

Clinical Review

COVID-19: The Vaccine Race Continues

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Abstract

Description

Over a year has passed since the discovery of SARS-CoV-2 and the subsequent COVID-19 pandemic. As mitigation efforts continue, COVID-19 has claimed over half a million lives in the United States and 3.1 million lives globally. The development and availability of vaccines delivering immunity to prevent COVID-19 offers hope to end the pandemic.

Emergency use authorizations from the Food and Drug Administration have been issued in the United States for three vaccines, one each from Pfizer-BioNTech, Moderna and Janssen/J&J. Pfizer-BioNTech and Moderna are both mRNA vaccines with efficacy of 95% and 94.1% respectively, while the vector-based vaccine from Janssen/J&J has an overall efficacy of 66.1%. The Janssen/J&J vaccine, having received the most recent authorization, is an attractive option due to high efficacy with a single dose.

With a high immunity rate of 70–80% needed to prevent the continued spread of the virus and mutations, the majority of the population will require vaccination. The rise of mutations from selective pressure has further increased the urgency. Recent discoveries of variants have led to uncertainties regarding the impact of immunity and effectiveness of vaccines. In order to end the global pandemic, it is essential that the Centers for Disease Control and World Health Organization monitor the variant potential and educate the public appropriately to encourage appropriate vaccination and allocation of product.

Achieving high vaccination rates in the U.S. has been challenged by supply, storage requirements and public hesitancy. In a recent Gallup poll, a random sample of 4,098 adults demonstrated that 71% of survey respondents were willing to receive a vaccine, which remains on the lower end of the 70–80% vaccination range required to end this pandemic. Despite these challenges, the United States has managed to surpass 225 million vaccinations.

Keywords

SARS-CoV-2; COVID-19; coronavirus infection; viral vaccines/adverse effects; COVID-19 vaccines; vaccines; vaccines/supply and distribution; mutation; pandemic; patient safety

Introduction

Global efforts to control coronavirus disease 2019 (COVID-19) infections developed from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have led to emergency use authorizations (EUA) in the United States (U.S.) for three vaccines and laid the production pipeline for several others. Although infection prevention strategies such as social distancing, closings of schools and offices, stay at home orders, mask mandates and capacity limitations have been implemented, as of April 25, 2021,

COVID-19 has surpassed 572,199 deaths in the U.S. and 3.1 million deaths worldwide.¹ Current COVID-19 medication treatment strategies provided mixed results, leaving our most promising avenue of ending this pandemic with vaccines.

The race to develop a safe and effective vaccine has contenders from multiple manufacturers globally, but is threatened not only by the hesitancy of the public, but also by recent SARS-CoV-2 variants. Immunity in 70–80%

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Table 1. All Vaccine Summary Table

	Pfizer-BioNTech	Moderna	Ox/AZ-ChAdV	Sputnik V-Ad26/Ad5	Sinopharm	Sinovac	Cansino	Bharat	Janssen/J&J	Novavax
Mechanism of action	mRNA	mRNA	Vector	Vector	Inactivated	Inactivated	Vector	Inactivated	Vector	Protein subunit
Doses	2	2	2	2	2	2	1	2	1	2
Storage	-20°C	-20°C	2–8°C	2–8°C	2–8°C	2–8°C	2–8°C	2–8°C	2–8°C	2–8°C
Activity against variants	B.1.1.7 B.1.135.1 B.1.1.28.1 B.1.429/7	Yes	Y-B.1.1.7 N-B.1.351	Yes	Yes	Yes	Unknown	Yes	Yes	B.1.1.7 86% B.135.1 60%
Efficacy	95%	95%	60–85%	92%	79%	50%	66%	Unknown	66%	89%
Countries available no.	63	27	44	9	11	6	1	1	1	Pending
United States	Yes	Yes	No	No	No	No	No	No	Yes	No
United Kingdom	Yes	Yes	Yes	No	No	No	No	No	No	No

of the population has been projected to stop COVID-19 spread and mutations.² Public polling results of willingness to receive the vaccine have been mixed. A U.S. Census Bureau survey of 68,000 adults from January 6 to 18, 2021, revealed only 51% of respondents would definitely receive the vaccine.^{2,3} Fortunately, the data from other surveys later in January showed that public support to receive a vaccine is growing, with an increased population reporting they would receive the vaccine as soon as it is available.^{4,5} Gallup poll results continued to improve in February 2021 with the highest rate of vaccine acceptance at 71%. The challenges of public acceptance of the vaccine coupled with the recent reports of mutations in the United Kingdom (UK), South Africa, Brazil and the U.S. are a critical concern.

Vaccine Approval Status

At the time of publication, three vaccines have been granted EUA approval by the Food and Drug Administration (FDA), 91 vaccines are in clinical development and 184 vaccines are in the pre-clinical development process worldwide.⁶⁻¹⁰ As of April 24, 2021, the U.S. has administered over 225 million doses of COVID-19 vaccines with 93 million people being fully vaccinated.^{11,12}

Each vaccine has specific storage requirements that are important considerations for administration sites. The Pfizer-BioNTech COVID-19 vaccine requires temperatures between -80°C to -60°C prior to dilution, while the Moderna COVID-19 vaccine requires temperatures

between -25°C to -15°C with resultant efficacies of 95% and 94.1% respectively.^{10,13} Recently, the FDA has allowed the Pfizer-BioNTech COVID-19 vaccine to be stored at -25°C to -15°C for up to two weeks after data was submitted to support stability at this temperature. Unlike the mRNA vaccines, which have freezer storage requirements, vector-based vaccine candidates are able to be stored at refrigerated temperatures.^{15,16} However, vector-based vaccines have shown reduced rates of efficacy: 70.4% for AstraZeneca/Oxford and 66.1% for Janssen/Johnson and Johnson (J&J).^{9,10,13-16} Janssen/J&J’s vector-based vaccine was submitted for EUA in the U.S. on February 4, 2021, and received approval on February 27, 2021, based on phase 3 data demonstrating that this single-dose vaccine met its primary and secondary endpoints.¹⁷

Outside of the U.S., alternative vaccines are available in various stages of approval. (Table 1) Phase 3 data has been made available for AstraZeneca/Oxford’s vector-based vaccine, which has been approved for emergency supply in the UK.^{15,16} Another notable vector-based vaccine is Gamaleya’s Sputnik V, which utilizes a combination of two adenoviruses rAd5 and rAd26, with 91.2% efficacy. Russia approved Sputnik V on August 11, 2020, prior to completion of phase 3 trials.¹⁸ China has multiple COVID-19 vaccines available, including Convidecia by CanSino Biologics with 65.7% efficacy, BBIBP-CorV by Sinopharm with 79.34% efficacy, CoronaVac by Sinovac Biotech with 50.38% efficacy, and Sinopharm-Wuhan by the Wuhan

Institute of Biological Products. India currently has Covaxin by Bharat Biotech, although its efficacy is unknown.¹⁹

Viral Vector Technology Implications for COVID-19 Vaccines

Viral vector vaccines were first introduced in the 1970s and have also been studied for gene therapy, cancer treatments and molecular biology research. Viral vector vaccines have also been used against a variety of infectious diseases including Zika virus, influenza viruses, respiratory syncytial virus (RSV), human immunodeficiency virus (HIV), malaria and Ebola.¹⁹⁻²³ Vector vaccines use a different virus than the targeted virus to trigger an immune response. For example, AstraZeneca/Oxford and Janssen/J&J's COVID-19 vaccines utilize a modified adenovirus vector, based on the common cold, to deliver a gene to human immune cells that triggers an immune response.^{20,23,24} The adenovirus is modified and inserted with genetic material for antigens against SARS-CoV-2 antigen spike proteins. The spike protein is a transmembrane protein specific to the SARS-CoV-2 virus and is found on the surface. Once the gene enters the human cell, the viral vector will use the cell's processes to develop a spike protein and lead the body's immune system to believe it is infected with COVID-19. When the cells are infected and instructed to make large amounts of antigen, they trigger an immune response, similar to what happens during a natural infection. This subsequently triggers a strong immune response by T cells and the production of antibodies by B cells.

One concern of using viral vectors is the recipient may have been exposed to the vector prior, leading to pre-existing immunity. Adenoviral vectors are based on natural viruses (e.g., common cold) that some people may have already been exposed to and may lead to the vaccine not working for everyone.^{24,25} Scientists have worked to overcome this issue by utilizing uncommon viruses or viruses found in other species. The AstraZeneca/Oxford vaccine utilized a chimpanzee adenovirus and the Janssen/J&J vaccine used a replication-incompetent human adenovirus.^{15,17} Adenoviruses are attractive vectors for vaccines as their genome has been well-studied and they induce a robust immune response. In addition, adenoviral vector vac-

cines are well-suited for pandemic responses as they are easy to design and produce at scale.²⁴ Adenoviral vector vaccines have been used during Ebola outbreaks and two recent vaccines were used in West Africa and the Democratic Republic of Congo. The technology has also been used to develop an oral rabies vaccine used in wild animals.²⁴

Findings

Vaccine Trial Efficacy

With a minimum threshold for efficacy set at 50% by the FDA and World Health Organization (WHO), the approved Pfizer-BioNTech and Moderna mRNA vaccines exceeded expectations at 95% and 94.1% efficacy against symptomatic COVID-19 infection respectively.^{26,27} The Janssen/J&J vector vaccine has demonstrated an overall efficacy of 66.1% in preventing moderate to severe COVID-19.¹⁷ There have been three other promising viral vector-based vaccine candidates in the pipeline, two from Merck and one from AstraZeneca/Oxford. (**Figure 1**) Merck, also known as MSD outside of the U.S. and Canada, made the decision to discontinue the development of both of their vector-based SARS-CoV-2/COVID-19 vaccines on January 25, 2021, and move to focus efforts on COVID-19 therapeutic treatment agents.^{15,28}

The AstraZeneca/Oxford's ChAdOx1 nCoV-19 (AZD1222) vaccine demonstrated 90.0% efficacy (95% CI 67.4, 97.0) in phase 3 trials when given as a half dose followed by a full dose, and 62.1% efficacy (95% CI 41.0, 75.7) when two full doses were administered.¹⁵ Of note, the trial COV001 (UK) was intended as a single dose study yet a small subgroup received a second dose at 28 days. COV002 (UK) intended a second dose at 28 days yet many received their vaccine after. COV003 (Brazil) offered a second dose at up to 12 weeks with a target of 4 weeks. And COV005 (South Africa) administered a second dose at 28 days. Interestingly, the more effective regimen was based on participants who mistakenly received a half dose of the vaccine followed by a full dose. These results have yet to be fully explained by the company, although it is theorized to have been highly efficacious due to the longer prime-boost interval.^{29,30} Of note, the safety and efficacy of AstraZeneca/Oxford's vector vaccine candidate against SARS-CoV-2 data

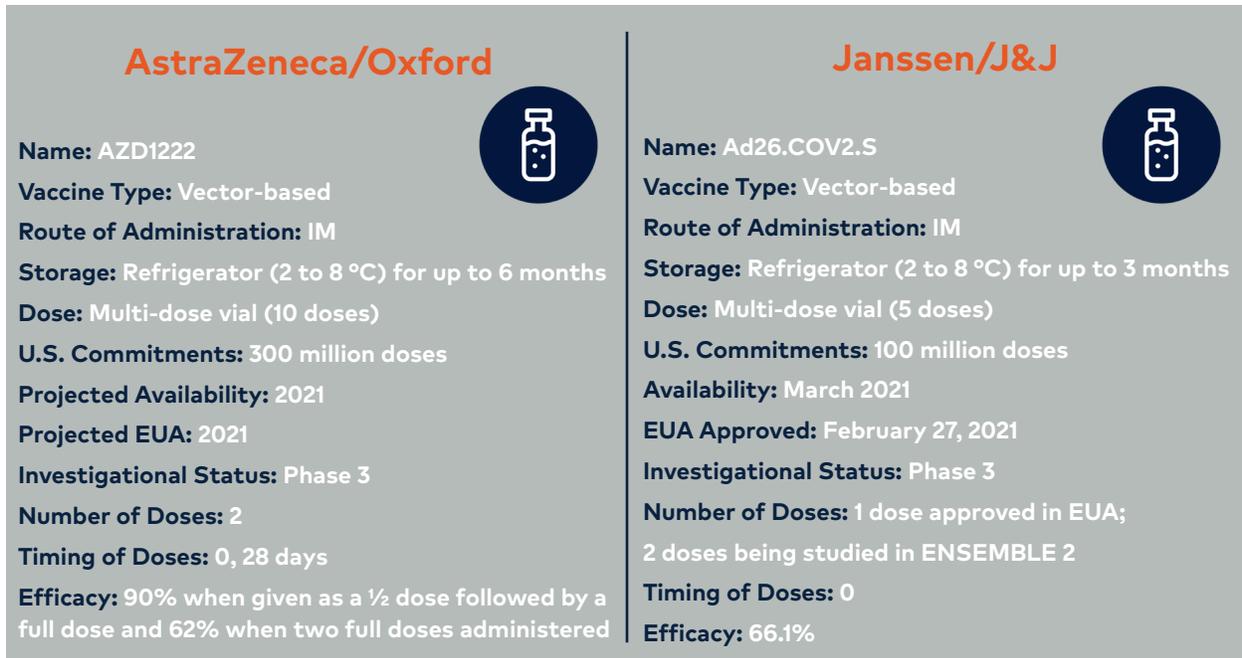


Figure 1. Vector-based COVID-19 Vaccines

combines results of four randomized controlled trials from Brazil, South Africa and two from the UK, reporting an overall efficacy of 70.4% (95.8% CI 54.8, 80.6). A combined total of 11,636 participants were included in the interim primary efficacy analysis. Among these patients, 131 of the 5807 participants (0.5%) in the treatment group and 101 of the 5,829 participants (1.7%) in the placebo group had nucleic acid amplification test (NAAT)-confirmed COVID-19 after 21 days. This vaccine also demonstrated a satisfactory safety profile with no statistically significant difference in serious adverse events between the treatment (n=79) and control (n=89) groups. In the UK phase 1/2 study, there was a case of hemolytic anemia in the control group and a case of transverse myelitis 14 days after the ChAdOx1 nCoV-19 booster in the treatment group. In South Africa, there was a reported serious adverse event in the treatment group with a fever of 40°C, who recovered without hospital admission. The UK Medicines and Healthcare Products Regulatory Agency authorized AstraZeneca/Oxford’s vaccine for emergency supply administered as two full doses four to 12 weeks apart on December 30, 2020.¹⁶

The Janssen Pharmaceuticals of Johnson and Johnson (J&J) adenovirus-based vaccine (Ad26.CoV2.S) demonstrated in its phase 3 trial that a single dose met all primary and second-

ary endpoints at day 14 and day 28. The trial, ENSEMBLE, was a multicenter, international, randomized, double-blind, placebo-controlled trial with 44,325 participants randomized to receive either a single dose of Ad26.CoV2.S or a placebo.¹⁷ This vaccine demonstrated an overall efficacy of 66.1% (95% CI 55, 74.8) in preventing moderate to severe COVID-19. Ad26.CoV2.S was 72% effective against moderate and severe disease at 28 days in the U.S., with 66% and 57% effectiveness in Latin America and South Africa respectively. ENSEMBLE also demonstrated the vaccine had an efficacy of 85.4% (95% CI 54.2, 96.9) against severe/critical COVID-19 disease at 28 days with a reduction in the risk of severe disease and a 100% reduction in hospitalization or death. Janssen/J&J filed for EUA in the U.S. and after approval, distribution began immediately. Janssen/J&J has agreed to provide 20 million doses by the end of March and 100 million doses by the end of June to add to the 300 million doses promised by Pfizer-BioNTech and Moderna by the end of July.³¹⁻³³ Janssen/J&J is currently recruiting for a second clinical trial (ENSEMBLE 2) to evaluate the safety and efficacy of a two-dose vaccine compared to a placebo.³² This will also be a multi-center, international, randomized, double-blind, placebo-controlled trial. Of note, Janssen/J&J has made a statement that there are no intentions for profit to be made off the pandemic for the company.³³ Safety and ef-

ficacy data will continue to be obtained with ongoing trials and required Vaccine Adverse Event Reporting System reports as outlined in the EUA.

Vaccine Hesitancy

Immunity from 70–80% of a region's population has been projected to stop the spread and mutations from COVID-19. A Gallup poll of 4,098 random sampling of adults at the end of January 2021, showed the highest rate of U.S. adults willing to be vaccinated on record at 71%. This is up from a low of 50% in September 2020. This 71% also includes 9% of adults who have already received the vaccine. If this rate of vaccination comes to fruition, it may be possible to reach the lower proposed threshold of herd immunity to stop the spread of COVID-19.³⁴

The public's acceptance to receive COVID-19 vaccines appears to be based on the perceived benefits in which the unknown long-term effects outweigh the immediate impact on daily life and movement to end the pandemic. Interestingly, public and expert perceptions may not align. For example, the public may have expectations that the vaccine provides immunity against the virus, and will also have an immediate impact on their daily life. When people are asked about why they would take the vaccine, 75% responded "to feel safe around other people" and 52% said, "It would allow me to go back to normal activities like work or school."³⁵ Fortunately, based on recommendations from the Centers for Disease Control and Prevention (CDC), after someone is fully vaccinated they may meet without masks in small groups with others who are fully vaccinated.³⁶

Among those hesitant to get the vaccine, safety is often cited as a reason. Similar to efficacy there is a misalignment in the viewpoints of the medical community and the public. All of the FDA EUA approved vaccines have demonstrated safety, but 71% of the public is concerned about the side effects and 57% have concerns regarding the development and approval process.³⁴ As health care providers, one important piece of data from polls shows that health care professionals including doctors, nurses and pharmacists are the most trusted source of vaccine information for the public at 58%, with the CDC at 46% and the pharmaceutical companies lagging behind at 20%.³⁵

The battle against vaccine hesitancy is not over but the likelihood of successful vaccination rates to stop this pandemic is becoming possible. As health care providers, we can support our patients, family, and friends with their questions and assist them in having accurate, scientific information with which to make their decisions.

Resistance and Mutant Strains

Viral resistance is well documented in other infections outside of SARS-CoV-2 and has made response to therapies difficult. The rise of variants specifically among SARS-CoV-2 increases concern due to increased transmissibility, causing more severe disease, evading viral diagnostic tests, reduced effectiveness of therapeutics and the ability to evade natural or vaccine-induced immunity.³⁷ According to the World Health Organization (WHO), variants of interest (VOI) refers to isolates that are phenotypically changed when compared to a reference isolate or genome mutations that lead to amino acid changes associated with established or suspected phenotypic implications. VOIs also have been identified to cause community transmissions with multiple cases or have been detected in multiple countries or otherwise assessed to be a VOI by WHO. WHO also defines variants of concern (VOC) as VOIs that also demonstrate increased transmissibility, detrimental change in COVID-19 epidemiology, increases in virulence or change in clinical disease or presentation, or decreases in effectiveness of public health and social measures, vaccines or therapeutics.³⁸ The CDC similarly defines VOIs as variants with "specific genetic markers that have been associated with changes to receptor binding, reduced neutralization by antibodies generated against previous infection or vaccination, reduced efficacy of treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity" and VOCs as those with "evidence of an increase in transmissibility, more severe disease (increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures." The CDC is additionally following variants of high consequence, which are defined as "having clear evidence that prevention measures or medical countermeasures have

significantly reduced effectiveness relative to previously circulating variants.³⁹ Currently no variants are defined under this category. With the new VOCs arising for SARS-CoV-2, (**Figure 2**) the question of continued effectiveness of available vaccines has been raised. Variants originating from the U.S., UK, South Africa, and Brazil have all been described.⁴⁰ The B.1.1.7 variant (UK origin) 20I/501Y.V1 was first reported in December 2020 and is worrisome due to its increased transmissibility and increased risk of hospitalizations and death. The B.1.351 variant (South Africa origin) 20H/501Y.V2 was first reported in October 2020 and while there is no information regarding disease severity, there is an increased transmissibility and impact on the neutralization of antibodies. The B.1.1.28.1 variant (Brazil/Japan origin) was also first described in October 2020 and this variant may have increased transmissibility and can also affect antibodies. All three of these variants were reported in the U.S. by the end of January 2021.³⁹⁻⁴¹

The U.S. has also begun to report its own variants originating internally. A non-peer-reviewed study detected at least seven home-grown variants in states across the country. There is a common single genetic letter mutation among them; however, they are theorized to have

developed independently.⁴¹ This study suggests that in order for the virus to have increased survival time in human hosts, the strains are converging toward a common variant.⁴¹ Of note, the emergence of a new variant originating from Southern California (B.1.429/7) has also been reported.⁴² This variant has been in circulation since October 2020 as well and contains the S protein L452R mutation, which has previously been found to be resistant to certain spike protein monoclonal antibodies. A potential contributor to the rise in resistance is theorized to be the selective pressure placed by patients receiving convalescent plasma, although previous evidence suggests the contrary.^{43,44} There is also a pressure to immunize globally, including countries with less resources to decrease the rates of rising variants as well. Fortunately, vaccines can be adapted to tackle variants with modifications to better match them if needed. The FDA has authorized EUA addendums rather than full EUA reviews for vaccines currently approved for use under an EUA as long as long as the same procedure is followed.⁴⁵

Of the currently available vaccines, individuals immunized with mRNA COVID-19 vaccines are theorized to neutralize the 501 mutations.⁴⁶ Moderna's mRNA vaccine has not been affect-

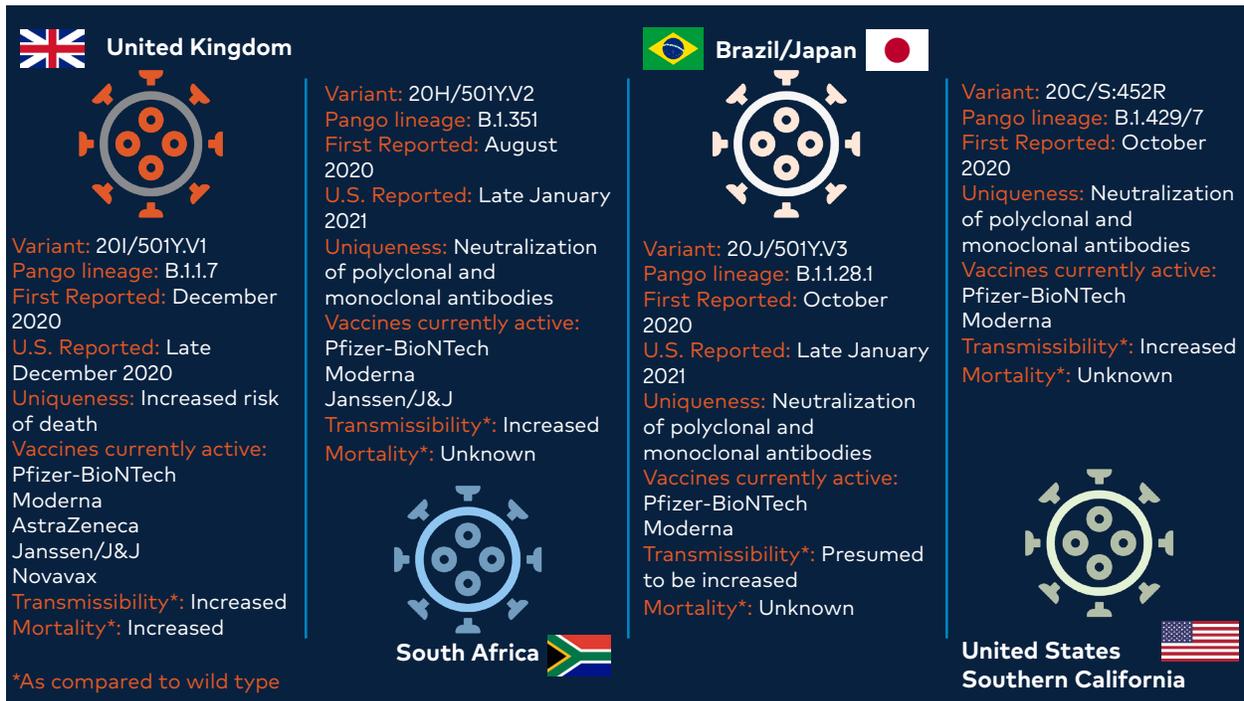


Figure 2. SARS-CoV-2 Variants of Concern

ed by B.1.1.7 variant but has shown a decreased efficacy against B.1.351, B.1.1.28.1 and B.1.429/7 variants.⁴⁷ Pfizer-BioNTech's mRNA vaccine has shown decreased efficacy of B.1.1.7, B.1.351 and B.1.28.1 variants.⁴⁸ Unfortunately, the campaign for the AstraZeneca/Oxford vaccine was suspended in South Africa due to ineffectiveness against the variant (B.1.351) circulating regionally.⁴⁹ This information comes from a small non-peer-reviewed study with 2,000 participants averaging 31 years old that demonstrated only 22% efficacy in South Africa. The Janssen/J&J vaccine has maintained a higher level of efficacy at about 85% protection against severe disease for the South African population.

Multiple strategies to combat variants have been implemented recently. The FDA has authorized vaccines that have previously received EUA approval to modify their COVID-19 vaccines to target variants without seeking a separate EUA. This process would allow for an amendment to the original EUA as long as the vaccine is made by the same manufacturer and process as the previously authorized COVID-19 vaccine.⁴⁵ Pfizer-BioNTech, Moderna and Johnson & Johnson have all developed their own strategies in the new battle against variants. Moderna has focused on updating its formula to include multivalent vaccines to target variants, while Pfizer-BioNTech has started their research with booster vaccines. Johnson & Johnson has focused on modifying their vaccines to target mutations, which could be a faster process for vector-based vaccines than mRNA-based vaccines.⁵⁰

Safety

While there are many strengths and weaknesses of different types of vaccines, it is important to note the safety and reactogenicity profiles of the EUA vaccines are similar. In all three U.S. approved COVID-19 vaccines, the rates of serious adverse events were similar in the treatment and placebo groups. For Pfizer-BioNTech, the overall incidence of any severe systemic event was 0.6%.⁹ Mild to moderate injection site pain experienced seven days after each injection for participants >55 years was 71% after dose 1 and 66% after dose 2. For participants 16 to 55 years old, the incidence was 83% after dose 1 and 78% after dose 2.¹³ Local reactions were mild to moderate and resolved within one to two days. With Moderna, the incidence

of any severe systemic event was 0.6%.⁵¹ Mild to moderate injection site pain experienced seven days after each injection for participants ≥65 years was 74% after dose 1 and 83% after dose 2. For participants 18 to 64 years old, the incidence was 87% after dose 1 and 90% after dose 2.¹⁰ In comparison, Janssen/J&J, the only U.S. approved vector vaccine, had a 0.4% incidence of serious adverse events. Participants experiencing mild to moderate injection site pain seven days after the injection was 33.3% for participants ≥60 years and 58.6% for participants aged 18-59 years.¹⁷ Although vaccine adverse event reporting is required in accordance with each EUA and routine monitoring of this data has been implemented, little has been reported to the public about this surveillance.^{52,53} On April 13, 2021 the CDC and FDA recommended a pause on administration of the Janssen/J&J vaccine and issued a Health Alert Network (HAN) alert to explain the safety concerns. The alert cited cases of cerebral venous sinus thrombosis (CVST) with thrombocytopenia after receipt of the Janssen/J&J vaccine. As of April 12, 2021, there were 6.86 million doses administered and six reports of CVST with thrombocytopenia following vaccination with Janssen/J&J product. Of these six cases the median age was 33 years, there was a median of 8 days for time to symptom onset and all cases occurred in White females with no coagulation disorders or obvious patterns of risk factors.⁵⁴ The Janssen/J&J vaccine pause was ended on April 23, 2021 upon completion of the safety review by the FDA and CDC that revealed only 15 cases of severe blood clots and low platelets of the 8 million vaccines administered.⁵⁵

Data from the Vaccine Adverse Event Reporting System (VAERS) has been reported for Pfizer-BioNTech and Moderna through February 16, 2021, when just over 55 million COVID-19 vaccines had been administered in the U.S. For the Pfizer-BioNTech vaccine, 48,196 reports were submitted, with 9% deemed to be a serious adverse event. The most common reported adverse events were headache (20%), fatigue (15.5%) and dizziness (14.3%). For Moderna, 56,567 reports have been filed on behalf of recipients with 3% coded as serious adverse events. The most common adverse events were headache (23.4%), pyrexia (18.9%) and chills (18.3%).⁵³ According to a recent

JAMA publication, Pfizer-BioNTech anaphylaxis reporting rate is 4.7 cases per million doses administered, and Moderna anaphylaxis reporting rate is 2.5 cases per million doses administered.⁵⁶ As of February 16, 2021, most reports to VAERS among pregnant women involved non-pregnancy specific adverse events (73%). Miscarriage was the most frequently reported pregnancy specific adverse event (15%), but is comparable to the expected background rate of the general population (26%).

It is important to know that the CDC's after vaccination health checker, V-safe, has enrolled participants who report pregnancy following COVID-19 vaccination are actively contacted to enroll in the pregnancy registry.⁵³ If enrolled, participants are contacted once per trimester, after delivery and when the infant is three months old to ask about outcomes of interest (pregnancy complications, adverse birth outcomes, neonatal death, etc.). As of February 19, 2021, there were 1,815 participants enrolled.⁵⁷

Equity

There are concerns with ensuring equitable access to a COVID-19 vaccine for populations at a disproportionate risk of COVID-19 morbidity and mortality. A national survey that collected data from January 6 to January 18, 2021, aimed to assess data from 67,000 respondents and found that Black non-Hispanic persons were 52% less likely to report vaccine initiation or planned vaccination. However, when controlling for factors (demographic and socioeconomic) Hispanics and Black non-Hispanics were no more or less likely than White non-Hispanics to have received ≥ 1 dose of a COVID-19 vaccine.⁵⁸ Ensuring equity in COVID-19 vaccination allocation and distribution has not been forgotten and is considered in allocation planning. The Health Resources and Services Administration (HRSA) and the CDC launched a program early February to help alleviate potential disparities.⁵⁹ A limited supply of COVID-19 vaccine was allocated to select HRSA-funded health centers. This allocation is separate from those jurisdictions' weekly allotment. The health centers were chosen based on their volume of serving one of the following disproportionately affected populations: public housing residents, migrant/seasonal agricultural workers, patients with limited English proficiency or individuals experiencing homelessness. HRSA anticipates

that approximately one million doses will be allocated to the program's initial phase.⁵⁹ This is a step in the right direction as federally qualified health centers serve nearly 30 million patients each year.⁵⁸ Vaccinating this population poses a unique challenge with a two dose vaccination series and the Janssen/J&J single dose vaccination EUA approval may improve access for millions of Americans.

Conclusion

There are many moving targets to end this global pandemic including vaccine availability, vaccine safety and effectiveness, public opinion on vaccines, other effective therapeutic treatment options and the rise of variants. However, one thing is certain, the healthcare community is working diligently to vaccinate, educate and provide effective care to all individuals.

Conflicts of Interest

The authors declare they have no conflicts of interest.

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