

## Vaccines in Development to Target COVID-19 Disease

August 24, 2020

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### Background

Since its emergence in December 2019, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has caused over 24 million cases of novel coronavirus 2019 (COVID-19) as of August 27, 2020.<sup>1</sup> To mitigate the spread of the disease, unprecedented investment in both SARS-CoV-2 vaccine development and simultaneous scale up of vaccine manufacturing has been taking place.

The Coalition of Epidemic Preparedness Innovations (CEPI)<sup>2</sup>; World Health Organization (WHO); Gavi, The Vaccine Alliance,<sup>3</sup> and other global health organizations have joined forces with other stakeholders, including governments across the world, to support SARS-CoV-2 vaccine development and develop mechanisms to ensure that populations across the world will be able to access a potential future vaccine. Additionally, other governments, particularly those of high-income countries like the United States, have funded their own initiatives to accelerate vaccine development and procurement for their populations. Operation Warp Speed, for example, is a US government initiative designed to provide funding to certain vaccine developers and manufacturers, as well as companies responsible for production of other supplies needed for eventual mass vaccination.<sup>4</sup>

WHO regularly provides updated information about the current landscape of candidate vaccines to address COVID-19.<sup>5</sup> Over the past couple months, the number of candidate vaccines has risen dramatically. In early April, there were just over 60 candidates; as of August 20, 2020, there were over 139 vaccine candidates undergoing preclinical evaluation and another 30 vaccines that had started at least Phase I of clinical trials. Phase I trials generally start with a small group of healthy adults and aim to assess safety as well as the immunogenicity—the ability to provoke an immune response in the body—of the vaccine candidate. Phase II trials also assess safety and immunogenicity, as well as inform appropriate dosing schedule and concentrations. Phase III trials are the last to occur prior to potential licensure, and generally involve tens of thousands of people. Like the earlier stages, Phase III trials assess safety and are particularly important for detecting the occurrence of rare adverse events. Additionally, these trials assess the efficacy of the vaccine to protect against the outcome of interest, which could include prevention of infection or disease depending on the vaccine. After licensure, postmarketing surveillance and trials may also be done to continue monitoring the safety, efficacy, or use of the vaccine in different contexts. This factsheet will focus on those listed in the WHO landscape as being in Phase II or Phase III.

### Vaccine Landscape

Each vaccine platform has its own set of advantages and disadvantages. For example, nucleic acid (ie, DNA, RNA) vaccines can be easier to develop, but DNA vaccines may not be as immunogenic and could require electroporation devices to use and mRNA vaccines can be very unstable unless frozen at very cold temperatures.<sup>6</sup> Additionally, viral vector vaccines and subunit vaccines generally exhibit higher safety profiles and are more immunogenic, but may have reduced efficacy due to preexisting immunity to the vector or may be too expensive, respectively.<sup>6</sup>

Table 1. Overview of Vaccine Candidates Currently Undergoing Clinical Trials<sup>5</sup>

Platform	Number of Vaccine Candidates
DNA	4
RNA	6
Inactivated	5
Nonreplicating viral vector	5
Protein subunit	8
Replicating viral vector	1
Virus-like particles	1
<b>Total</b>	<b>30</b>

## Key Examples of Candidate Vaccines Undergoing Clinical Trials

Of the 30 candidate vaccines undergoing clinical trials as of August 20, 2020,<sup>5</sup> this fact sheet focuses primarily on the select subset of candidates that, according to WHO, are in the Phase II or III stage. The one exception is a vaccine that has not officially surpassed early trials but is planned to be used in populations of certain countries. The goal of this document is to highlight key points about some of the leading vaccine candidates to date; they are discussed in no particular order. It is important to underscore that this document is not a fully comprehensive reporting of all candidate vaccines. As, vaccine development is rapidly evolving, we are only discussing information that was current as of August 20, 2020.

### Candidate Vaccines in Phase II or Beyond

- University of Oxford and AstraZeneca (ChAdOx1-S/AZD1222)

The University of Oxford Jenner Institute and pharmaceutical company Astra Zeneca have developed and are testing a vaccine candidate that leverages the ChAdOx1 nonreplicating simian adenoviral vaccine vector.<sup>7,8</sup> The ChAdOx1 platform consists of a transgenic nonreplicating virus vector that would express and lead to the host cell expressing and displaying the antigenic coronavirus spike protein upon immunization, thus prompting an immune response.<sup>9,10</sup> An advantage of viral vectored vaccines is their ability to produce humoral/antibody- and T cell-mediated responses.<sup>10</sup> CEPI has also previously funded this group to develop vaccines against a range of other emerging diseases including Middle East respiratory syndrome (MERS).<sup>11</sup>

Preclinical assessments in mice and rhesus macaques indicated that the vaccine elicited immune response in both model animals. Additionally, the vaccine developers reported that after 9 rhesus macaques were injected with 1 dose of vaccine, 6 had significantly less viral loads in bronchoalveolar lavage fluid and respiratory tissue compared with 3 control animals, and they did not develop pneumonia symptoms.<sup>12,13</sup> While the preclinical results have moved this candidate forward, there has been some criticism about the interpretation of findings. Although the vaccinated animals had a reduction in viral load in bronchoalveolar lavage fluid, they exhibited the same amounts of virus in nasal swabs, which is generally what is gathered when testing in people. Additionally, critics have pointed out that the concentration of important neutralizing antibodies was not particularly high.<sup>14</sup> Despite these issues with the preclinical data, the vaccine progressed through early clinical trials. A notable advantage of this candidate is that it is single dose, unlike nearly all of the other candidates in late stage clinical evaluation.<sup>5</sup>

Phase I trials began in late April in the United Kingdom.<sup>8,13</sup> Since then, the candidate has progressed to Phase II/III, with Phase III trials being conducted in multiple locations, including Brazil, South Africa, and the United Kingdom. The Phase II/III trial in the United Kingdom is anticipated to enroll up to about 10,000 people across multiple age groups, including children. While the Phase II portion of the trial will assess immunogenicity, particularly in older adults and younger children, the Phase III portion will assess efficacy in a large number of individuals over 18.<sup>15</sup> Sponsored by Brazilian entrepreneurs, and in collaboration with the Universidade Federal de São Paulo, the Brazilian trial started on June 20, 2020, with the goal to enroll about 5,000 participants across

multiple sites.<sup>16</sup> The South African vaccine trial (called VIDA-Trial) is being conducted in collaboration with the University of the Witwatersrand.<sup>17</sup> Results across these trials could take up to 6 months or longer to be finalized, as analyses of efficacy are dependent on having a sufficient number of participants in the trial develop COVID-19 through exposure in their communities.

In late May, the US government awarded AstraZeneca about US\$1.2 billion to facilitate late-stage clinical testing with simultaneous large-scale manufacturing, thereby securing doses to vaccinate a proportion of the US population if the vaccine is eventually approved.<sup>18</sup> Additionally, the Australian government recently made a deal with the company to purchase enough vaccine to provide free doses to its entire population of 25 million people.<sup>19</sup>

- **Beijing Institute of Biotechnology and CanSino Biological, Inc. (Nonreplicating Viral Vector)**

CanSino Biological, Inc. (CanSinoBIO), a Chinese-based company, is collaborating with the Beijing Institute of Biotechnology to develop a nonreplicating viral vector vaccine called Ad5nCoV.<sup>5</sup> One of the few single-dose vaccines, the candidate uses a nonreplicating adenovirus type 5 viral vector containing the gene encoding the antigenic SARS-CoV-2 spike protein.<sup>20</sup> The viral vector delivers the spike protein gene into human cells, leading to production of the protein that is designed to trigger an immune response.<sup>21</sup> CanSinoBIO successfully developed an Ebola vaccine using the same viral vector approach, which Chinese regulators approved in 2017.<sup>9,10</sup> In mid-March, CanSinoBIO became the first company to initiate clinical trials among over 100 participants aged 18 to 60 years old in a hospital located in Wuhan, China.<sup>22,23</sup> By late May, the company published the results of the Phase I trial in *The Lancet*.<sup>24</sup> The trial assessed the safety and immunogenicity induced from low, medium, and high doses of the vaccine. Notably, in addition to measuring adverse reactions to the vaccine, the publication reported on percentage of participants in each dosage category that developed neutralizing antibodies. While about 75% of the high-dose group developed neutralizing antibodies, only about 50% of the low- and middle-dose groups did. As Phase II trials began in April, the high-dosage analysis was stopped due to safety concerns. It is unknown what concentration of neutralizing antibodies is needed to incur protective immunity. However, the relatively lower percentage of these antibodies produced in the low- or middle-dose groups underscores concerns that higher doses are needed for protective efficacy.<sup>25</sup> Clinical trials are also underway in Canada.<sup>26</sup>

The Chinese military announced in late June that the vaccine had been approved for 1 year by the Chinese government for use among members of the military. It is unclear whether it will be mandatory for military, but the announcement came before the Phase III trials were completed to confirm the vaccine's efficacy.<sup>27,28</sup> The Chinese government also recently approved the patent for CanSinoBIO's vaccine candidate.<sup>29</sup> Meanwhile, Phase III trials have commenced in several countries, including Pakistan and Saudi Arabia, in trial sizes ranging from 5,000 to 10,000 participants.<sup>30,31</sup>

In addition to possible safety concerns of adenovirus-vectored vaccines at higher concentrations, other possible limitations exist. The type of adenovirus used in this candidate is a virus associated with the common cold. Consequently, it is possible that people may have already been exposed to that viral vector, which could hinder human cell uptake of the viral vector, or that their immune system may respond to the adenovirus component of the vaccine rather than the SARS-CoV-2 antigen.<sup>21,32</sup>

- **The National Institutes of Allergy and Infectious Diseases and Moderna, Inc. (mRNA)**

US company Moderna, Inc., in collaboration with the National Institutes of Allergy and Infectious Diseases (NIAID), has developed an mRNA lipid nanoparticle-based vaccine.<sup>5</sup> The sequence for the vaccine candidate, mRNA-1273, was first identified in mid-January and contains the genetic code for a spike protein. When administered, the mRNA sequence prompts cells to start producing the antigenic spike protein, initiating an immune response. The advantages of using mRNA vaccines, compared to more traditional attenuated or inactivated formulations, include the lack of infectious material in the vaccine and the relative ease of identifying and producing potential candidates.<sup>33</sup> Despite these possible advantages, past mRNA vaccine candidates, including those developed by Moderna, have not made it past Phase III clinical trials.<sup>21</sup>

Clinical trials run by NIAID's Vaccine Research Center began in early March and involved approximately 15 people per dose cohort, with 3 dose cohorts.<sup>34</sup> On May 11, the US Food and Drug Administration granted

Moderna a fast track designation for the candidate, and preliminary results were released a week later from 8 participants in the trial.<sup>35</sup> The press release reporting the study results indicated that all participants exhibited neutralizing antibody responses when receiving 2 doses of between 25 mcg and 100 mcg doses. Recently published preclinical data found that immunized mice exhibited neutralizing antibodies and were protected from viral replication in the lungs when challenged with SARS-CoV-2 infection.<sup>36-38</sup> Since May, data from the Phase I trials, involving 45 participants aged 18 to 55 years, have been published in a peer-reviewed journal.<sup>39</sup> Participants received 2 vaccinations at 28 days apart in concentrations of either 25 mcg, 100 mcg, or 250 mcg. Immune responses were dose-dependent, with the lowest antibody responses observed in the 25 mcg group and comparably higher responses seen in the 100 mcg and 250 mcg groups. Neutralizing antibody responses were observed in all participants after the second dosage and at concentrations comparable to the “upper half of the distribution” of values found in convalescent sera measured. About 50% of the participants in the 25 mcg dose group and 100 % of participants in the 100 mcg and 250 mcg dosage groups reported mild, moderate, or severe systemic symptoms. Pain, headache, and fatigue were some of the most common symptoms reported.

Recruitment for Phase II trials to assess safety, reactogenicity, and immunogenicity has been completed. Phase III trials involving up to approximately 30,000 participants aged 18 years or older have also commenced, becoming the first vaccine candidate in the United States to reach this stage. However, recent reports indicate that the start of the trial was delayed due to unspecified changes in the trial protocol.<sup>40</sup> The Phase III trials will start dosing at the highest dosage used in the Phase I trials (100 mcg).<sup>41,42</sup> The Phase III trial primary endpoints of occurrence of symptomatic COVID-19 disease starting 14 days after the second dose, measurement of occurrence of adverse events, and occurrence of severe disease as well as infection, irrespective of severity, are among the secondary outcomes assessed.

The US government has provided currently 4 separate allocations of funding to Moderna to support evaluation and scale up of its candidate, with amounts ranging from US\$53 million to, most recently, US\$1.5 billion in August.<sup>18</sup> While Moderna has reportedly already recruited over 8,000 participants for its Phase III trial in its first week, there are some concerns about the current lack of racial and ethnic diversity among participants. This could have potential implications for possible approval, given the disproportionate impact that COVID-19 has had on Black and Latino communities.<sup>43</sup>

- **Wuhan Institute of Biological Products and the Beijing Institute of Biological Products and Sinopharm (Inactivated)**

Sinopharm, a Chinese state-run pharmaceutical developer, has developed 2 different inactivated formulations with the Wuhan Institute of Biological Products and the Beijing Institute of Biological Products.

The Wuhan Institute of Biological Products formulation began Phase I/II clinical trials among over 1,000 healthy subjects age 6 years and older in April, and preliminary findings were recently published.<sup>44</sup> Participants received 3 doses of low-, medium-, or high-concentrations of the vaccine. The middle dosing concentration (5 mcg) was used in Phase II and tested at 2 different immunization schedules (day 0 and day 14 [0,14] and day 2 and day 21 [0,21]).<sup>44-47</sup> The Phase II trials found that antibody responses were higher at the 0,21 day schedule than the 0,14 day schedule. Interestingly, it should be noted that while the middle dosing concentration was used in Phase II, that group performed slightly worse than the other comparison groups with respect to neutralizing antibody concentration.<sup>44,47</sup> The Beijing Institute of Biological Products formulation has also progressed.<sup>45</sup> In late June, the company announced via Weibo that it had completed Phase I/II safety trials and that this formulation, too, had generated neutralizing antibodies. Phase III trials are expected to begin in the United Arab Emirates.<sup>48</sup>

Phase III trials of the candidates are ongoing in the United Arab Emirates<sup>49</sup> and have been approved for other countries including Peru and Morocco.<sup>50</sup> One key challenge of conducting large Phase III trials for these candidates is that the trials have to occur in countries where virus transmission is occurring at higher rates than in China, since China has substantially controlled its epidemic.<sup>51</sup>

- **Sinovac (Inactivated with Alum Adjuvant)**

The Sinovac Research and Development Company has developed an inactivated formulation with alum adjuvant called CoronaVac.<sup>5</sup> The vaccine formulation was reportedly one of the first to exhibit protection against SARS-CoV-2 lung infection when rhesus macaques were challenged with the virus.<sup>52,53</sup> Phase I/II clinical trials began in April, with the goal of recruiting over 400 adults aged at least 60 years. Participants received 2 doses of low, medium, or high concentrations of the vaccine at 28 days apart, with a subsequent trial focusing on just the medium and high doses.<sup>54</sup> In mid-June, Sinovac announced that preliminary results from the study indicated the vaccine generated robust neutralizing antibody immune response among more than 90% of people tested after 2 weeks of receiving the vaccine; the company also reported no severe side effects.<sup>55</sup> The company has since engaged in preparations to commence Phase III clinical trials and is collaborating with a Brazilian pharmaceutical company to conduct the trial in Brazil. The trial of over 8,000 participants will involve adults aged 18 to 59 years and those over 60 years.<sup>55,56</sup> Additionally, a small Phase III trial involving 1,620 adults aged 18 to 59 years has begun in Indonesia.<sup>57</sup>

- **BioNTech and Pfizer (mRNA)**

German company BioNTech, in partnership with Pfizer pharmaceutical company conducted Phase I/II trials of 4 candidate vaccines,<sup>58</sup> each consisting of different mRNA sequences encoding different SARS-CoV-2 antigens.<sup>59</sup> The Phase I portion of the trial enrolled up to 360 adults, aged between 18 and 55 years and 65 and 85 years, and tested participants at 3 doses, including 10 mcg, 30 mcg, and 100 mcg. Preliminary results of candidate BNT162b1, a lipid nanoparticle formulated mRNA vaccine encoding the spike protein, have been released. The data was collected from 45 participants between the ages of 18 and 55 years.<sup>60</sup> Fatigue, headache, chills, fever, and muscle pain were more common in the vaccine recipients than in the placebo group, with half of the participants in the highest dosing category experiencing fever within the first week after vaccination. Neutralizing antibodies were found to be between 1.8 and 2.8 times higher in vaccinated recipients than in recovered COVID-19 patients, although it is unclear whether that corresponds to protective efficacy.<sup>61</sup>

Phase II/III trials have also commenced for the other candidate, BNT162b2 (B2), at 2 separate doses and in age groups of 18 to 55 years and 65 to 85 years.<sup>62</sup> The candidate was selected to proceed over BNT162b1 due to its better tolerability profile and comparable immunogenicity.<sup>63</sup> Preliminary results from the Phase I/II trial indicate that immune responses were weaker in the oldest age categories. Also, nearly all of the recipients of B2 in the initial study were white, non-Hispanic participants. It is anticipated the Phase II/III trial will enroll about 30,000 participants.<sup>64</sup> According to a recent press release, Pfizer aims to seek regulatory review as early as October 2020 and produce about 100 million doses by the end of 2020, with as many as 1.3 billion doses by the end of 2021.<sup>65</sup> The US government has provided US\$1.95 billion in funding to support efforts to conduct large-scale manufacturing and fill finish of 100 million doses of mRNA vaccine.<sup>18</sup>

- **The Institute of Microbiology at the Chinese Academy of Sciences and Anhui Zhifei Longcom Biopharmaceutical (Subunit)**

A joint effort between Zhifei Longcom Biopharmaceutical and the Chinese Academy of Sciences has led to the development of an adjuvanted protein subunit vaccine containing a recombinant receptor binding domain dimer.<sup>66</sup> Two fragments of the spike protein containing the receptor-binding domain of the protein are joined together to form a dimer, which serves as the antigen. This approach was used by the vaccine developers to develop candidates against other coronavirus pathogens, including SARS-CoV and MERS. The protein subunit antigen can be scaled up for production by being transformed into a certain cell line called Chinese Hamster Ovarian cells, which then are cultured to produce the protein on a large scale.<sup>66</sup> Phase I trials involving about 50 participants began in late June,<sup>67</sup> after Chinese authorities approved the commencement of clinical studies for the candidate.<sup>68,69</sup> Participants in the Phase I trial received multiple doses and were divided into placebo, low-, and high-dose groups. The primary outcome measure assessed the occurrence of adverse events, with SARS-COV-2 neutralizing antibody, S protein binding IgG antibody, and the receptor-binding domain binding antibody levels measured as secondary outcomes. In mid-July, recruitment began for Phase II trials of the vaccine among 900 subjects receiving either 2 or 3 doses of vaccine or placebo. Results from the Phase I trial are not yet published but, according to news media, are anticipated to be released September 20, 2020.<sup>70</sup>

- **CureVac (mRNA)**

CureVac AG is a German-headquartered pharmaceutical company that focuses on developing mRNA-based vaccines and therapeutics. Its mRNA candidate, CVnCoV, is currently in Phase II trials. CureVac received funding from CEPI in 2019 to develop a mobile unit for rapid mRNA production for lipid-nanoparticle-formulated mRNA vaccine candidates, potentially at the site of an outbreak.<sup>71,72</sup> This platform could be used against long-known pathogens, such as yellow fever and rabies viruses, or against novel pathogens, such as SARS-CoV-2. Vaccines relying on this platform contain mRNA that, upon being injected into the vaccine recipient, initiates cells to produce protein antigen from the pathogen of interest, thus stimulating an immune response.<sup>33</sup>

Recruitment for Phase I clinical trials began in late June, with an estimated total enrollment of about 168 people.<sup>73</sup> Participants received either placebo or were vaccinated with 2 escalating doses ranging from 2mcg to 8 mcg. Safety and immunogenicity were assessed by measuring the presence of spike protein antibodies and neutralizing antibodies. On August 17, the Phase II trials for the vaccine began, with an anticipated 691 participants.<sup>74</sup> Individuals received either control vaccines (including hepatitis A or pneumococcal vaccine) or 2 doses of vaccine ranging in concentration from 4 mcg to 8 mcg. The company said it anticipates starting Phase III trials in late 2020.<sup>75</sup>

News from earlier in the year of CureVac executives being approached by members of the Trump Administration and the European Union to purchase vaccine<sup>76</sup> highlights concerns of ensuring an equitable supply of vaccine once it is potentially available for clinical use. The European Commission recently announced that they have concluded the first round of talks to acquire almost 230 million doses to EU countries.<sup>75</sup> Additionally, the National Institutes of Health is reportedly working with CureVac to develop 2 additional RNA vaccine candidates.<sup>77</sup>

- **Gamaleya Research Institute (Nonreplicating Viral Vector)**

While the other vaccines discussed in this document have generally passed the early stages of the clinical trial process, the nonreplicating adenovirus-vectored vaccine candidate, Sputnik V, produced by the Russian Gamaleya Research Institute is considered an exception. This candidate is highlighted because it was recently approved for use by Russian regulatory authorities, despite having been tested in only 76 people at the time of approval.<sup>78</sup> The move, largely criticized by both the global scientific community and the Russian Association of Clinical Research Organizations, currently allows the vaccine to be given to small numbers of “vulnerable populations,” but will allow wider use of the vaccine in the general population in January 2021.<sup>79</sup> The vaccine, which President Putin described as working “effectively enough” at the time of approval, is reportedly going to be tested in about 40,000 individuals. Countries, including the Philippines, Mexico, and Brazil, are reportedly planning to receive doses of the vaccine to conduct trials.<sup>80,81</sup>

## **Considerations for Vaccines to Address COVID-19 Pandemic**

The rate at which potential vaccine candidates against SARS-CoV-2 have been identified is unprecedented, with some candidates starting Phase 1 clinical trials in less than 2 months from preclinical development, showing the promise that platform technologies bring. Despite this initial progress, substantial hurdles related to technological capability, logistical feasibility, and social equity still lie ahead.

### **Technological**

No vaccine candidates against a coronavirus, including SARS and MERS, have successfully completed clinical trials. These vaccines have proven challenging to develop for multiple reasons, including possible enhancement of respiratory disease in vaccine recipients, potential financial constraints, and concerns about prioritization.<sup>82,83</sup> For SARS-CoV-2 vaccines currently undergoing clinical trials, questions remain about what immunological measures correlate with protection. Additionally, while assessments characterizing immune response to SARS-CoV-2 continue to be conducted, questions remain about the duration of both natural and vaccine-induced immunity.<sup>84</sup>

### **Logistical**

Once a vaccine candidate is approved for clinical use, rapid scale up of manufacturing will be a challenge. Governments and global health stakeholders have worked to fund the expansion of manufacturing capacity for leading vaccine candidates while those candidates undergo clinical trials, with the goal that this will expedite the

availability of a safe and effective vaccine. This approach, however, comes with a great financial risk if the candidates fail.<sup>85</sup> Furthermore, supply chain shortages in other materials needed for widescale mass vaccination, such as glass vials, also could present potential logistical bottlenecks.<sup>86</sup> Additionally, not all vaccines are equally practical to use across diverse settings. Most SARS-CoV-2 vaccine candidates currently need to remain in the cold chain at 2 to 8 degrees Celsius. Some vaccines, such as the RNA candidates, have even more constraining cold chain requirements and must be kept frozen at -60 to -80 degrees Celsius. These temperature requirements can reduce the feasibility of widespread mass vaccination both in lower- and high-income countries depending on the setting.<sup>87</sup>

## Equity

A range of challenges related to health equity and ethics also remain. Equitable allocation of a high-demand vaccine product across the world will be incredibly difficult, both nationally and globally. While WHO has resources and frameworks for vaccine allocation of COVID-19 vaccines and countermeasures and the US CDC has outlined allocation strategies for domestic influenza vaccine allocation, there are not enough established and binding systems to adjudicate allocation decision making for novel emerging pathogens.<sup>83,88,89</sup> Determining which groups should be prioritized within a country requires making difficult decisions about what factors, end goals, and ethical principles to emphasize.<sup>90,91</sup>

Allocation decision-making challenges are further exacerbated with rising “vaccine nationalism” and “vaccine sovereignty,” where high-income countries that have the financial capacity to fund vaccine development or make deals with pharmaceutical companies to ensure vaccine supply has prompted concerns that poorer countries or those without those capabilities could be left behind.<sup>92,93</sup> Countries have already instituted export controls on key medical resources during this pandemic, and it is anticipated that similar situations could arise if and when a vaccine becomes available.<sup>93</sup> While stakeholders such as WHO and governments from lower-income countries have argued for collaboration and equitable distribution of “a people’s vaccine,” it is unclear what can be done to ensure that occurs.<sup>94</sup>

Challenges also remain with ensuring vaccine acceptance and uptake among those who could have access to the vaccine. Exacerbated by criticism about lack of transparency, as well as rhetoric and timelines that have emphasized speed without properly addressing safety concerns, about 50% of Americans surveyed in a recent poll have expressed hesitancy at getting vaccinated once a SARS-CoV-2 vaccine gets developed.<sup>95</sup> Racial disparities in the clinical trial process, and longstanding issues of distrust in the medical system among certain racial and ethnic minority population, have also contributed to antivaccination sentiment and hesitancy.<sup>95,96</sup>

In the coming months, as various candidates progress along the development pipeline, these issues will become even more pressing to address.

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