¹¹ These tools, combined with antibody/molecular testing, potentially could provide better information about the connection between symptoms and disease. Antibody testing will additionally be critical in vaccine development as well as treatment. For example, people with positive antibody tests have already been able to donate convalescent plasma, a therapeutic treatment currently under investigation.¹²

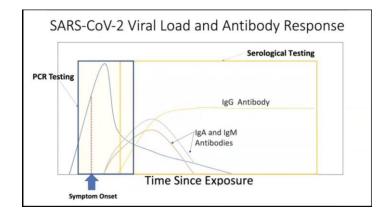


Figure 1: SARS-CoV-2 Viral Load and Antibody Response¹³

Testing limitations and unknowns. While researchers have made significant strides in COVID-19 molecular and serologic test development, a considerable number of limitations and unknowns remain. For example, as Figure 1 illustrates, COVID-19 operates like other viruses: patients usually develop IgG and IgM antibodies, leading to a decrease in viral load. Most studies show that individuals who have recovered from COVID-19 eventually test PCR-negative and antibody-positive,¹⁴ but this does not appear to be universal. In fact, some fatal cases consistently tested PCR negative, even though they tested antibody positive before death.¹³ In other cases, individuals continue to have detectable virus (i.e., they test positive on a molecular diagnostic test) for several weeks following the development of detectable antibodies.⁸ Nevertheless, as of mid-May, replication-competent virus has not been successfully cultured more than 9 days after illness onset,¹⁵ so while the virus may occasionally be detectable for more than 9 days, it does not appear that being PCR positive for weeks on end means that the virus is still infectious or causing active disease.⁸ The Centers for Disease Control and Prevention currently recommends that persons recovering from COVID-19 remain in isolation for at least 10 days after illness onset and at least 3 days after recovery from symptoms,¹⁵ ¹⁵while consistently PCR positive but asymptomatic individuals, or so-called "long-haulers" who experience symptoms for months on end, are managed on a case-by-case basis.¹⁶

Complicating matters further, there are a number of molecular and serologic tests available on the market and the sensitivity and specificity of those tests vary widely. In early April 2020, the Federal Drug Administration (FDA) granted Emergency Use Authorization (EUA) to two serologic tests, and in the following weeks they allowed more than 70 tests to hit the market without this authorization, provided companies offered appropriate disclaimers.¹⁷ In early May, the FDA revised their policy, but only to require commercial manufacturers to submit an EUA request and self-report validation data in order to continue distribution.¹⁸ As a result, dozens of antibody tests remain on the market that have not been validated by third-parties.

The significant debate and uncertainty regarding the sensitivity and specificity of existing tests is worrisome. Test manufacturers self-report sensitivity and specificity rates ranging from 90-100% in both metrics. This may seem high, but if a test with 95% specificity were administered

to a population in which 5 percent of people have the virus, there would be as many false negatives as true ones. The **negative predictive value** of a test indicates the proportion of individuals who test negative who in fact do not have the disease. The lower the disease prevalence, the greater the need for a highly specific test in order to ensure that it has a high negative predictive value.

Third-party analyses even call into question the accuracy of these manufacturer self-reported rates. A study of PCR-technology published May 13, 2020 reported a median false-negative rate of 38% on the typical day of symptom onset (Day 5 after infection), with the rate decreasing to 20% on Day 8, only to steadily increase again starting on Day 9.¹⁹

This discrepancy may be attributed in part to the difference between analytic and clinical validity. **Analytic** sensitivity and specificity rates measure validity ascertained in a laboratory setting. **Clinical** sensitivity and specificity rates measure the validity of a test done in the field, because of variability in the quality of specimen collection and when a test is administered during the course of an illness. Further third-party research is needed to determine the clinical validity of COVID-19 tests. For this reason, if clinical suspicion is high, infection should not be ruled out on the basis of testing alone.

Antibody testing is riddled with many unknowns. As mentioned earlier, we do not know the proportion of those infected by COVID-19 who fail to develop antibodies. Nor do we know whether or which antibodies or antibody levels indicate protection from future infection, nor for how long. While most studies show that individuals who have recovered from COVID-19 have developed quantifiable IgG and IgM antibodies, some of these patients have very low levels of neutralizing antibodies in their blood. While governments and companies would like antibody testing to identify who has immunity and could thus safely return to work, the substantial uncertainty regarding the efficacy and utility of antibody testing renders this policy option moot at this time. The World Health Organization has issued clear guidance on this point.¹⁴

Table 1: The utility and limitations of the main tests in circulation at this time

| Test type* | Time to results** | Public health utility | Limitations | Policy implications |
|---------------------------------------|----------------------|---|--|--|
| Molecular: PCR | 2-4 hours | Recommended for individual diagnosis, especially within two weeks of exposure and/or when symptomatic. | The time needed to complete the test; trained personnel and special equipment to analyze the results. | Molecular tests identify active infection. As the most accurate molecular test on the market, PCR tests are advised for diagnosis of symptomatic patients and/or those who suspect exposure. Those who suspect exposure are advised to get tested and quarantine for at least 14 days. |
| Molecular: Rapid Antigen Test | 15-10 minutes | Offer rapid diagnostic qualitative results at point of care. Recommended for individual diagnosis, especially within two weeks of exposure and/or when symptomatic. | Less sensitive than PCR. | Once rapid antigen testing technology offers accurate, highly specific results, it may be effectively used to identify contagious individuals before they enter densely populated areas, like workplaces, theaters, or airplanes. Because it can take up to 14 days for the virus to incubate and become detectable, routine testing (ideally every 2-3 days) is advisable to screen out infected individuals. |
| Serologic: ELISA | 2-5 hours | Offer quantitative or qualitative assessment of IgG and/or IgM antibodies. Helpful for diagnosis of symptomatic PCR negative patients. Useful for population tracking. Possibly helpful for convalescent | The time needed to complete the test; trained personnel and special equipment to analyze the results. Does not indicate if the antibodies detected are capable of neutralizing the virus. We do not know if antibodies confer immunity. | Serologic tests identify that a patient had prior infection. These tests are currently used in epidemiological studies to aid researchers in determining disease prevalence, patterns of spread, risk factors for infection, and improve estimates of the case-fatality ratio. At this time, antibody testing has limited utility at the individual level, due to significant risk of false negatives and false positives. |
| Serologic: RDT | 10-30 minutes | plasma research. Offer rapid qualitative assessment of presence of IgG and/or IgM antibodies. Helpful for diagnosis of symptomatic PCR negative patients. Useful for population tracking. | Less sensitive and less specific than ELISA. Does not indicate if the antibodies detected are capable of neutralizing the virus. We do not know if antibodies confer immunity. | While governments and companies hope that antibody testing can be used as a means for distinguishing which people have immunity and can return to the workforce without risk to self or others, the substantial uncertainty regarding immunity as well as the efficacy and utility of antibody testing described above renders this policy option moot at this time. |
| Serologic: Neutralization Assay | 3-5 days | Offers insight into whether or not the antibodies present in a sample can effectively fight off a virus in a lab setting. | Lengthy time needed to complete the test; trained personnel and special equipment to analyze the results. We still do not understand the role that neutralizing antibodies play. | Given how little is known regarding how long immunity can last, this labor intensive test will be critical for research but has minimal individual or public health utility at this time. |

* For an exhaustive list and explanation of all molecular and serologic test types currently on the market, visit <u>https://www.centerforhealthsecurity.org/resources/COVID-19/molecular-based-tests/index.html</u> and <u>https://www.centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html</u>

** Time to results is the lab turnaround time. Actual notification of results to patients may take anywhere from 12 hours to 6 days depending on the lab.

<u>Contact Tracing.</u> When implemented at scale, COVID-19 molecular testing can help governments curb transmission by detecting infection in symptomatic and asymptomatic people, isolating those people, and using contact tracing programs to isolate their close contacts. This is a long-standing public health process by which a health worker helps an infected patient identify their contacts, then tells those contacts that they have been exposed to an active case of COVID-19, explains that they too may become contagious and sick, and offers resources for testing treatment and self-isolation to prevent further transmission.²⁰ In traditional or **manual contact tracing**, public health staff work directly with patients to help them recall their contacts and then they reach out directly to those contacts. ²¹ Contact tracing has proven especially useful when fear and stigma may drive infected individuals to withhold their infection status from those they may have exposed.

Contact tracing has been highly effective in curbing infectious disease outbreaks, such as sexually transmitted infections and tuberculosis,²² and emerging research indicates the same holds true for COVID-19. A retrospective cohort study in China²³ and a prospective case study in Taiwan²⁴ both illustrate that contact tracing and subsequent isolation of individuals exposed to COVID-19 more effectively reduced the spread of infection than did surveillance-based isolation of symptomatic patients alone. Research attributes Germany's relatively successful containment of COVID-19 to contact tracing, and suggests that implementing a more aggressive program earlier in the outbreak would have curbed infection even further.²⁵ Japan has pioneered a variant of this program, retrospectively identifying links between patients with COVID-19 and tracing their common contacts to identify clusters of infection.²⁶ Ongoing evaluation of a domestic program conducted by Partners in Health in Massachusetts, and those launched by other states, will provide more information on the efficacy of contact tracing in curbing the infection rate of COVID-19 in the United States.

The labor-intensive process of manual contact tracing works best when caseloads are low, and is less feasible when caseloads surge. For this reason, its use is highly recommended in the early stages of an outbreak, and may again prove useful when implemented in tandem with other interventions intended to prevent a second peak of cases. Companies and governments throughout the world have started experimenting with **digital contact tracing** smartphone apps methods to complement manual contact tracing programs. GPS data enable **location tracking**, whereas **proximity tracing** apps log Bluetooth "handshakes" when two devices are within close proximity to one another.²⁷ In both cases, digital contact tracing attempts to track possible contagion by monitoring the physical location of a smartphone. Like manual contact tracing, digital contact tracing tools retrospectively identify possible instances of exposure. Note that this approach differs from other technology-based surveillance policies intended both to retrospectively trace exposure and to prospectively monitor, enforce and publicly share the location of PCR-positive individuals.^{28, 29}

Singapore pioneered the use of proximity tracing at a national scale in March 2020 in an attempt to curb the spread of COVID-19, and the efficacy, utility and implications of this technology need further study.³⁰ A hot debate has emerged about where proximity tracing app data should be stored. Singapore, Australia, France, United Kingdom, Norway have opted for a

centralized approach,³⁰ in which anonymized data is uploaded to a remote server, where matches are made with other contacts, should a person start to develop COVID-19 symptoms. By contrast, Germany, Italy, Ireland, Canada and others have opted for a decentralized approach, backed by Apple and Google, who claim the model will give users greater privacy and control over their data by logging contacts on individual devices as opposed to a central server. There have not yet been studies comparing the public health utility of centralized versus decentralized models.

One of the biggest pitfalls of proximity tracing apps is that statistical models suggest that 60 to 90 percent of the public must use them in order for them to be effective.^{31, 32} Singapore experienced the consequences of this drawback when fewer than 20 percent of their population participated in the program, and there was a resurgence of the virus.³⁰ In addition, apps that log every 6-foot "handshake" do not collect meaningful data, because duration of the proximate encounter matters. Public health data indicates that disease transmission usually happens only if people spend at least 10 minutes together within 6 feet of each other.³³ Therefore proximity tracing applications will only be functionally useful if they log Bluetooth "handshakes" that occur for 10 minutes or more.

Enforcement. Contact tracing programs operate on the assumption that individuals have a right to exposure notification, education, testing, social service referrals and treatment. Until we have effective treatment and/or a vaccine, trainings for those conducting COVID-19 contact tracing must emphasize that the role of these programs is to offer resources and information in order to ensure the health and safety of the index patient, as well as their loved ones and contacts. As self-isolation is only feasible for people from lower-income households if meaningful support is provided, it may be necessary to offer alternative short-term housing (for example in vacant hotel rooms), income replacement and access to food, medications and other essential services. Cultural competency trainings will be key to ensuring effective communication of these messages. Effective education includes offering advice on strict quarantine practices as well as information about harm reduction tactics for those unwilling or unable to adhere to the strictest protocols. Such individually focused efforts need to be situated within a broad public health education campaign which explains and encourages testing, preventive health behaviors and the social good. Messages for individuals and the population at large need to emphasize care, love and social responsibility, as opposed to punishment and deprivation.

Mandatory isolation policies compromise the efficacy of test and trace programs and are counterproductive. To ensure patient confidentiality and ease concerns related to enforcement, data about infected people and their contacts should reside with public health or health care agencies, not with private entities, nor criminal justice or immigration authorities. This has long been standard practice in the United States, as otherwise many infected people are likely to fear the consequences of being identified and therefore resist participation in test and trace programs. New York City's recently launched contact tracing program reports that only 35% of index cases have provided information about contacts, raising questions about trust in the program or its consequences.³⁴ High refusal rates occurred although the city had

clarified that testing will not be considered grounds for designating someone as a public charge.³⁵

Concerns have been expressed about the possible spread of COVID-19 from the current demonstrations against racial injustice occurring throughout the world. In fact, protesting outdoors rather than assembling indoors, using PPE and physical distancing will significantly reduce the chance of exposure. Risk mitigation need not be conceptualized as an all-or-nothing proposition. Yelling and singing increase the velocity of droplet expulsion and the particle field, making facial coverings essential.³⁶ Maintaining a 6-foot distance may be difficult during protests, but avoidance of physical contact, including handshakes and hugging, and use of hand sanitizer will mitigate spread. Those unable to exercise these precautions should get tested 5 to 7 days later. Immuno-compromised individuals and those experiencing symptoms of any kind should be advised to stay home. Crowd-control tactics that deploy teargas or other corrosive, inhalable chemicals compromise the body's ability to fight off infection, cause mild infections to become more severe and are likely to exacerbate the spread of the virus.³⁷

Symptom Screenings. Screening employees for COVID-19 symptoms, including fever, cough, sore throat, shortness of breath, loss of taste or smell, nasal congestion or a runny nose has become commonplace. However, while this type of screening helps employers identify symptomatic cases, it does not protect workplaces from exposure, as we know that the majority of cases are highly contagious for several days before they become symptomatic, and some remain mildly symptomatic or asymptomatic throughout the course of the disease. Therefore, temperature checks alone are not protective, as they only screen out those who have this one symptom (more than half of cases do not have a fever during the early, most contagious phase of infection³⁸) and fail to screen out others who are infectious but afebrile. Even programs that add symptom screening to temperature checks will miss those who are sick but asymptomatic. Accordingly, China's use of drones to conduct temperature checks and the New York State pilot hospital visitation program which relies on temperature and symptom screens may fail to effectively identify enough infected people to make the programs worthwhile. Employers need to be clear that these types of simple screens do not ensure worker safety and that businesses that reopen post-lockdown need to implement measures that have been proven to limit transmission: hand hygiene, physical distance, and protective personal equipment as well as any other protocols, such as indoor air disinfection measures, if they prove to be effective.³⁹

Despite the relatively low clinical sensitivity and specificity of existing rapid diagnostic tests, employees and school children in Germany and elsewhere are conducting self-administered PCR tests, and individuals in South Korea are subjected to PCR checkpoints throughout the country. If and when molecular tests become highly sensitive and specific, with rapid point of care results, policymakers and companies could consider using these tests to screen people at points of entry in densely populated environments, like workplaces, theaters or airplanes. However, unless salaries are maintained for PCR-positive individuals, and resources are offered to people needing to self-isolate, widespread testing measures like these are likely to be resisted in the United States. Some governments, like those in South Korea and China, have implemented preventive quarantine for international travelers when second waves of cases were traced back to international travelers. In the United States, interstate travel poses a similar threat, given the very different degrees of quarantine and shutdown orders that were imposed in different states, and the ways that state governments are designing their re-opening strategies. Nevertheless, the imposition of mandatory quarantine or limits on interstate travel is fraught with operational difficulties.

Part II: Health care delivery policies during COVID-19

During the initial surge of cases, hospitals in New York City and other "hotspots" were overwhelmed by patient volume, severe shortages of personnel and insufficient supplies of PPE, intensive care unit beds and critically needed equipment such as ventilators. These institutions had to simultaneously grapple with how to provide care to critically ill patients and how to protect staff and patients from infection. In response to this emergency, given the high estimates of asymptomatic and nonspecific mildly symptomatic COVID-19 cases, hospitals halted delivery of "non-essential" or "elective" healthcare services, limited visitation, and provided most outpatient services through telemedicine. The following is an assessment of these policies during the emergency phase of the pandemic, and newer policies that are being considered during the coming post-surge phases.

Services that can be delayed. Temporarily halting delivery of some services made sense during the initial pandemic surge of cases. Accordingly, healthcare institutions designated services as either "essential" or "non-essential." These designations, however, have significant financial implications because of the way healthcare services are reimbursed in the United States, so we prefer to categorize services as those that can or cannot be delayed during a pandemic. At the height of a pandemic, services should not be delayed if clinicians and patients consider them urgent and hospitals have the capacity to perform them. Medical evidence should underlie these decisions, which should not be driven by political controversy nor profit-making interests, as transpired during the initial surge of the COVID-19 pandemic.

Reproductive healthcare offers the prime example of care that has been buffeted by political and commercial interests. In the months following the domestic COVID-19 outbreak, governors in Texas, Louisiana, Mississippi, Alabama, and Oklahoma designated abortion as non-essential, and therefore banned provision of both medication and in-clinic abortion procedures, while governors in other states halted only in-clinic procedures.⁴⁰ These decisions flouted the medical and legal consensus that terminations cannot be delayed. Other states opposed these bans on abortion access, and eighteen attorneys general from throughout the country signed onto an amicus brief supporting Planned Parenthood in challenging the Texas policy. Elsewhere, countries like France classified abortion procedures as "urgent interventions,"⁴¹ and extended the gestational age limit for medication abortion from 7 to 9 weeks.⁴² French physicians also

advocated to increase the gestational age limit for in-clinic abortion procedures from 12 to 14 weeks, although action on that designation has not yet been taken.

Some assisted reproductive technology corporations and individual providers have lobbied to influence the list of services that cannot be delayed, despite professional bodies' recommendations. For example, while some fertility clinics temporarily closed in response to the pandemic, other clinics and clinicians argued strenuously that their services be designated as essential, despite the recommendation of the American Society for Reproductive Medicine's *New Guidance on Fertility Care during COVID-19 Pandemic* (first posted March 17, 2020), that new treatment cycles be suspended, including in-vitro fertilization, intrauterine insemination and non-urgent gamete preservation.⁴³

Visitation. In recent years, the focus on patient-centered care has encouraged providers to welcome patient supports and advocates into the doctor/patient relationship. Research demonstrates that patient supports affect some patient outcomes. For example, one systematic review of randomized control trials found that women allocated continuous support during childbirth had shorter labors, were less likely to have a caesarean or instrumental vaginal birth, or to report dissatisfaction.⁴⁴

However, during the height of the surge, those policies were amended to ban patient visitors in many hospitals in New York City. Some supplied iPads so that patients could have virtual company, but many patients died and suffered alone, and women delivered babies without supportive accompaniment. Reportedly in response to a petition drive, rather than hospital capacity, the New York State Department of Health mandated that hospitals modify those bans to allow visitors for pediatric patients and women in labor and delivery.⁴⁵ Later, the New York State Department of Health a single support person be permitted when deemed essential to the care of the patient,⁴⁶ and for patients in imminent end-of-life situations.⁴⁷

Anecdotal reports suggest that an adverse consequence of this temporary prohibition on visitation was that some patients avoided even medically useful and necessary hospitalizations – for delivery, for those severely ill with COVID-19, and for those with other significant medical problems. Given the serious inequities in health outcomes by race/ethnicity and income that characterize the United States, such a result is likely to aggravate health disparities. Policies that limit patient visitors need to be continually re-evaluated in terms of hospital capacity, stage of the pandemic and unanticipated consequences of such policies, such as avoidance of needed care.

Telehealth. Since March, health systems throughout the United States have rapidly pivoted to provision of non-emergent services via telemedicine. Here too, reproductive health was buffeted by political forces that began long before COVID-19 hit the US. Eighteen states require the clinician providing a medication abortion to be physically present during the procedure, thereby effectively precluding delivery of abortion services via telemedicine. In addition, the FDA has imposed a Risk Evaluation and Mitigation Strategy (REMS) which requires medication

abortion to be administered only by certified prescribers and only in clinics, medical offices or hospitals.⁴⁸ Accordingly, only the providers from 8 states participating in a TelAbortion study are able to provide medication abortion via telemedicine in the United States. This measure has been robustly critiqued as not evidence-based, and the American College of Obstetrics and Gynecology formally requested that the FDA suspend this medically unnecessary policy during the pandemic.⁴⁹

Physicians in several other countries advocated that telemedicine be used for provision of abortions during the pandemic as a means to reduce COVID-19 transmission and to ensure access to timely care. One such example is Ireland, where lawmakers increased accessibility and reduced infection risk during the COVID-19 outbreak by allowing the required two in-person visits prior to the procedure to take place via telehealth.⁵⁰

In order to be sustainable, insurance plans will need to adjust reimbursement rates for telehealth services so that there is equity with payments for office-based care. It will also be necessary to establish clinical outcomes and measure patient and clinician satisfaction in order to assess the effectiveness of telehealth compared to usual office-based care.

Conclusion

There will be no silver bullet policy solution to curb the continued spread of COVID-19; all policies will need to be used in conjunction with one another. No test can yet diagnose this disease early enough to prevent its transmission, so no single test or policy will be sufficient on its own. Containment will require continued hygiene measures, social distancing practices, use of PPE, and robust contact tracing programs. When assessing a prospective policy, it is important to be clear and transparent about its purported goal. Policies aimed at protecting the general population will differ from those aimed at early diagnosis of disease, or from those established to gather epidemiologic data for planning.

Containment strategy recommendations should be informed by what we do and do not know regarding the efficacy and utility of existing technologies. Testing and treatment options will improve over time, so periodic reassessment of pandemic policies will need to continue to be refined. Sunset clauses and triggers for reassessment of COVID-19 policies will ensure that restrictions are not left in place beyond their utility for decreasing the spread of the disease.

During the peak of a pandemic surge, healthcare delivery policies, including the designation of whether services can or cannot be delayed, limits on patient visitation, and telehealth requirements need to be considered within the context of protecting staff and patients from infection and maintaining smooth hospital functioning. As caseloads decline, shortages abate and capacity increases, these policies should be reviewed and evidence- based criteria used for staged resumption of normal business. The rise in cases in those states that have relaxed precautions underscore the necessity of learning quickly from our own and others' recent experiences so that we can be intelligently and effectively prepared.

References

- World Health Organization Office for Europe. About pandemic phases. Copenhagen: WHO; 2009 [updated 2009 Jun 11; cited 2020 Jun 21]. Available from:<u>http://www.euro.who.int/en/health-topics/communicable-</u> <u>diseases/influenza/data-and-statistics/pandemic-influenza/about-pandemic-phases</u>
- Centers for Disease Control and Prevention. Coronavirus Disease 2019: Cases in the U.S. Atlanta: CDC; 2020 [updated 2020 June 21; cited 2020 June 21]. Available from: <u>https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html</u>
- 3. Arons MM, Hatfield KM, Reddy SC, Kimball A, James A, Jacobs JR, et al. Presymptomatic SARS-CoV-2 Infections and Transmission in a Skilled Nursing Facility. New England Journal of Medicine. 2020;382(22):2081-90.
- 4. Sutton D, Fuchs K, D'Alton M, Goffman D. Universal Screening for SARS-CoV-2 in Women Admitted for Delivery. New England Journal of Medicine. 2020;382(22):2163-4.
- 5. Ing AJ, Cocks C, Green JP. COVID-19: in the footsteps of Ernest Shackleton. Thorax. 2020. doi:10.1136/ thoraxjnl-2020-215091
- 6. Oran DP, Topol EJ. Prevalence of Asymptomatic SARS-CoV-2 Infection: A Narrative Review [published online ahead of print, 2020 Jun 3]. Ann Intern Med. 2020;M20-3012. doi:10.7326/M20-3012
- Johns Hopkins Bloomberg School of Public Health. Molecular-based Tests for COVID-19. Baltimore: Johns Hopkins; 2020 [cited 2020 Jun 21]. Available from: <u>https://www.centerforhealthsecurity.org/resources/COVID-19/molecular-based-tests/index.html</u>
- U.S. Food & Drug Administration. FAQs on Testing for SARS-CoV-2. Silver Spring: FDA; 2020 [cited 2020 Jun 21]. Available from: <u>https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2</u>
- 9. Johns Hopkins Bloomberg School of Public Health. Serology-based Tests for COVID-19. Baltimore: Johns Hopkins; 2020 [cited 2020 Jun 21]. Available from: <u>https://www.centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html</u>
- 10. Garg S, Kim L, Whitaker M, et al. Hospitalization Rates and Characteristics of Patients Hospitalized with Laboratory-Confirmed Coronavirus Disease 2019 — COVID-NET, 14

States, March 1–30, 2020. MMWR Morb Mortal Wkly Rep 2020;69:458–464. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm6915e3external icon</u>

- 11. Chan AT, Brownstein JS. Putting the Public Back in Public Health Surveying Symptoms of Covid-19. New England Journal of Medicine. 2020 Jun 5. Available from: <u>https://www.nejm.org/doi/full/10.1056/NEJMp2016259</u>
- 12. Shen C, Wang Z, Zhao F, Yang Y, Li J, Yuan J, et al. Treatment of 5 Critically III Patients With COVID-19 With Convalescent Plasma. JAMA. 2020;323(16):1582-9.
- Harvard Medical School Medicine Grand Rounds. How diagnostic tests got us into, and will leave us out of, the pandemic. 2020 April 30. Available from: <u>https://externalmediasite.partners.org/Mediasite/Play/c36c9ab405ed4c93833721a468</u> <u>e7a38b1d</u>
- 14. World Health Organization. "Immunity passports" in the context of COVID-19: scientific brief, 24 April 2020. Available from: <u>https://www.who.int/news-</u> room/commentaries/detail/immunity-passports-in-the-context-of-covid-19
- 15. Centers for Disease Control and Prevention. Symptom-Based Strategy to Discontinue Isolation for Persons with COVID-19. 2020 May 3. Available from: <u>https://www.cdc.gov/coronavirus/2019-ncov/community/strategy-discontinue-isolation.html</u>
- 16. Yong E. COVID-19 Can Last for Several Months. The Atlantic. 2020 June 4. Available from: <u>https://www.theatlantic.com/health/archive/2020/06/covid-19-coronavirus-longterm-symptoms-months/612679/</u>
- 17. Abbasi J. The Promise and Peril of Antibody Testing for COVID-19. JAMA. 2020;323(19):1881-3.
- U.S. Food & Drug Administration. Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy [Internet]. Silver Spring: FDA; 2020 [updated 2020 May 4; cited 2020 Jun 21]. Available from: <u>https://www.fda.gov/news-events/fdavoices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy</u>
- Kucirka L, Lauer S, et al. Variation in False-Negative Rate of Reverse Transcriptase Polymerase Chain Reaction–Based SARS-CoV-2 Tests by Time Since Exposure. Annals of Internal Medicine. 2020 May 13. Available from: <u>https://www.acpjournals.org/doi/full/10.7326/M20-1495</u>
- 20. Crocker A, Opsahl K, Cyphers B. The Challenge of Proximity Apps For COVID-19 Contact Tracing. Electronic Frontier Foundation. 2020 April 10. Available from:

https://www.eff.org/deeplinks/2020/04/challenge-proximity-apps-covid-19-contacttracing

- 21. Centers for Disease Control and Prevention. Contact Tracing: Part of a Multipronged Approach to Fight the COVID-19 Pandemic. 2020 April 29. Available from: <u>https://www.cdc.gov/coronavirus/2019-ncov/php/principles-contact-tracing.html</u>
- 22. Armbruster B, Brandeau M. Contact tracing to control infectious disease: when enough is enough. Health Care Manag Sci. 2007;10(4):341-355. doi:10.1007/s10729-007-9027-6
- 23. Bi Q, Wu Y, Mei S, et al. Epidemiology and transmission of COVID-19 in 391 cases and 1286 of their close contacts in Shenzhen, China: a retrospective cohort study. Lancet Infect Dis. Published 2020 April 27. Available from: <u>https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(20)30287-5.pdf</u>
- 24. Cheng H-Y, Jian S-W, Liu D-P, Ng T-C, Huang W-T, Lin H-H, et al. Contact Tracing Assessment of COVID-19 Transmission Dynamics in Taiwan and Risk at Different Exposure Periods Before and After Symptom Onset. JAMA Internal Medicine. 2020 May 1. doi:10.1001/jamainternmed.2020.2020
- 25. Bennhold K. A German Exception? Why the Country's Coronavirus Death Rate Is Low. New York Times. 2020 April 4. Available from: <u>https://www.nytimes.com/2020/04/04/world/europe/germany-coronavirus-death-rate.html</u>
- 26. Adelstein J. Japan's contact-tracing method is old but gold. Asia Times. 2020 June 2. Available from: <u>https://asiatimes.com/2020/06/japans-contact-tracing-method-is-old-but-gold/</u>
- 27. Gebhart G. COVID-19 and Technology: Commonly Used Terms. Electronic Frontier Foundation. 2020 April 30. Available from: <u>https://www.eff.org/deeplinks/2020/04/covid-19-and-technology-commonly-used-terms</u>
- 28. Park S, Choi GJ, Ko H. Information Technology–Based Tracing Strategy in Response to COVID-19 in South Korea—Privacy Controversies. JAMA. 2020;323(21):2129-30.
- 29. Kharpal A. Use of surveillance to fight coronavirus raises concerns about government power after pandemic ends. CNBC. 2020 March 26. Available from: <u>https://www.cnbc.com/2020/03/27/coronavirus-surveillance-used-by-governments-to-fight-pandemic-privacy-concerns.html</u>

- Criddle C, Kelion L. Coronavirus contact-tracing: World split between two types of app. BBC. 2020 May 7. Available from: <u>https://www.bbc.com/news/amp/technology-52355028</u>
- 31. Roberts L, Bowman V, Penna D. Contact tracing: how will the UK's test, track and trace plan help ease lockdown. The Telegraph. 2020 May 25. Available from: https://www.telegraph.co.uk/news/0/contact-tracing-what-test-track-trace-plan-uk/
- 32. Pueyo T. Coronavirus: How to Do Testing and Contact Tracing. Medium. 2020 April 28. Available from: <u>https://medium.com/@tomaspueyo/coronavirus-how-to-do-testing-and-contact-tracing-bde85b64072e</u>
- 33. Bromage E. Coronavirus risks: Know them, avoid them. CommonWealth Magazine. 2020 May 15. <u>https://commonwealthmagazine.org/environment/coronavirus-risks-know-them-avoid-them/</u>
- 34. Otterman S. N.Y.C. Hired 3,000 Workers for Contact Tracing It's Off to a Slow Start. New York Times. 2020 June 21. Available from: <u>https://www.nytimes.com/2020/06/21/nyregion/nyc-contact-tracing.html</u>
- 35. New York City Mayor's Office of Immigrant Affairs. Public Charge Rule. NYC. 2020 March 16. Available from: <u>https://www1.nyc.gov/site/immigrants/help/legal-services/public-charge.page</u>
- Asadi S, Wexler A, Cappa C, Barreda S, Bouvier N, Ristenpart W. Aerosol emission and superemission during human speech increase with voice loudness. Sci Rep. 2019;9(1):2348. Published 2019 Feb 20. doi:10.1038/s41598-019-38808-z
- 37. American Thoracic Society. Tear Gas Use During COVID-19 Pandemic Irresponsible; Moratorium Needed, Says American Thoracic Society. Press Release 2020 June 11. Available from: <u>https://www.thoracic.org/about/newsroom/press-</u> <u>releases/journal/2020/tear-gas-use-during-covid-19-pandemic-irresponsible-</u> <u>moratorium-needed,-says-american-thoracic-society.php</u>
- Guan W-j, Ni Z-y, Hu Y, Liang W-h, Ou C-q, He J-x, et al. Clinical Characteristics of Coronavirus Disease 2019 in China. New England Journal of Medicine. 2020;382(18):1708-20.
- 39. Nardell EA, Nathavitharana RR. Airborne Spread of SARS-CoV-2 and a Potential Role for Air Disinfection. JAMA. Published 2020 June 01. doi:10.1001/jama.2020.7603

- Bayefsky MJ, Bartz D, Watson KL. Abortion during the Covid-19 Pandemic Ensuring Access to an Essential Health Service. New England Journal of Medicine.
 2020;382(19):e47.
- 41. Makooi B. Coronavirus: In France, professionals look to extend legal abortion time limit. France 24. 2020 April 2. Available from: <u>https://www.france24.com/en/20200402-</u> <u>coronavirus-in-france-professionals-look-to-extend-legal-abortion-time-limit</u>
- 42. Elzas S. France extends access to abortions during Covid-19 pandemic. Radio France Internationale. 2020 April 11. Available from: <u>http://www.rfi.fr/en/france/20200411-</u> <u>france-extends-access-to-abortions-during-covid-19-pandemic</u>
- 43. American Society for Reproductive Medicine. ASRM Issues New Guidance on Fertility Care During COVID-19 Pandemic: Calls for Suspension of Most Treatments. 2020 March 17. Available from: <u>https://www.asrm.org/news-and-publications/news-andresearch/press-releases-and-bulletins/asrm-issues-new-guidance-on-fertility-careduring-covid-19-pandemiccalls-for-suspension-of-most-treatments/</u>
- 44. Hodnett ED, Gates S, Hofmeyr GJ, Sakala C. Continuous support for women during childbirth. Cochrane Database Syst Rev. 2013;7:Cd003766.
- 45. New York State Department of Health. Health Advisory: COVID-19 Guidance for Hospital Operators Regarding Visitation Updated Guidance regarding Obstetrical and Pediatric Settings. New York State. 2020 March 27. Available from: <u>https://coronavirus.health.ny.gov/system/files/documents/2020/03/doh_covid19_obpe_dsvisitation_032720.pdf</u>
- 46. New York State Department of Health. Health Advisory: COVID-19 Updated Guidance for Hospital Operators Regarding Visitation. New York State. 2020 April 10. Available from: <u>https://opwdd.ny.gov/system/files/documents/2020/04/doh_covid19_hospitalvisitatio_n_4.10.20.pdf</u>
- 47. New York State Department of Health. Health Advisory: COVID-19 Updated Guidance for Hospital Operators Regarding Visitation. New York State. 2020 May 20. Available from: <u>https://mail.google.com/mail/u/0/#label/COVID+Project/FMfcgxwHNWBVWPwtxVqtdB</u> <u>mrLBbKSFdJ?projector=1&messagePartId=0.1</u>
- 48. Ramaswamy A, Weigel G, Sobel L, Salganicoff A. Medication Abortion and Telemedicine: Innovations and Barriers During the COVID-19 Emergency. 2020 June 08. Available from: <u>https://www.kff.org/coronavirus-policy-watch/medication-abortion-telemedicine-innovations-and-barriers-during-the-covid-19-emergency/</u>

- 49. American College of Obstetrics and Gynecology. ACOG Suit Petitions Court to Remove FDA's Burdensome Barriers to Reproductive Care During COVID-19. Press Release. 2020 May 27. Available from: <u>https://www.acog.org/news/news-releases/2020/05/acog-suit-</u> <u>petitions-the-fda-to-remove-burdensome-barriers-to-reproductive-care-during-covid-19</u>
- 50. Holland K. Coronavirus: GP visits regarding abortions to take place remotely. Irish Times. 2020 April 8. Available from: <u>https://www.irishtimes.com/news/social-affairs/coronavirus-gp-visits-regarding-abortions-to-take-place-remotely-1.4223488</u>