UNIVERSITY OF DELAWARE
COMMUNITY ENGAGEMENT INITIATIVE

Partnership for Healthy Communities

A Safe & Effective Vaccine for COVID-19: Opportunities, Challenges and an Equity Imperative

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Background: COVID-19

In December 2019, a novel coronavirus emerged in Wuhan, China, and quickly spread around the world resulting in a global health pandemic. Coronaviruses are a family of viruses that can cause respiratory illness like severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS) and the common cold. Although coronaviruses share certain characteristics, this virus had not been previously identified and is, therefore, considered "novel". The World Health Organization named this novel coronavirus "SARS-CoV-2", and the illness that it causes is called "COVID-19", or "coronavirus disease 2019" because it was discovered in 2019.

The most common symptoms of COVID-19 are fever, dry cough, difficulty breathing and tiredness. Individuals infected with the virus may also experience aches and pains, nasal congestion or runny nose, headache, sore throat, nausea, vomiting or diarrhea, and loss of taste and/or smell. Symptoms usually appear within 2-14 days after being exposed to the virus. Many people with COVID-19 report mild symptoms, however, it can be more serious for others leading to severe illness and death.

As of early June 2020, COVID-19 has affected over 7 million people worldwide and over 2 million people in the United States, including over 110,000 deaths in the US alone. COVID-19 is mainly spread through respiratory droplets when someone with the virus coughs, sneezes or talks. These droplets can land in the mouths or noses of people who are nearby or can

Key Points:

COVID-19 is a disease with potential serious consequences which spreads relatively easily, and a vaccine is our best hope for preventing further COVID-19 related illness and death and ending the global pandemic.

The vaccine development timeline is a major challenge, but scientists around the world are working hard to move quickly, while ensuring safety.

Governments should invest in vaccine development and work with pharmaceutical companies to streamline the development and approval process, while ensuring critical attention to safety at each stage.

Until a vaccine has been approved and can be administered to everyone, it is critical to follow expert advice to help prevent the spread of COVID-19, including practicing physical distancing, wearing cloth face coverings in public, maintaining proper personal hygiene, and getting tested and isolating yourself if you have been exposed or are infected.

The current pandemic is a reminder of the importance of vaccines. To the extent possible, parents should remain attentive to well child visits and the vital need to stay up to date on their children's immunizations to protect against other serious vaccine-preventable diseases.

Once a safe and effective vaccine has been developed, equity and racial justice considerations should guide decision-making about distribution of the vaccine.

be inhaled directly into the lungs. The droplets are very small, often invisible. This is why experts recommend physical distancing or standing at least 6 feet (or about 2 arms' length) apart from other individuals and wearing a cloth face covering when in public. This is particularly important because some people with COVID-19 do not have any symptoms (asymptomatic) or have very mild symptoms. This means they may not know that they have the disease and could be spreading it to others. It is also possible for the virus-containing droplets to land on objects that others may touch, which is why it is important to wash your hands regularly with soap and water or an alcohol-based hand sanitizer, and avoid touching your eyes, nose and mouth.

Scientists around the world are working on developing new pharmaceutical drugs, and testing existing drugs approved for other purposes, to treat COVID-19. However, as of early June 2020, there are no medicines that have been shown to prevent or cure COVID-19 (though some are showing promise in shortening the time to recovery for some kinds of patients). Because of the seriousness of this novel disease, and how easily it spreads, the consensus among experts is that the best hope of containing COVID-19 and preventing further illness and death is with a vaccine.

Vaccines & Herd Immunity

The routine use of vaccines has resulted in dramatic reductions in illness and death associated with infectious diseases and is considered one of the ten greatest public health achievements of the 20th century. Successful vaccination programs have led to the elimination of polio in the US, and smallpox has been eradicated worldwide. Other infectious diseases have the potential for global eradication.

Vaccines work by creating immunity to (or protection from) an infectious agent, such as a virus. A vaccine essentially trains an individual's immune system to identify an infectious agent and counteract it before it has the chance to harm the body. There are different ways to create an immune response in the body and the effectiveness of a vaccine to protect against a specific virus often depends on which approach is used. This has led to the development of different kinds of vaccines, including "live" vaccines which use a weakened form of

the virus; inactivated vaccines, which use a killed form of the virus; as well as gene-based vaccines, which have not yet been used on a large scale but show potential.

When most people living in a certain area become immune to an infectious disease, we call that "herd immunity". Herd immunity is important for controlling the spread of disease and indirectly protects people who may not be able to get vaccinated, such as newborn babies or individuals with underlying health conditions. The level of the population that needs to be immunized to create protection for the entire "herd" depends on how contagious the disease is; usually 70%-90% of a population needs to be vaccinated.

For many infectious diseases, individuals who become ill are subsequently immune to reinfection. Similar to vaccination, when enough people become infected with a disease over time this can lead to herd immunity. Some have suggested that allowing people to get sick with COVID-19 will eventually lead to this natural herd immunity. However, there are many reasons why this would be a dangerous strategy. First, while the death rate for COVID-19 is still not known, we do know that it can be very serious, and many more people would likely die before achieving natural herd immunity. While not everyone who is infected gets seriously ill, experts don't know why some people develop severe cases of the disease while others do not. Further, we do not yet know the infection rate that would be needed to achieve herd immunity, though experts estimate that at least 70% of the population would have to be infected to reach this threshold. Finally, it is not yet clear if contracting this disease ensures future immunity or for how long. For all of these reasons, scientists around the world are working to develop a vaccine for COVID-19 as quickly as possible.

Vaccine Development for COVID-19

Vaccine development is a complex and scientifically rigorous process that typically takes 10-15 years. The process begins when a new virus is identified, and scientists begin an "exploratory" stage, usually in a lab setting, in which they try to identify the best way to create immunity against the virus. This includes trying to identify which type of vaccine is likely to be most effective. Scientists typically then test their ideas in animal models to see if it works and if it is safe. This is

described as the "pre-clinical" stage and testing follows strict guidelines.

Once scientists believe they have a potentially safe and effective vaccine, they begin "clinical development," which involves a three-phase process of testing the vaccine in human volunteers. In phase I, the vaccine is tested on a small group of people who are closely monitored to make sure the vaccine is safe and appears to work in humans.

Phase II involves testing the vaccine on a larger number of people (often several hundred) to see if different kinds of people react differently (e.g. younger versus older adults) and to determine the most common short-term side effects. Phase II is also important for figuring out the right dose of the vaccine and determining the likelihood it will be effective on a larger scale.

Finally, during phase III, scientists test the vaccine on an even larger group of people (usually thousands) and continue to monitor if it actually prevents people from getting sick if they are exposed to the virus. Safety continues to be a primary concern and this phase is important for identifying rare side effects or adverse reactions that might only become apparent when a very large number of people are tested. Ideally, people are followed for a period of time to make sure any potential side effects that might emerge are identified. Even after vaccines are approved and widely used, public health experts continue to monitor their use for any safety concerns.

In the US, the Food and Drug Administration (FDA) is responsible for regulating vaccines (as well as other pharmaceutical drugs). Once a vaccine goes through the various stages of development and testing, the FDA reviews the scientific information from the clinical trials and makes a determination to approve the vaccine (or not) based on a careful assessment of risks and benefits. Once a vaccine is approved, the FDA continues to oversee the manufacturing process to make sure safety standards are followed. After FDA approval, the Centers for Disease Control and Prevention (CDC) develops recommendations for the use of the vaccine based upon considerations like how widespread or serious the disease is, and other factors related to supply and cost. Both the FDA and the CDC are

responsible for monitoring safety once vaccines have been approved and recommended for use.

While vaccine development usually takes many years, experts believe we will have a safe and effective vaccine for COVID-19 available much sooner. This is because scientists are not starting from scratch. Rather, past research on SARS and MERS, other similar coronaviruses, provide a head start. Similarly, scientists in China, where the SARS-CoV-2 virus is believed to have originated, were quickly able to identify the genetic sequence of the virus and shared it with the global scientific community in January 2020. Finally, the global scale of this coronavirus pandemic has led to unprecedented global cooperation and investment by both private and public funders. Given the health and economic consequences of an ongoing pandemic, most leaders appear to be committed to working together to find a vaccine solution.

As of early June 2020, more than 200 vaccine development efforts were underway. While most of these candidate vaccines will likely fail, experts believe that some will succeed. Importantly, scientists are working simultaneously on a number of different types of vaccines (e.g. live, inactivated, gene-based, etc.), which experts believe may also be important for addressing a pandemic of this scale. Public health leaders and scientists are also working together to streamline the testing processes, while working to ensure continued safety. A number of vaccine developers are already testing their vaccines in humans, and many more are expected to begin clinical trials before the end of 2020. For all of these reasons, experts believe that a safe and effective vaccine (or vaccines) for COVID-19 may be available in 12-18 months (i.e., summer/winter 2021).

Opportunities & Challenges

Although experts are optimistic about the prospect of rapid development of a safe and effective vaccine for COVID-19, there are many challenges to consider. First, it is important to understand that unlike new treatments for a particular disease, vaccines are given to *healthy* people. When testing a new drug for high blood pressure, for instance, the human subjects already have high blood pressure and the new drug is intended to improve their health. Clinical trials would

typically involve giving half of the individuals the new drug and the other half would receive a placebo (e.g. a sugar pill with no medicinal benefit), or perhaps the new drug is compared to an existing drug. In both instances, the drugs are given to people who are already sick, with the hope of finding a new or better treatment for their existing illness. With vaccines, the human subjects are healthy and by testing a new vaccine we are introducing a new potential threat. Therefore, many would argue we need to be even more careful that the benefits of the new vaccine outweigh any potential harms or risks.

Unfortunately, identifying all potential risks takes time. There will inevitably be a trade-off between speed of development and scientists' abilities to protect human subjects in the clinical trials, as well as FDA's ability to ensure longer-term safety once a vaccine is approved. Of course, during the time it takes to develop and test new vaccines, more people will likely become infected and die due to COVID-19. Scientists, public health experts and leaders are all working together to try to ensure safety, while moving forward as quickly as possible.

A related challenge has to do with the nature of prevention and the way in which infectious diseases are spread. Specifically, the clinical trials rely on people naturally becoming exposed to the virus to learn if the vaccine works in preventing infection. Ideally, vaccine developers would give the vaccine to a large number of healthy people in a geographic area where COVID-19 is prevalent and give the other half of the people a placebo. Then all of the participants in the study would be followed for a certain length of time to see who develops the disease and if those in the vaccine group were less likely to become infected. This takes time, requires large numbers of volunteers, and can be complicated by the possibility that infection rates may vary naturally.

Some people have suggested the use of "challenge trials," also known as "controlled human infection models," to speed up this process. With this approach, scientists would deliberately infect the human subjects to see if the vaccine works. Challenge trials have been used in the past and can be helpful, however, there are many conditions that would need to be met before endorsing this strategy. Most importantly, we would

need a viable treatment for COVID-19, so that if the vaccine did not work, we could treat people who become infected with the disease. So much about COVID-19 is still unknown that it would be unethical to deliberately infect individuals, even well-informed volunteers, without an effective treatment and a better understanding of how different people react to the disease.

Another important consideration with respect to the vaccine timeline, is the fact that to be effective in ending the pandemic, we would need to produce, distribute and administer a vaccine on a global scale. That means we need to be prepared for hundreds of millions to billions of doses worldwide. This requires a much larger infrastructure than is currently in place. Fortunately, the challenge of scaling up manufacturing is one that experts and leaders around the world are already trying to address. Governments, private pharmaceutical companies, philanthropic organizations, and others are investing in different platforms for manufacturing in the hope that more than one type of vaccine will become available and they will be prepared to manufacture different types simultaneously. Importantly, however, preparing for manufacturing and distribution is a costly endeavor, particularly given the risk that some vaccines in development may ultimately fail. Private companies may not be willing to take this financial risk and it is falling largely on national governments to make these financial investments. Similarly, to be most effective, building a global infrastructure for manufacturing, distribution and administration of vaccines requires greater international cooperation than ever before.

Although hard to imagine given the global devastation associated with COVID-19, the anti-vaccine movement may pose a challenge to the administration of effective vaccine programs once a safe and effective vaccine is developed. Public health leaders will need to remain vigilant in their efforts to ensure transparency of information regarding vaccines and continue to work to dispel myths and correct misinformation about vaccines across various media. Fortunately, general public support for vaccines remains high and anti-vaccine efforts represent a small minority of the population (albeit a vocal one).

Finally, scientific challenges related to understanding the SARS-CoV-2 virus and how the immune system responds to infection still exist. Scientists continue to work to understand issues related to potential re-infection and long-term immunity, how different at-risk populations are affected by the virus and how they may respond differently to potential vaccines, as well as any long-terms effects of infection. While it is important to recognize the scientific challenges, a full discussion of these issues is beyond the scope of this brief.

Policy Implications

Given the health and economic consequences of the COVID-19 global pandemic, governments have a clear interest in intervening to prevent the future spread of disease. Experts agree that the development of a safe and effective vaccine (or multiple vaccines) is our best hope of ending the pandemic and preventing future illness and death. There are many things that governments can and should do to support this effort and ensure that there is ultimately equity in access to any future vaccines. Following are a list of policy recommendations for government leaders in the US and beyond:

➢ Governments should invest in vaccine development and work with pharmaceutical companies and other stakeholders to streamline the development and approval process, while ensuring critical attention to safety at each stage. Ethical treatment of human subjects is paramount, as is transparency regarding potential risks once a vaccine(s) is approved.

➢ Governments should invest now in the infrastructure needed to scale-up manufacturing, distribution and administration of vaccines in order to be prepared as soon as viable vaccines are approved for use.

➢ Government leaders must work closely with one another across national and international borders, and with global health organizations, to ensure there is a coordinated global response to vaccine development, distribution and administration, with a particular emphasis on low-resource countries, ensuring that ALL have access to safe and effective vaccines.

➢ Given the expected timeline for vaccine development, governments should continue to support efforts to understand and prevent outbreaks of COVID-19, including enforcing physical distancing recommendations and those related to face coverings, as well as educating the public about other prevention strategies. This may include the need to revisit policy strategies (such as "lockdowns") as needed. Further, governments must ensure that our healthcare system is adequately resourced to respond to COVID-19 outbreaks, including ensuring access to necessary personal protective equipment (PPE) and other medical supplies and equipment. Finally, governments should continue to identify and dispel myths regarding vaccine safety and encourage the public, especially families with young children, to visit their primary care providers to stay up to date on scheduled immunizations.

➢ Although unlikely, if the global pandemic subsides naturally before vaccines are ready, governments should continue to invest in vaccine development, as well as in the global infrastructure for manufacturing and distribution, in order to be prepared for the next (inevitable) disease outbreak.

Finally, special attention must be paid to equity and racial justice with respect to COVID-19. In the US, and elsewhere, racial and ethnic minorities and individuals with lower socioeconomic status experience poorer health than other more privileged groups. These health inequities are a direct result of structural racism and other forms of discrimination that create poor living conditions in communities of color, lack of access to resources needed for good health, and increased exposure to health threats. COVID-19 is no exception and communities of color have been hardest hit by this health crises—not because of any inherent vulnerability or weakness, but because of social and economic conditions created and perpetuated by unjust policies and practices. The current COVID-19 crisis has again illuminated cracks in our healthcare system, as well as elements of our other social and political systems that favor the white and the wealthy.

In one sense vaccines have the potential to be one of the most equitable health interventions we have at our disposal, but only if all have access. Experts have been

modeling different disease outbreak scenarios and making predictions about the vaccine timeline. Most are optimistic about the prospect of a vaccine in the near future. However, there is also consensus that even once a safe and effective vaccine is developed, it will be a scarce resource in the short-term and we will need to make difficult decisions about who is first in line. Most would probably agree that healthcare workers and first responders should be a priority, but beyond that, careful decisions must be made regarding who is most at risk and who is most likely to benefit from a vaccine. These decisions should be made with equity and justice in mind, as well as transparency in the process. There is an ethical imperative to remedy racial and economic inequities in health with respect to COVID-19. At the same time, a fair and equitable distribution of vaccines also serves our natural tendencies to want to protect ourselves and our loved ones (our self-interest)—for any of us to be protected, we must all be protected.

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Our Vision: Healthy, Thriving Communities for All
The Partnership for Healthy Communities is inspired by the possibility of this reality for all Delaware communities; as well as being inspired by a vision of equity in health. This prompts our work so that all of our residents can live in communities with the resources that are necessary to promote optimal health, and the burdens or threats to good health are minimized. We focus especially on communities currently experiencing social inequities.

The mission of the UD Partnership for Healthy Communities is to align and strengthen University of Delaware research, educational, and service capabilities to improve the health and well-being of Delaware communities and beyond through effective community partnerships.