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Clinical Review

Covid-19: Race For A Vaccine

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Abstract

Description

The world is in the midst of a pandemic from COVID-19, a disease caused by the virus SARS-CoV-2. Despite broad mitigation efforts, new cases continue with 74 million cases and 1.6 million deaths worldwide. Regardless of previous research efforts, there is no commercially available vaccine for any coronavirus. Novel vaccine development has historically taken at least 10 years from discovery to availability with only a 6% market entry probability.

With the global impact, there is an urgency to expedite a vaccine to protect the population. The U.S. government launched Operation Warp Speed with the goal to produce and deliver 300 million doses of safe and effective vaccines by January 2021. Efforts toward this goal have included coordinated government agency support, parallel clinical trial deployment, de-risking manufacturing earlier in the development process and real-time U.S. Food & Drug Administration evaluation of the safety and efficacy data. Safety is a priority and key analysis has not been eliminated during the compressed timeframe. The two frontrunner candidates show promising efficacy rates for preventing COVID-19 with Moderna reporting 94.1% efficacy and Pfizer reporting 95.0% efficacy.

Despite the herculean efforts by scientists to develop an effective vaccine in such a short timeframe, several national surveys suggest that public confidence in these vaccines is low with less than 50% of the survey respondents willing to be vaccinated. According to experts, the U.S. needs the vaccine to be at least 70–80% effective and a 70–80% vaccination rate in order to return to normal. Significant education and promotion is planned in coordination with the Centers for Disease Control.

Keywords

SARS-CoV-2; COVID-19; coronavirus infection; viral vaccines/adverse effects; COVID-19 vaccines; vaccines; messenger RNA; pandemic; epidemic; immunization; patient safety

Background

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first reported in late 2019 in Wuhan, China. The virus SARS-CoV-2 was quickly deemed to be the origin of the upper respiratory infection now called coronavirus disease 2019 (COVID-19). Since then, the virus has caused a global pandemic; as of December 28, 2020, there have been a reported 81 million cases and 1.8 million deaths worldwide.[1] Broad infection mitigation efforts have been implemented including stay at home orders, mandatory masking, capacity limitations, expansion of laboratory testing and emergency use authorization (EUA) of novel therapeutic treatments for COVID-19. Many of these mitigation efforts have had broad societal impacts and have disrupted the lives of billions. Through this, the public remains hopeful that a vaccine protecting against SARS-CoV-2 will allow a "return to normal" and an end to the COVID-19 pandemic.

Coronavirus vaccines have been studied within clinical trials but until recently had not been available for widespread use. Development of a vaccine for the 2003 SARS-CoV virus epidemic was started and eventually stalled as the disease was tempered by traditional methods. COVID-19 shows no sign of remediation without the development of a highly effective

vaccine. Scientists around the world are competing in a race to produce, test and release coronavirus vaccines to combat an already year-long pandemic. Novel vaccines have historically taken upwards of 10 years from discovery to availability and have a successful development rate of only 6%.[2] To accelerate the lengthy development and approval process (**Figure 1**), the United States (U.S.) government launched Operation Warp Speed (OWS). This initiative, which is overseen by the Department Health and Human Services and the Department of Defense, has the goal to "deliver 300 million doses of safe and effective vaccines with the initial doses available by January 2021."[3] OWS has coordinated government agency support, parallel clinical trial development, preemptive manufacturing of vaccines and real-time FDA evaluation of safety and efficacy data. Vaccine safety has been a priority of OWS, and key analyses of safety data have not been eliminated nor bypassed during the compressed vaccine development timeline.[3]

Vaccine Approval Status

There are currently 61 COVID-19 vaccines globally that are in some stage of human clinical trials, with at least an additional 85 in preclinical investigation.[4] In the U.S., there have been two EUA-approved vaccines, Pfizer-BioNTech and Moderna.[5,6] Two other vaccine candidates (AstraZeneca and Janssen) are currently in Phase 3 clinical trials and could submit for EUA in spring 2021. The two leading vaccines, the Pfizer COVID-19 Vaccine and the Moderna COVID-19 Vaccine, which have both received EUA, are based on messenger RNA (mRNA) technology. The vaccine candidates in development by AstraZeneca and Janssen are vector-based vaccines. Please refer to **Table 1** for comparison of the COVID-19 vaccine frontrunners.

At the time of this writing, Phase 3 data has been announced for Pfizer, Moderna and AstraZeneca. Pfizer's vaccine was approved for use in the United Kingdom on December 2, 2020, received EUA in the U.S. from the FDA on December 11, 2020 and approved by the European Medicines Agency for the European Union on December 21, 2020.[5,14,15] The Moderna vaccine received EUA from the FDA on December 18, 2020.[6] Both vaccines are currently being distributed via allocations to states.

mRNA Technology

Currently approved viral vaccines (i.e., influenza vaccines) use either weakened viruses or viral particles to generate an immune response, antibody production and ultimately immunity against the targeted virus. The Pfizer and

Table 1. Comparison of COVID-19 Vaccine Frontrunners[4-13]

	Pfizer/BioNTech	Moderna	AstraZeneca	Janssen
Name of vaccine	Pfizer-BioNTech COVID-19 Vaccine BNT162b	Moderna COVID-19 Vaccine mRNA-1273	AZD1222	Ad26.COV2.S
Type of vaccine	mRNA	mRNA	Vector-based	Vector-based
Route of administration	IM	IM	IM	IM
Number of doses	2 doses 21 days apart	2 doses 28 days apart	2 doses 28 days apart	1 dose (potentially 2 doses)
Storage requirements*	-70° C	-20° C	2° to 8° C	2° to 8° C
U.S. commitments	100 million doses	200 million doses	300 million doses	100 million doses
Projected availability	December 15, 2020	December 21, 2020	Early/mid 2021	2021
Projected/actual emergency use authorization (EUA)	December 11, 2020	December 18, 2020	Early 2021	Early/Mid 2021

*Only long-term (up to 6 months) storage requirements shown

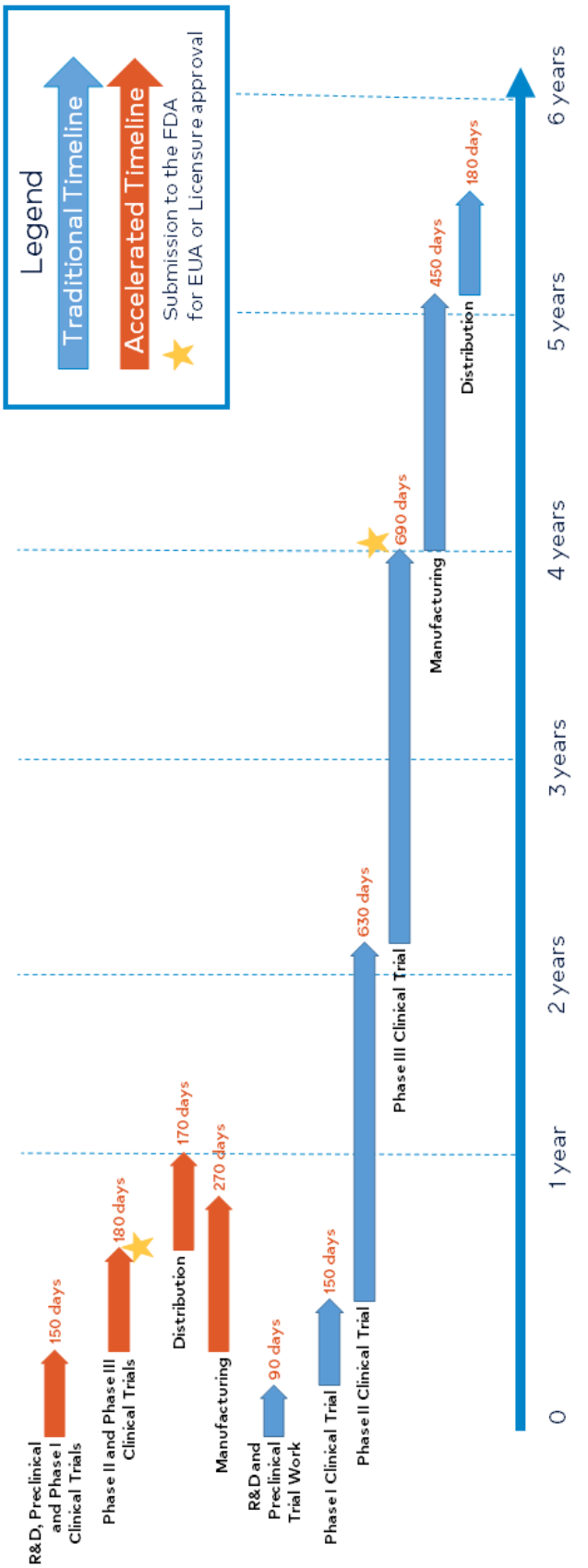

Figure 1. Traditional vs. Accelerated Vaccine Development Timeline for COVID-19. Adapted from Operation Warp Speed Accelerated Process.[3]

Table 2. Historical Vaccine Efficacy[20-29]

Disease	Efficacy*
Tetanus	100%
Polio	99-100%
Diphtheria	97%
Measles	97%
Rubella	97%
Shingles	91-97%
COVID-19	**94-95%**
Anthrax	93%
Chickenpox	92%
Mumps	88%
Pertussis	34-98%†
Influenza	19-60%‡

* The efficacy of non-COVID-19 vaccines reported as efficacy (determined by a study with ideal conditions, e.g. a clinical trial) or effectiveness (determined by a study with typical/real-world conditions) as reported by the CDC29

† Efficacy is high within the first year of vaccination but decreases by 4-5 years

‡ Based on influenza vaccines from 2010-11 to 2018-19 seasons

Moderna COVID-19 vaccines utilize a synthetic mRNA technology. Unlike DNA, which carries genetic information for every cell in the human body, mRNA directs the body's protein production. The mRNA vaccines take advantage of this protein production process by providing instructions to the recipient's cells to make a harmless spike protein that is found on the surface of SARS-CoV-2. This spike protein is unique to COVID-19 and part of a full protein and will not cause harm to the patient who is vaccinated. The resulting spike protein is antigenic and will lead to activation of the immune system to produce antibodies and fight off what it thinks is an infection.[16] There are currently no FDA-approved mRNA vaccines in the U.S., but the concept has been studied for decades. mRNA technology has the advantage of a faster development process than traditional vaccines, as the development process does not require growing weakened virus in lab cultures.[16] This is reflected in the current mRNA vaccine candidates, Pfizer and Moderna, which were the first to gather sufficient data from Phase 3 trials to submit to the FDA for EUA approval.

Findings

Vaccine Trial Efficacy

The FDA and World Health Organization (WHO) have both set minimum thresholds for COVID-19 vaccine efficacy at 50%, with WHO preferring at least 70% efficacy.[17,18] According to experts, a vaccine with at least 70–80% efficacy and 70–80% vaccination uptake is needed to end the ongoing COVID-19 pandemic (reduce the peak by >99% in a population/region) and end the need for counter measures such as social distancing.[19] COVID-19 vaccines from Pfizer and Moderna have shown efficacy rates of 95.0% (95% confidence interval [CI] 90.0, 97.9) and 94.1% (95% CI 89.3, 96.8), respectively.[20,21] Refer to **Table 2** for how these new vaccines compare to vaccines for various other vaccine-preventable diseases. An interim analysis for AstraZeneca's vaccine candidate found an efficacy of 90.0% (95% CI 67.4, 97.0) when the vaccine was given as a half dose followed by a full dose and 62.1% (95% CI 41.0, 75.7) when 2 full doses were given. However, given the unexpected results, additional analysis is needed to further elucidate its efficacy.[30]

Table 3. Interim Phase 3 Clinical Trial Results[21,31]

	Pfizer-BioNTech COVID-19 Vaccine[41]	Moderna COVID-19 Vaccine[21]
Study began	July 2020	July 2020
Enrollment	>43,000 participants	>30,000 participants
Participant demographics	Age ≥65 years: 21% Hispanic/Latinx: 28% African: 9% Asian: 4%	Age ≥65 years: 25% Hispanic/Latinx: 21% African: 10% Asian: 5%
Efficacy rate	95.0% (95% CI 90.0, 97.9)	94.1% (95% CI 89.3, 96.8)
COVID-19 cases	Total: 170 Vaccinated group: 8 Placebo group: 162	Total: 196 Vaccinated group: 11 Placebo group: 185
Severe COVID-19 cases	Total: 10 Vaccinated group: 1 Placebo group: 9	Total: 30 Vaccinated group: 0 Placebo group: 30
COVID-19-related deaths	Total: 0 Vaccinated group: 0 Placebo group: 0	Total: 1 Vaccinated group: 0 Placebo group: 1

CI = confidence interval

Pfizer and Moderna's COVID-19 vaccine efficacy rates are based on data from their respective Phase 3 trials. Details of these two trials and the efficacy outcomes are listed in **Table 3**. Both trials consisted of over 30,000 participants and included patient populations with diverse backgrounds.[20,21,31] The primary efficacy endpoint was calculated from the proportion of laboratory-confirmed, symptomatic COVID-19 cases in vaccinated participants versus participants who received placebo.[20,21,31,32] In the Pfizer study, laboratory-confirmed, symptomatic COVID-19 occurred in 8 participants in the vaccinated group and in 162 participants in the placebo group.[20] In the Moderna study, the same endpoint occurred in 11 participants in the vaccinated group and in 185 participants in the placebo group.[21] The vaccines also showed efficacy in preventing severe COVID-19 (e.g., severe illness per the National Institutes of Health [NIH] definition, or respiratory failure, or evidence of shock or significant acute renal, hepatic or neurologic dysfunction, or admission to an intensive care unit [ICU], or death).[20,21,31] One participant in the vaccinated group and nine participants in the placebo group experienced severe COVID-19 in the Pfizer study, and zero participants in the vaccinated group and 30 participants in the placebo group experienced severe COVID-19 in the Moderna study. Both Pfizer and Moderna reported that their efficacy was consistent across age, gender, race, and ethnicity demographics with Pfizer and Moderna reporting 94.7% (95% CI 66.7, 99.9) and 86.4% (95% CI 61.4, 95.5) efficacy, respectively, in those age 65 years and older.[21,31]

While efficacy rates for the COVID-19 vaccines from Pfizer and Moderna are high, it is important to understand the caveats of this data. Due to the known fact that vaccines are not effective immediately, Pfizer's study began measuring the primary efficacy endpoint 7 days after the second dose.[21,31] Moderna's study began measuring efficacy 14 days after the second dose.[21] As a result, recipients may not be fully protected until at least 7 or 14 days after their second dose for the Pfizer and Moderna vaccines, respectively. It will be important to educate recipients that infections occurring after vaccination but prior to these time points are due to virus exposure prior to when adequate immunity was acquired. Furthermore, Phase 1 studies showed significantly lower immune responses after only one dose compared to 2 doses, and Pfizer's Phase 3 study found an efficacy rate of 52.4% (95% CI 29.5, 68.4) during the time period after the first dose but before the second dose. This suggests efficacy is likely much lower after only 1 dose of vaccine.[20,33,34]

Recipients should be educated on the necessity of the second dose for adequate protection.

Timing of the 2 doses can also affect vaccine efficacy. Generally, a vaccine with multiple doses administered too close together does not generate an optimal immune response.[35] The Centers for Disease Control and Prevention (CDC) recommends a "grace period" of ≤4 days from the recommended date for the second dose (day 21 for the Pfizer vaccine and day 28 for the Moderna vaccine). However, it is not currently recommended that an earlier second dose be repeated. Additionally, a delayed second dose does not warrant restarting the series, but it does increase the interval of time in which a patient does not have full protection.[36]

Further research is needed to determine the duration of COVID-19 vaccine efficacy and if vaccination will need to be repeated or require a booster. For example, the influenza vaccine requires annual revaccination. The duration of natural immunity to COVID-19 is still unknown, but reinfection is possible. Thus, those with prior COVID-19 infection can benefit from vaccination. Finally, it is imperative to understand that the Pfizer and Moderna vaccines were evaluated on their ability to prevent symptomatic COVID-19, not asymptomatic infection or transmission. Therefore, it is currently unknown whether the vaccines prevent asymptomatic infection or transmission. It is recommended that vaccinated individuals will need to continue using other preventive measures including masking and social distancing, especially if vaccination uptake is suboptimal and cases remain high.[37,38]

Efficacy continues to be evaluated even after two COVID-19 vaccines have gained EUA. Clinical trials will continue to gather data. Additionally, the CDC intends to coordinate with other government agencies and to leverage existing systems (such as the Emerging Infections Program, the COVID-2019-Associated Hospitalization Surveillance Network [COVID-NET], and systems used to estimate influenza vaccine effectiveness) to monitor COVID-19 vaccine effectiveness in the general population.[39]

Vaccine Confidence

Vaccine confidence will play a pivotal role in the U.S.'s ability to fight the COVID-19 pandemic. Research published this summer showed that the vaccine efficacy rate would need to be at least 70% with a vaccination rate of 75% to prevent an epidemic and at least 80% efficacy with 75% coverage to extinguish the ongoing pandemic.[19] Vaccination rates of at least 75% are likely too lofty of assumptions based on recent surveys that show between 45–67% vaccination rates are expected.[40,41] This research also showed that if vaccination rates drop to 50% and ≥5% of the population has been exposed, it is no longer possible to extinguish an ongoing epidemic, even when vaccine efficacy is 100%.[19] This further highlights the critical need to improve COVID-19 vaccine confidence in the U.S.

Understanding the population differences in vaccine confidence will be important to vaccine providers and educators as well. Surveys have found clear differences in vaccine confidence in categories such as age, gender, political preference, education level, race/ethnicity and regions of the country. The populations identified in these surveys that were less likely to be vaccinated were middle age (45–64 years), females, political status designated as Independent or Republican, no college degree, African American and from the South and Midwest U.S. regions. The populations that consistently have been the most willing to receive the vaccine are elderly (≥65 years), males, college educated, Democrat, Asian and from the Northeast and Western U.S. regions.[40,41] (**Table 4**)

The most commonly reported reason for hesitancy was the speed with which these vaccines were produced and approved, concerns about side effects, the need for more information on efficacy, unclear need to be vaccinated and the cost of the vaccine.[40,41] The rate of vaccine confidence has fallen over time based on many surveys that have taken measurements during multiple periods. These surveys highlight the need to address these concerns as early as possible and through multiple communication channels. The CDC has created a new "Vaccinate with Confidence" strategy that will be a targeted campaign to focus on the concerns outlined above.[42] Tactics include reinforcing trust, empowering health care providers and engaging communities and individuals to increase collaboration.

Table 4. COVID-19 Vaccines: Local and Systemic Adverse Reactions from Solicited Data Within 7 Days After Each Dose[21,31]

		Pfizer-BioNTech COVID-19 Vaccine		Moderna COVID-19 Vaccine	
		Solicited Dose 1 % (n/total population)	Solicited Dose 2 % (n/total population)	Solicited Dose 1 % (n/total population)	Solicited Dose 2 % (n/total population)
Local Reactions					
Redness	Age 18-64 years*	4.5% (104/2,291)	5.9% (123/2,098)	3.0% (344/11,406)	8.9% (982/10,985)
	Age ≥ 65 years†	4.7% (85/1,802)	7.2% (120/1,660)	2.3% (86/3,762)	7.5% (275/3,692)
Swelling	Age 18-64 years*	5.8% (132/2,291)	6.3% (132/2,098)	6.7% (767/11,406)	12.6% (1,389/10,985)
	Age ≥ 65 years†	6.5% (118/1,802)	7.5% (124/1,660)	4.4% (165/3,762)	10.8% (400/3,692)
Pain at the Injection Site	Age 18-64 years*	83.1% (1,904/2,291)	77.8% (1,632/2,098)	86.9% (9,908/11,406)	89.9% (9,873/10,985)
	Age ≥ 65 years†	71.1% (1,282/1,802)	66.1% (1,098/1,660)	74.0% (2,782/3,762)	83.2% (3,070/3,692)
Systemic Reactions					
Fever	Age 18-64 years*	3.7% (85/2,291)	15.8% (331/2,098)	0.9% (105/11,406)	17.4% (1,908/10,985)
	Age ≥ 65 years†	1.4% (26/1,802)	10.9% (181/1,660)	0.3% (10/3,762)	10.0% (370/3,692)
Fatigue	Age 18-64 years*	47.4% (1,085/2,291)	59.4% (1,247/2,098)	38.4% (4,384/11,406)	67.6% (7,430/10,985)
	Age ≥ 65 years†	34.1% (615/1,802)	50.5% (839/1,660)	33.3% (1,251/3,762)	58.3% (2,152/3,692)
Headache	Age 18-64 years*	41.9% (959/2,291)	51.7% 1,085/2,098)	35.3% (4,030/11,406)	62.8% (6,898/10,985)
	Age ≥ 65 years†	25.2% (454/1,802)	39.0% (647/1,660)	24.5% (921/3,762)	46.2% (1,704/3,692)
New or Worsened Muscle Pain	Age 18-64 years*	21.3% (487/2,291)	37.3% (783/2,098)	23.7% (2,699/11,406)	61.6% (6,769/10,985)
	Age ≥ 65 years†	13.9% (251/1,802)	28.7% (477/1,660)	19.7% (742/3,762)	47.1% (1,739/3,692)

Solicited: reactions were collected in an electronic diary from day 1 to day 7 after vaccination

*For Pfizer-BioNTech ages assessed were 18-55 and 8 participants were between the ages of 16 and 17 years of age

†For Pfizer-BioNTech ages assessed with ≥ 56 years of age

Speed of Approval and Production

Prior to the first EUA for the COVID-19 vaccines which occurred in under 10 months, the fastest approval for a vaccine was the mumps vaccine (Mumpsvax®), developed in 4 years by Merck Pharmaceuticals in the 1960s.[43] Both of these vaccines had several years of research done ahead of time that helped hasten their development. The mumps vaccine utilized research identified in the 1940s and 50s such as the use of embryonic chicken eggs and inactivated vaccine technology that use dead virus particles.[43] The COVID-19 vaccine is utilizing information from a decade of coronavirus research and past vaccine development efforts for Ebola and Middle East Respiratory Syndrome (MERS). The two leading candidates for FDA approval are also utilizing mRNA technology, which has been researched and studied for years prior to becoming the backbone of the COVID-19 vaccines for Pfizer and Moderna.

Table 5. Characteristics of Populations Likely To Be Vaccinated[40-41]

Populations Less Likely to be Vaccinated	Populations Most Likely to be Vaccinated
• Age 45–64 years • Female • Political status designated as Independent or Republican • No college degree • African American • Living in regions of South and Midwest U.S.	• Age ≥65 years • Male • Political status designated as Democrat • College educated • Asian • Living in regions of Northeast and Western U.S.

Evaluating Adverse Events

Adverse events for the Pfizer and Moderna COVID vaccines have been evaluated and included in the published EUA Vaccine Fact Sheets for Health care Providers.[44,45] Patients for both trials were monitored from day 1 to day 7 after each vaccine dose, and solicited events were documented via an electronic diary. (**Table 5**) Unsolicited adverse events were monitored for at least 28 days after each dose, and follow-up is ongoing. Patients were evaluated for specific local and systemic adverse events. More vaccine participants than placebo participants reported any adverse event or a related adverse event. In general, reactogenicity, or the inflammatory response to vaccination, was generally mild or moderate, and most systemic reactions were less common and milder in older adults than in younger adults. Systemic reactogenicity was more common and severe after the second dose than after the first dose. Local reactogenicity was similar after the two doses. For the Pfizer vaccine, a total of 6 patients of the 43,448 enrolled died during the reporting period.[31] Two vaccine recipients died (1 from arteriosclerosis, 1 from cardiac arrest), and 4 placebo recipients died (2 from unknown causes, 1 from hemorrhagic stroke and 1 from myocardial infarction). The investigators concluded these deaths were not related to the vaccine or placebo.[31] For the Moderna vaccine, a total of 13 patients of 30,351 enrolled died during the reporting period. Six vaccine recipients died (1 from cardiac arrest, 1 after myocardial infarction, 1 from multiorgan failure, 1 by suicide and 2 from unknown causes 37 and 57 days after the vaccine dose).[21] The investigators concluded these deaths were not related to the vaccine.

In regards to non-solicited adverse events, those that are likely related to both the Moderna and Pfizer vaccine include lymphadenopathy. The Moderna vaccine group had 3 cases of Bell's palsy and Pfizer had 4 cases in the vaccine group. The rate of reported Bell's palsy in the vaccine groups is consistent with the rate in the general population, and there is no basis to conclude a causal relationship. However, the FDA is recommending surveillance for cases of Bell's palsy for the vaccines.[21,31]

The most common non-fatal serious adverse events for Pfizer group were appendicitis (0.04%), acute myocardial infarction (0.02%) and cerebrovascular accident (0.02%).[44] The most common non-fatal serious adverse events for the Moderna vaccine was 2 cases of facial swelling in vaccine candidates with a history of dermatological fillers. It has been determined that the swelling is likely related to the vaccine.[45]

Severe anaphylaxis has been reported with the Pfizer COVID-19 Vaccine since its release for the first phase of vaccinations in the UK and U.S.[46-48] The CDC has recommended that patients with a history of anaphylaxis due to any cause be monitored for thirty minutes after vaccine injection.[48] Appropriate medical treatment for severe allergic reactions must be immediately available in the vaccine clinic in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.[48]

Special Patient Populations

Special populations often include subsets of the population where clinical trials are difficult to administer or where there are too few recipients in the subset to make recommendations. CDC guidance (**Table 6**) has been issued on the Pfizer COVID-19 Vaccine for special populations and is subject to change as new information

Table 6. Considerations for Special Patient Populations[36]

Special Population	CDC Recommendation
Current History of SARS-CoV-2 Infection	Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness and has met CDC criteria to discontinue isolation. Consider waiting up to 90 days post infection.
Prior History of SARS-CoV-2 Infection	Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Consider waiting up to 90 days post infection.
Previous Passive Antibody Therapy for COVID-19	Vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, and to avoid interference of the antibody treatment.
Underlying Medical Conditions	Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination.
Immunocompromised Persons	Data are not currently available to establish safety and efficacy. May still receive COVID-19 vaccination but the person should be counseled about the unknown safety and efficacy and potential for reduced immune response.
Pregnant Persons	No available data on safety of COVID-19 vaccines in pregnant persons. Experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant. Pregnant persons may choose to be vaccinated but should consult with their healthcare providers to weigh the risks and benefits.
Lactating Persons	No data on the safety of COVID-19 vaccines in lactating people. mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person may choose to be vaccinated and should consult with their healthcare provider to weigh the risks and benefits.
Adolescents (Age 16–17)	Vaccine safety and efficacy data in this group are limited to 153 participants. No safety concerns were identified and no biologically plausible reasons identified to differentiate them from persons 18 years of age and older. With appropriate assent, adolescents aged 16-17 may receive the vaccine.

becomes available. The overarching theme of the recommendations are that the benefit of protection against SARS-CoV-2 infection outweighs the risk of the vaccine data limitations.

Cost and Access

One of the core principles of OWS is to bring the vaccine to market as rapidly as possible while ensuring that any vaccine developed using U.S. tax dollar funded programs will be supplied free of charge to the population. HHS has worked with the Centers for Medicare and Medicaid Services, as well as private insurers, to ensure that patients will have access to COVID-19 vaccines with no out-of-pocket costs. This allows vaccine access to all U.S. citizens and removes insurance and affordability concerns.[49]

Conclusion

The world is ready to return to some level of normalcy and remedy the burden of this pandemic on human lives, social capital and financial resiliency. However, the commitment of community and individual accountability is paramount. We are all part of the solution. COVID-19 vaccines are a critical part of the strategy to ending the perils of this pandemic. The efficacy and safety data for the vaccines is slowly entering into the public sector for our review and scrutiny. Each person will need to weigh the risk and benefit of the vaccine with local health care professionals for their own health and future. Being aware of the science and safety of the vaccines will help local health care providers with the conversations and recommendations for their patients. There is

still much work to be done, but the race for the vaccine has produced two EUA approved vaccines giving hope for a solution.

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Conflicts of Interest

The authors declare they have no conflicts of interest.

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