

CENTERING ON CORONAVIRUS

VACCINE DEVELOPMENT

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Introduction

In late December 2019, authorities in Wuhan, China treated several individuals with cases of pneumonia caused by an unknown virus. On January 11, a 61-year old man from Wuhan died from the virus, becoming its first victim.

Fast forward to March 2020: there are now over 400,000 confirmed cases of what is now known as a new strain of coronavirus (COVID-19) around the world. The World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern and all U.S. states have declared a state of emergency amid rising infections and death tolls.

As infection rates multiply, a top priority for health officials has become not only containing the spread but also developing a vaccine. Although several treatments may be available in the coming weeks that could treat the symptoms of COVID-19, it is likely to take a year or more to develop the vaccine necessary to give the global population widespread immunity. According to the World Health Organization, as of March 21, 2020, there are two candidate vaccines in the clinical evaluation stage and 48 candidate vaccines in the preclinical evaluation stage.

In this issue brief, The New Center will explore how vaccine development typically works in the U.S. and how both regulatory and technological changes could accelerate the timeline to find a COVID-19 vaccine.

WHAT IS CORONAVIRUS?

According to the World Health Organization, a coronavirus is a member of a family of viruses that can cause a varying range of symptoms and illnesses. While contracting some can result in a mild cold, others—such as previously identified Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS)—can cause serious respiratory illnesses and can be fatal, especially to those with pre-existing conditions. The coronavirus first identified in China in December 2019 is a novel coronavirus and is referred to as COVID-19 (CO stands for corona, VI stands for virus, D stands for disease, and 19 refers to the year in which it was identified). Those infected by the virus are commonly reported to suffer from cough, fever, and difficulty breathing, though much is still unknown about COVID-19. As of March 2020, the World Health Organization announced the fatality rate for COVID-19 to be 3.4% (although this is still an early estimate, and other estimates suggest the true fatality rate could be under one percent once more data is available on the total number of infections), making it less deadly than MERS (34.4%) and SARS (9.6%).



How Does Vaccine Development Typically Work?

Vaccine development has historically occurred in six stages: the exploratory stage, pre-clinical stage, clinical development, regulatory review and approval, manufacturing, and quality control. The exploratory phase refers to initial vaccine development, while animal testing usually occurs in the pre-clinical stage before human trials are set up during clinical development. Traditionally, the exploratory stage would last between two and four years, but present-day technological advancements allow vaccines to reach the preclinical stage in months to a year. The health care industry is utilizing newly-developed artificial intelligence and technological capabilities to conduct a range of tasks from testing the probability of drug efficacy in humans to detecting virus attributes. This gives researchers the opportunity to speed through initial exploratory phases that previously took months and dive into clinical development.

INNOVATION SPOTLIGHT: GOOGLE DEEPMIND

On March 5, 2020, DeepMind Technologies (acquired by Google in 2014) released a publicly-available dataset featuring six predictions for protein structures associated with SARS-CoV-2 and the novel coronavirus. DeepMind hopes that their predictions, built off of a deep learning technique called free modeling, can “contribute to the scientific community’s interrogation of how the virus functions, and serve as a hypothesis generation platform for future experimental work in developing therapeutics.”

Progress is still stalled on cutting the time down on the preclinical stage and clinical development stages, which typically involve extensive testing on animal specimens followed by three distinct phases of human trials. Animal testing can take between one and two years, although The College of Physicians of Philadelphia notes that “many candidate vaccines never progress beyond this stage because they fail to produce the desired immune response.” If a drug does prove successful in the preclinical stage, an Investigational New Drug (IND) application is filed with the Food and Drug Administration (FDA), after which clinical trials on humans can begin. In total, the three phases of clinical trials—which test for safety, proof of concept, and risk-benefit—can take multiple years.

Following success in clinical trials, the FDA must approve the New Drug Application, after which the drug undergoes Phase IV trials, which the Centers for Disease Control and Prevention notes can take place after the vaccine has already been approved and licensed. In total, due to the regulations and standards involved in animal and human testing, life-saving vaccines have often taken 10 to 15 years to reach those in need.

This process, though arduous and time consuming, has been critical to ensuring the safety and effectiveness of vaccines. One need not look far into the past to understand the consequences of rushed vaccine development; in 1976, for example, several hundred people developed Guillain-Barré syndrome—a rare neurological disorder—after receiving a swine flu vaccine. And in 2009, the Pandemrix vaccine against H1N1 influenza created an increased risk for developing narcolepsy in some European countries. Beyond just ensuring that a vaccine is safe, diligent testing to reduce side effects plays an important factor in increasing public trust in critical health measures and mitigating vaccination reluctance.

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Vaccine Development amid the Coronavirus Crisis

As the world races to develop a therapy and vaccine for coronavirus and other emerging diseases, new technological advancements, funding structures, and regulatory relief efforts have been implemented to allow government and industry to meet the demand spurred on by this global pandemic.

Funding Structures and Technological Advancements

As increased globalization leads to a higher chance that small outbreaks will develop into pandemics, global health leaders have recently turned to more collaborative methods to not only respond to crises but also mitigate their spread. One such effort is the Coalition for Epidemic Preparedness Innovations (CEPI), officially launched at the World Economic Forum in Davos in 2017 with backing from individual governments, the Wellcome Trust, and the Bill & Melinda Gates Foundation. With an initial investment of \$500 million, CEPI works towards its mission to “accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks.” As of March 2020, CEPI is funding eight programs—undertaken by private companies and universities—working to develop a COVID-19 vaccine.

One CEPI-funded company, Moderna Inc., uses messenger RNA (mRNA) to develop its vaccine as opposed to using inactive viral samples that expose patients to the virus. RNA vaccines have shown to not only be safer for patients but also take less time to develop and are highly effective in countering certain diseases. Inovio Pharmaceuticals, another CEPI grantee, is creating a DNA vaccine, which involves the “direct introduction into appropriate tissues of a plasmid containing the DNA sequence encoding the antigen(s) against which an immune response is sought.”

Cutting the Red Tape: Current Policies and Proposed Solutions

Technological innovation can only do so much to spur on development if it is being held back by bureaucratic red tape. To that end, the U.S. Food and Drug Administration has taken some steps to waive requirements related to development in the hopes of bringing a coronavirus vaccine to the market.

- On February 4, 2020, the FDA enabled emergency use of the Centers for Disease Control and Prevention’s (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel, which is a test used to detect COVID-19 in individuals. Now, it can also be used at CDC-qualified labs and labs certified to perform high complexity tests.
- On February 29, 2020, the FDA authorized certain laboratories (which, according to the FDA, are “certified to perform high-complexity testing consistent with requirements under Clinical Laboratory Improvement Amendments”) to use tests that they have developed before the FDA completes their Emergency Use Authorization requests. As an update to this authorization, on March 16, 2020, the FDA increased the scope of laboratories authorized to use their developed tests to commercial manufacturers as well, under certain circumstances. The FDA also announced their intention not to object to the distribution and use of serological tests (which solely identify the presence of antibodies) as opposed to more complex molecular tests.

Beyond breaking down regulatory barriers, policymakers and industry leaders have also proposed initiatives to not only spur on development but to ensure an adequate supply of vaccines in the future.

- Senator Steve Daines (R-MT) put forward a \$10 billion proposal for the federal government to pay for manufacturing of several promising vaccines in the late stages of their development but before full approval for public use. This will help ensure any approved vaccine will be able to be deployed immediately without having any lag time to produce the necessary doses. This proposal was adopted in the coronavirus relief package the Senate passed on March 25, 2020.
- Sendhil Mullainathan and Richard Thaler, economists with the Chicago Booth School of Business, recommended briefly suspending patents to encourage innovation. And Daniel Hemel and Lisa Larrimore, professors at Stanford Law School proposed a cash prize to incentivize vaccine development. Neither of these ideas have been adopted.

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ABOUT THE NEW CENTER

American politics is broken, with the far left and far right making it increasingly impossible to govern. This will not change until a vibrant center emerges with an agenda that appeals to the vast majority of the American people. This is the mission of The New Center, which aims to establish the ideas and the community to create a powerful political center in today's America.

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