Insight

The Bridge to a Vaccine: Antiviral and Antibody Therapies for COVID-19

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Executive Summary

- Antiviral therapies are the best approach to bridging the gap between now and an effective vaccine for COVID-19.
- Several types of antiviral therapies, such as remdesivir, look promising for treating the virus, and it seems likely that antibody therapies will be available soon.
- Policymakers should seek to lower the regulatory barriers to these treatments in order to accelerate their availability.
- Continuing to support private-public partnerships will promote faster data dissemination and better decision-making by both policymakers and private industry.

Introduction

Emerging research suggests transmission of SARS-CoV-2 (the specific virus causing the coronavirus pandemic) seems to occur when patients are asymptomatic, with some evidence suggesting transmission may even peak right before or around the time symptoms manifest. These data illuminate a gap in the effectiveness of a syndromic surveillance system, as such a system relies on the rapid transmission of data from largely symptomatic COVID-19 cases to identify hotspots and facilitate contact tracing. As a vaccine is likely a year or two from full implementation, a hole exists in the United States' current approach to addressing the pandemic: how to treat the virus before a vaccine arrives. The answer lies in antiviral therapy development.

Potential COVID-19 Therapeutics

In a recent op-ed, Dr. Scott Gottlieb, former commissioner of the Food and Drug Administration (FDA), argued that society will need a therapeutic drug before a vaccine arrives in order to mitigate the development of severe illness in infected individuals. Antivirals come in many forms, however, and there are several classes of antivirals under development for treatment of COVID-19, with varying degrees of promise and success.

Hydroxychloroquine

Despite controversy surrounding Sanofi's hydroxychloroquine, specifically when used in conjunction with azithromycin, this anti-malarial drug continues to be a viable candidate for activity against SARS-CoV-2. While it was originally approved decades ago for the treatment of malaria, some small, preliminary studies have demonstrated its possible efficacy against SARS-CoV-2. More work needs to be done before any conclusions are drawn. Clinical trials are currently underway, with major manufacturers including Novartis and Mylan promising to donate tens of millions of tablets each.

Remdesivir

Gilead's remdesivir is a broad-spectrum antiviral drug—meaning it works on many different types of viruses—that has shown activity against coronaviruses. It has been previously demonstrated to work in coronaviruses generally, and in in-vitro tests—experiments outside of living organisms—it demonstrates activity against SARS-CoV-2 itself. The National Institutes of Health funded clinical trials that are currently underway, and recent, leaked clinical trial data from the University of Chicago provides preliminary validation of its efficacy. The research on remdesivir and COVID-19 is the furthest along compared to other antivirals and seems promising, with Gilead taking steps to ramp up production to get millions of 10-day courses to patients across the globe.

Antibody Therapies

Therapeutic antibodies are drugs that introduce exogenous antibodies into the body, providing the specific tools for the immune system to fight a particular virus. They are the ideal choice to fight COVID-19 for a couple of reasons. First, they can be used to treat symptomatic patients, especially if they are early in disease progression. Second, they can be taken prophylactically—before you are infected—so if exposed the individual has a greater chance of fighting off the illness. Currently, several pharmaceutical companies have antibody therapies in development; Regeneron has an antibody drug that could enter human trials as early as June.

Should current efforts to build an effective antibody drug come to fruition, this treatment may provide the stopgap society needs before a vaccine comes available. Fortunately, even before antibody drugs are available, there is convalescent plasma transfusion, a parallel treatment that utilizes similar principles of antibody therapies. By taking plasma from recently recovered COVID-19 patients and transfusing it into severely ill patients, the antibodies from the transfused plasma provide similar effects to therapeutic antibodies against SARS-CoV-2. While this treatment has been used with some past success against H1N1, SARS, and Ebola, the FDA has released guidance on convalescent plasma treatments with calls for more clinical trials to solidify its effectiveness against COVID-19.

Policy and Regulatory Steps

As promising therapies are being developed, there is a need for policy and regulatory solutions to hasten their delivery to individuals. There are several steps policymakers can take to accelerate availability of these therapies, both as evidence accrues and on the grounds of compassionate use.

Convalescent Plasma

A challenge to implementing convalescent plasma treatment widely is the supply from known COVID-19 recovery cases. Since serologic testing—testing for antibodies in the body—for SARS-CoV-2 is only now being introduced and scaled up, the United States does not have the necessary infrastructure to identify sources of

convalescent plasma. A syndromic surveillance plan, such as the one that the Margolis Center for Health Policy at Duke University has proposed, could help solve this problem. By having a definitive, multi-phase system to establish strong testing infrastructure—including broad serologic testing—the United States can not only achieve the syndromic surveillance needed but open avenues to identify recovered individuals willing to donate convalescent plasma. Government and public health officials should focus on rapidly approving and scaling up serologic tests to facilitate demand for this interim therapy.

Antibody and Other Antiviral Therapies

Under normal circumstances, novel drug development takes 10 to 17 years from the initial exploratory phases to its entrance onto the market, and drug repositioning—repurposing a drug for treatment of a different disease—takes an additional 3 to 12 years. As this timeline is unfeasible given the current pandemic, the FDA should consider Emergency Use Authorizations (EUAs), as evidence allows, for all compounds under consideration to allow health care providers to administer them on the basis of compassionate use. The FDA has already granted hydroxychloroquine an EUA; given the growing evidence for remdesivir as an effective treatment, the FDA should be primed to grant the drug an EUA in a timely manner. Furthermore, the FDA should devote special attention to antibody therapies and position itself for rapid approval during the summer.

Private-Public Data Partnerships

The private companies developing these antiviral and antibody therapies against COVID-19 are, naturally, also core sources of research and data collection. Gilead, for example, is currently conducting two randomized, open label, phase three clinical trials on patients with moderate and severe COVID-19, respectively. Between the research coming out of private and public institutions, there is a wealth of potential discoveries available in the space that composes the meeting point of each domain's data. Opening streamlined data-dissemination pathways for therapeutic options between the public and private sectors will help researchers form the most cohesive picture of COVID-19 treatment possible and thus optimize decision-making for both industry and policymakers. One method for policymakers to consider is building cross-sector registries to collect and organize aggregate patient data on the clinical effectiveness of certain therapeutics along with more comprehensive patient-characteristic data.

Conclusion

In the battle to end the COVID-19 pandemic, the United States needs myriad tools at its disposal and the ability to act quickly. Antiviral and antibody therapies have demonstrated potential to provide a critical bridge between now and the time a vaccine becomes available. In order to facilitate these treatments, policymakers should act to implement serologic testing on a national scale and to implement the necessary policy and regulatory measures that would give health care providers the tools and knowledge they need as quickly as possible. Given the pace at which the pandemic has spread, speed is of the essence for treatments, and policymakers should therefore work to reduce regulatory barriers and streamline patients' access to promising therapies.