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EMERGING THERAPEUTICS

Coronavirus Disease 2019 (COVID-19)
Searching for Safe and Effective Vaccines

Updated May 13, 2021

Summary

Controlling the spread of Coronavirus 19 (SARS-CoV-2, COVID-19) through direct or indirect immunity will be important for society to mitigate the global pandemic, which was declared by the World Health Organization (WHO) on March 11, 2020. Vaccines offer indirect protection by working with your body to imitate disease and produce natural immunity. While over 100 vaccines are currently in development, none of them have been approved by the U.S. Food and Drug Administration (FDA). On December 11, 2020, the FDA granted Emergency Use Authorization (EUA) for Pfizer/BioNTech COVID-19 Vaccine. On December 18, 2020, the second vaccine from Moderna was given EUA. Janssen's COVID-19 vaccine was the third authorized on February 27, 2021. As development of therapies for COVID-19 is rapidly evolving, we will update this document to include significant new information as it arises.

Highlights

- Coronavirus disease 2019 (COVID-19) is an infection from a new strain of coronavirus that has been associated with respiratory symptoms, including progression to acute respiratory distress syndrome (ARDS) and death in some patients.
- Currently, three vaccines are approved under Emergency Use Authorization (EUA).
- More than 100 vaccines are in early clinical development with several options in late stage clinical trials.
- Experimental use of vaccines deemed safe and effective are being be rolled out to high-risk groups, such as healthcare workers and residents of long term care facilities.
- Widespread commercial availability of a vaccine is still likely a few months away. Typically, a vaccine takes 10 years to develop. However, the COVID-19 pandemic is challenging the science, scale and speed at which traditional vaccines are being developed.
- As development of therapies is rapidly evolving, we will update this document frequently to provide the latest available information on potential vaccines for COVID-19.

Vaccines

Vaccines are important to prevent infection and limit the spread of dangerous diseases. Immunity to a contagious disease often is achieved after successfully overcoming an infectious pathogen and developing T-lymphocytes or "memory cells" against it. Whenever that specific pathogen is encountered again, T-lymphocytes recognize it and activate B-lymphocytes to produce antibodies that prevent the disease from reoccurring. By introducing small amounts of the pathogen's proteins, vaccines generate an immune response without causing disease or infection. When a high percentage of the population develops immunity to a pathogen, either through recovering from infection, being vaccinated or a combination of both, the infection is less likely to spread from person to person. The resulting "community" or "herd immunity" is central to protect vulnerable patients, such as those who are immunocompromised, infants and the aging population.

FDA and Government Actions

To help expedite the availability of therapies for COVID-19, the FDA has loosened the process for vaccines to enter the market. An Emergency Use Application (EUA) can be issued to permit the use, based on scientific data, of medical products that may be effective for the diagnosis, treatment or prevention of a disease or condition when the U.S. Department of Health and Human Services (HHS) determines that a public health emergency has a significant potential to affect national security or the health and security of U.S. citizens. Recently, HHS issued a

EUA to increase the availability of additional diagnostic tests for the SARS-CoV-2 virus, and the production of ventilators.

Vaccines in Development

Several vaccines are in late-phase development to protect against COVID-19. Data will be collected over at least six months to determine if the vaccines are both safe and effective for preventing infection with SARS-CoV-2. FDA will accelerate development for the more promising vaccines through its approval process. However, while the first vaccine is not expected to be commercially available for several months, experimental use products that show promise of being safe and effective could be rolled out to high-risk groups, such as healthcare professionals, as early as December of 2020. For comparison, typical vaccine development can take 10 years as the product advances from the lab, through animal testing and finally into the multiple stages of human clinical trials that support the safety and efficacy of the vaccine. The COVID-19 pandemic is challenging the science, scale and speed at which the vaccines are being developed. Table 1 includes examples of vaccines currently in development for COVID-19.

Investigational COVID-19 Vaccines

Vaccine	Manufacturer	Route	Status
mRNA-1273	Moderna	Intramuscular (two doses)	Phase 3*
BNT-162	Pfizer/BioNTech	Intramuscular (two doses)	Phase 2/3*
Ad26.COV2.S	Janssen	Intramuscular (one dose)	Phase 3*
NVX-CoV2373	Novavax	Intramuscular (two doses)	Phase 3
ChAdOx1 nCoV-19	Oxford/AstraZeneca	Intramuscular	Phase 2/3
Coronavirus Vaccine	Sanofi/GlaxoSmithKline	Unspecified	Phase 1/2
INO-4800	Inovio	Intradermal	Phase 1
AdCOVID™	Altimmune	Intranasal (one dose)	Phase 1
Coronavirus Vaccine	CureVac	Intramuscular (one to three doses)	Preclinical
COVID-19 S-Trimer	GlaxoSmithKline/Clover	Unspecified	Preclinical

*EUA= Emergency Use Authorization

Express Scripts' Recommendations

Currently, no vaccines are FDA approved for the prevention of SARS-CoV-2 infections. According to the Centers for Disease Control and Prevention (CDC), the best mitigation is avoidance through social distancing, thoroughly washing hands, covering your mouth and nose while in public, covering coughs or sneezes, disinfecting frequently touched surfaces daily and isolating those with confirmed or suspected infections for at least 10 days.

Once a vaccine is approved and commercially available, Express Scripts will review the product for formulary status and make recommendations on coverage to the independent team of health professionals who form our P&T committee. As always, the Office of Clinical Evaluation and Policy will continue to monitor developments and provide updates as more information becomes available.

Stay up to date with the latest information regarding COVID-19 infections in the United States at:
https://www.cdc.gov/coronavirus/2019-ncov/index.html
https://www.nih.gov/health-information/coronavirus

Updates

Date	Vaccine	Comment
5.18.2020	mRNA-1273 (Moderna) Phase 1 Results	Positive interim data was announced in a phase I study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study evaluated safety and immunogenicity for a total of 45 patients from 18 to 55 years of age. Participants were given one of three different intramuscular (IM) doses; 25µg, 100µg, and 250µg. Patients were given two doses; the first on day 1 followed by the second dose on day 29. Upon receiving the second injection, each patient will be monitored for an additional 12 months. A dose dependent immune response was seen in all three doses and COVID-19 specific antibodies were detected by day 15. By day 43, antibody results for the first four patients, in both the 25µg and 100µg showed neutralizing antibody titers at or above levels generally seen in someone who has recovered from a COVID-19 infection. Ongoing studies will be amended to include a 50µg dose and include patients 55 years of age and older. The vaccine was generally safe and well tolerated. One participant at the 100µg dose experienced grade 3 redness at the injection site. The most serious adverse events occurred when three patients, all whom received 250µg dose, had grade 3 systemic symptoms. Grade 3 systemic symptoms occurred following the second injection and were self-limiting, resolving over time. An additional animal study was also provided to show replication of the virus was inhibited within the lungs of mice and provided full protection. Phase II trials are expected to begin soon while phase III trial protocols are finalized. The phase III trial is expected to start in July 2020. Moderna Announces Positive Interim Phase 1 Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus
6.30.2020	INO-4800 (Inovio) Phase 1 Results	Preliminary results were announced following two phase I studies, which Inovio plans to publish following peer review. In the trial, 40 healthy adults 18-50 years of age received two doses 28 days apart. Each patient had either a 1mg or 2mg dose via intradermal administration using the Inovio CELLECTRA 2000®. Overall 10 individuals reported adverse events that were localized and considered grade 1 injection site reactions. Immune response rates were observed in 94% of eligible participants analyzed, although levels for binding antibodies, neutralizing antibodies, and T-cell response were not reported. The company also reported that INO-4800 prevented viral replication in the lungs of mice and is undergoing similar testing in ferrets as part of the non-human primate (NHP) challenge for the U.S. Operation Warp Speed program. Inovio plans to increase its phase I study to include patients over 50 years of age and is seeking regulatory clearance for phase 2/3 trials this summer. INOVIO Announces Positive Interim Phase 1 Data For INO-4800 Vaccine for COVID-19
7.1.2020	BNT-162 (Pfizer/BioNTech) Phase 1/2 Results	Preliminary results of a placebo-controlled, observer-blind, dose-escalation phase 1/2 study have been announced for BNT-162 (Pfizer/BioNTech). BNT-162 is a lipid nanoparticle mRNA vaccine with a modified nucleoside. Forty-five patients between 18 and 55 years of age were assigned to dose arms of 10µg, 30µg, 100µg or placebo. The 100µg dose was given at day 1, only; the others were given at days 1 and 21. Due to severity of pain with the 100µg dose it was not repeated. Benefits were observed through day 35. Neutralizing antibodies and receptor binding domain (RBD) IgG levels showed a dose-dependent increase at each dosage level and upon the second injection. Two weeks after the second dose, plasma concentrations of RBD binding IgG and neutralizing antibodies from study participants were compared to samples of convalescent plasma from patients who have recovered from COVID-19. After the two-dose regimens the RBD-binding IgG concentrations were eight to 50 times greater

		and neutralizing antibodies were 1.8 to 2.8 times greater in plasma of vaccinated individuals. Although the 100µg cohort was not repeated, it provided no considerable benefit following the first dose. Pain at the injection site was the most common adverse event (AE) with all actively treated patients reporting pain with one or both injections. Systemic AEs included fever, chills and body aches, which all resolved within seven days. Except for one severe case of pain at the 100µg dose, all AEs were considered mild to moderate. Investigators plan to monitor for safety and efficacy for six to 24 months. Assuming that natural infection provides immunity to COVID-19, then the stronger vaccine response also could provide protection that warrants further investigation. Phase 1/2 Study to Describe the Safety and Immunogenicity of a COVID-19 RNA Vaccine Candidate (BNT162b1) in Adults 18 to 55 Years of Age: Interim Report
7.20.2020	ChAdOx1 nCoV-19 or AZD-1222 (AstraZeneca/University of Oxford) Phase 1/2 Results	Preliminary results of a blinded, randomized phase I/2 study have been announced for AZD-1222 (AstraZeneca/University of Oxford). AZD-1222 is a vaccine made from a chimpanzee "common cold" adenovirus vector re-engineered to contain genetic information from the COVID-19 virus's spike protein. The study enrolled 1,077 healthy adults between 18 and 55 years of age. One-half of the participants received one dose of AZD-1222 at 5 x 10^{10} viral particles and one-half got a meningococcal vaccine, MenACWY, as a control. Ten participants received a second dose of AZD-1222 one month after the first. At both two weeks and two months following the AZD-1222 injection, all participants receiving it had an increased response in white blood cells known as T-cells. Some evidence indicates that patients who contract COVID-19 but remain asymptomatic have a sizeable T-cell response without an increase in anti-COVID-19 antibodies. For 91% of treated patients, one injection of AZD-1222 produced neutralizing antibodies at the level of a patient who has recovered from COVID-19. All ten participants who had two doses of AZD-1222 produced additional neutralizing antibodies. The most common AEs were temporary pain at the site of injection, mild headache, fatigue, chills, fever and body aches, which all were treatable with non-prescription pain relievers. Investigators plan to follow up with patients at six months and one year. Phase 2/3 clinical trials are being conducted to confirm results and to study different dosages and effectiveness for other age groups. Safety and Immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of phase 1/2, single blind, randomized controlled trial
9.9.2020	ChAdOx1 nCoV-19 or AZD-1222 (AstraZeneca/University of Oxford) Phase III – Voluntary Clinical Hold Announced	On September 9, 2020, AstraZeneca announced a voluntary clinical hold on the United Kingdom (U.K.) Phase III trial for AZD-1222 following an independent standard review that was prompted following an unexplained illness. Statement on AstraZeneca Oxford SARS-CoV-2 vaccine, AZD1222, COVID-19 vaccine trials temporary pause
9.12.2020	ChAdOx1 nCoV-19 or AZD-1222 (AstraZeneca/University of Oxford) Phase III – Trial Resumed	On September 12, 2020, AstraZeneca announced that they have resumed the U.K. Phase III trial for AZD-1222 following a voluntary clinical hold. COVID-19 vaccine AZD1222 clinical trials resumed in the UK
9.25.2020	Ad26.COV2.S Phase I/2a Study Results, Initiates Phase III Study.	On September 25, 2020, Johnson & Johnson reported preliminary results of its double blind, randomized, placebo-controlled phase I/IIa trial demonstrating that its COVID-19 vaccine triggered an immune response. The study evaluated a single dose and a two-dose schedule, separated 56 days apart, in healthy adults 18-55 years of age and healthy adults over 65 years of age. At 29 days post administration, detectable neutralizing antibodies was observed in 98% of

		participants. A significant T-cell and Th1 response was observed in subsets of patients believed to show immune protection against the disease. Adverse events (AEs) occurred in 64% of healthy adults and 36% of healthy adults over 65 years old. The most common AEs included fever, injection site pain, fever, muscle aches, fatigue and headache. The company indicated that safety and immunogenicity after one dose provided significant benefit and would warrant further study. Earlier, on September 23, 2020, Johnson & Johnson announced the start of its Phase III study evaluating safety and efficacy of a single dose vaccine vs. placebo in 60,000 adults 18 years of age and older. Preliminary Results for Phase I/IIa Study on COVID-19 Vaccine
10.13.2020	Temporary Pause on Johnson & Johnson's Phase III Ad26.COV2.S Vaccine Trial	On October 13, 2020, Johnson & Johnson announced that it is pausing all of its COVID-19 vaccine trials temporarily while it investigates an unexplained illness. An independent Data Safety Monitoring Board (DSMB) will evaluate the illness along with internal physicians. The study pause was due to the company's pre-determined safety protocols, not a regulatory body. Johnson & Johnson Temporarily Pauses Phase III Trial
10.23.2020	ChAdOx1 nCoV-19 or AZD-1222 (AstraZeneca/University of Oxford) Phase III – Trial Resumed in the U.S.	On October 23, 2020, AstraZeneca announced that they have resumed the U.S. Phase III trial for AZD-1222 following a voluntary clinical hold. ChAdOx1 nCoV-19 or AZD-1222 (AstraZeneca/University of Oxford) Phase III - Trial Resumed in U.S.
10.23.2020	Johnson & Johnson Phase III Ad26.COV2.S – Trial Resumed in the U.S.	On October 23, 2020, Johnson & Johnson announced they have resumed the U.S. Phase III trial for Ad26.COV2.S following a voluntary clinical hold. Johnson & Johnson Phase III - Trial Resumed in the U.S.
11.9.2020	BNT-162 (Pfizer/BioNTech) Preliminary Phase III Results	On November 9, 2020, Pfizer and BioNTech announced that early study results from a Phase III trial evaluating BNT-162. Data show the vaccine to be more than 90% effective at preventing COVID-19 – exceeding the FDA's minimum requirement for at least 50% efficacy for a COVID-19 vaccine. To date, the Phase III trial has enrolled 43,538 patients with almost 90% of patients receiving their second (final) dose. Up to 42% of participants in the trial are from an ethnically diverse background and 40% of participants are over 55 years of age. The trial is still enrolling patients until 164 confirmed COVID-19 cases have occurred. An independent Data Monitoring Committee (DMC) reviewed efficacy analysis on November 8, 2020. To date, the total confirmed COVID-19 case count is at 94 patients and the difference between vaccinated patients and those receiving placebo indicates at least 90% efficacy. The DMC did not report any serious safety concerns. The FDA has specified safety guidance for Emergency Use Authorization (EUA) at a medium of two months of data following second dose administration, which the company expects to reach by the third week of November. If BNT-162 is approved, as many as 50 million doses should be available this year with an additional 1.3 billion doses ready in 2021. BNT-162 (Pfizer/BioNTech) Preliminary Phase III Results
11.16.2020	mRNA-1273 (Moderna) Preliminary Phase III Results and Shelf Life Update	On November 16, 2020, Moderna's mRNA-1273 vaccine met its pre-specified primary endpoint with 94.5% efficacy based on an interim analysis from its ongoing phase III trial. The trial has enrolled 30,000 participants in the U.S., and data were reviewed by an independent Data Safety Monitoring Board (DSMB) appointed by the National Institutes of Health (NIH). The analysis was based on 95 confirmed COVID-19 cases, two weeks following the second dose of vaccine. Five cases were in the treatment group vs. 90 cases in the placebo group. Severe COVID-19 disease, pre-defined by the study protocol, occurred in 11 patients who received a placebo with none of the patients in treatment having severe disease. The positive cases included 15 adults 65 years of age or older and 20 patients who have ethnically diverse backgrounds. The DSMB

		considered the vaccine to be safe and well-tolerated with most adverse events (AEs) being mild to moderate. As positive COVID-19 cases accumulate in study participants, the vaccine efficacy may change. Moderna plans to submit an Emergency Use Authorization (EUA) within the next few weeks based on two or more month's median duration of data. Moderna expects to have 20 million doses available in the U.S. this year, with an additional 500 million to 1 billion doses available globally in 2021. Furthermore, the company announced that the vaccine remains stable at 2°C to 8°C (36°F to 46°F) for 30 days and at room temperature for 12 hours. The vaccine will have up to six months of shelf life when stored at -20°C (-4°F). The vaccine will not require onsite dilution before administration, which will allow for less complex handling in a variety of healthcare settings. mRNA-1273 (Moderna) Preliminary Phase III Results mRNA-1273 Shelf Life Update
11.18.2020	BNT-162 (Pfizer/BioNTech) Final Efficacy Analysis	On November 18, 2020, Pfizer/BioNTech's COVID-19 vaccine, BNT-162 had a 95% efficacy rate as measured seven days after the second (booster) dose. The study met all primary efficacy endpoints based on reaching 170 positive cases of COVID-19. The placebo group had 162 patients positive for COVID-19 infection compared to eight positive cases in the vaccine group. Similar efficacy was observed across all ages and demographics, with greater than 94% for patients over the age of 65 years. Severe cases of COVID-19 infection were seen in 10 patients, with nine among patients in the placebo group. The vaccine has shown to be safe with no serious adverse events (AEs). The only grade 3 AEs noted occurring more than 2% were fatigue and headache. Since the FDA's requirement for two month's of safety information has been met, the companies plan to submit a request for Emergency Use Authorization (EUA) within days. Doses will be shipped in GPS-enabled thermal containers containing dry ice that maintains the vaccine temperature at -70°C±10°C. Replenishing the dry ice will allow the containers to be used as temporary storage space for up to 15 days. BNT-162 (Pfizer/BioNTech) Final Efficacy Analysis
11.23.2020	Preliminary Results for Oxford/AstraZeneca's AZD-1222	On November 23, 2020, Oxford/AstraZeneca released preliminary results of a clinical study for their COVID-19 vaccine, AZD-1222. Two dosing regimens were evaluated in the trial; the average efficacy rate was 70% following 131 confirmed COVID-19 infections. None of the vaccine-treated patients, in either group, had severe COVID-19 or the need for hospitalization. Among the 2,741 individuals given a half-dose, followed up with a full dose at least one month later, vaccine efficacy was 90%. Unexpectedly, the efficacy of two full doses, given a month or more apart to 8,895 participants was only 62%. The company did not elaborate on why the variance occurred; however, the smaller size for the half-dose group may warrant further investigation. As part of the trial, patients were screened for COVID-19 weekly, as compared to studies of m-RNA vaccines that relied on the numbers of symptomatic cases as a measure of efficacy. An independent Data Safety Monitory Board (DSMB) reported that AZD-1222 reached the primary endpoint of protecting patients from COVID-19 infection for 14 days or longer after both regimens. It also appears safe with no serious adverse events (AEs) observed. The company, which will file for approval in several countries, including the U.S., also will ask the World Health Organization (WHO) for an Emergency Use Listing that could ease distribution to underdeveloped countries. Unlike the Pfizer and Moderna vaccines that are in development, AZD-1222 does not need to be frozen. It remains active for six months or longer when refrigerated. Additionally, it can be administered in a variety of common healthcare settings. AstraZeneca expects to produce 3 billion doses next year. Preliminary Results for Oxford/AstraZeneca's AZD-1222

12.11.2020	Emergency Use Authorization for the First COVID Vaccine	As expected, the U.S. Food and Drug Administration (FDA) followed its independent Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommendation to approve an emergency use authorization (EUA) for the Pfizer/BioNTech COVID-19 vaccine, BNT162b2, on Dec. 11, 2020. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) gave its authorization on Dec. 12, 2020, allowing distribution to begin. Administered as two intramuscular (IM) injections at least three weeks apart, the vaccine is indicated to prevent COVID-19 for individuals age 16 and older. The first vaccine that is based on mRNA, BNT162b2 must be stored at ultra-low temperatures. Under Operation Warp Speed, shipments to more than 600 designated distribution centers began immediately, with the Federal Aviation Administration (FAA) giving priority airspace to planes carrying the vaccine. Initially, each state will receive a supply of vaccine decided by the state's population and administered according to state rules. Most of the first immunizations are earmarked for front-line healthcare workers and the residents and staff of long-term care facilities. The EUA is provided with a factsheet for healthcare providers found here. The EUA factsheet that should be provided to recipients and caregivers can be found here. Pfizer-BioNTech COVID-19 Vaccine Receives Emergency Use Authorization (EUA)
12.18.2020	Second COVID-19 Vaccine Approved Under Emergency Use Authorization	The U.S. Food and Drug Administration (FDA) granted an emergency use authorization (EUA) on Dec. 18, 2020, for Moderna's vaccine to prevent COVID-19. Approval on the following day from the Centers for Disease Control and Prevention (CDC) allowed for immediate shipping. The first doses are expected to be given on Dec. 21, 2020. Administered by intramuscular (IM) injection, it needs two 100mcg doses that are 28 days apart to be fully effective. Because it can withstand higher temperatures, handling for Moderna's vaccine is less complicated than transporting and administering Pfizer's COVID-19 vaccine, which got an EUA earlier in December. No cost will be charged for the vaccine, although administration fees may apply in some cases. Moderna plans to provide the U.S. with enough doses for 10 million patients by the end of 2020. An additional 180 million doses have been contracted by the U.S government with the possibility of 300 million more in negotiation. Operation Warp Speed will manage allotment and delivery to regional distribution centers. Here is Moderna's Fact Sheet for providers of its COVID-19 vaccine and here is one for patients. Second COVID-19 Vaccine Approved Under Emergency Use Authorization
1.28.2021 2.4.2021	Novavax Efficacy Data and Rolling Submission	On January 28, 2021, Novavax's NVX-CoV2373 preliminary data showed that it was 89.3% effective preventing symptomatic COVID-19 in a phase III trial in the UK, where the predominant UK variant exists. Over one-half of the sixty cases in the trial were positive for the UK variant, but the vaccine showed 85.6% efficacy against the UK variant and 95.6% efficacy against the original strain, a point estimate of 89.3% efficacy. The company also announced preliminary results from a phase 2b trial in South Africa where 94% of the positive cases consisted of the South African variant. The vaccine showed 49.4% efficacy overall against the South African variant and 60% efficacy for patients who are HIV-negative. Novavax began work on candidates for a booster or combination to address the new strains. On February 4, 2021, Novavax announced it would start the rolling review authorization with multiple worldwide agencies, including the U.S. Food and Drug Administration (FDA) as clinical and manufacturing data becomes available. Preliminary Results for Novavax COVID-19 Vaccine in UK and South Africa Novavax Starts Rolling Review Process

2.27.2021	Janssen's COVID-19 Vaccine Approved Under Emergency Use Authorization (EUA)	On February 27, 2021, Emergency Use Authorization (EUA) was granted to Janssen's COVID-19 vaccine (Ad26.COV2.S), by the U.S. Food and Drug Administration (FDA). It is the third COVID-19 vaccine to be approved in the U.S. On Feb. 26, 2021, a unanimous vote by the FDA's independent Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended EUA. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) gave its authorization on Feb. 28, 2021, allowing distribution to begin. The vaccine is given as just one (0.5mL) dose intramuscularly (IM) to prevent COVID-19 in patients 18 years of age or older. The U.S. government will help coordinate the delivery of 20 million doses by the end of March – with a goal of 100 million in the first half of 2021. Janssen is providing vaccine on a not-for-profit basis during the pandemic emergency at $10 per vial charged to the U.S. federal government for 100 million five-dose vials. The vaccine can be stored at regular refrigeration temperatures 36°to 46°F (2° to 8°C) for a maximum of three months. If stored at -4°F (-20°C) the vaccine will remain stable for up to two years. The EUA is provided with a factsheet for healthcare providers found here. The EUA factsheet that should be provided to recipients and caregivers can be found here. Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot Vaccine in Fight Against Global Pandemic
4.15.2021	Pause for Janssen COVID-19 Vaccine	The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have recommended a pause, as an extreme precaution, on the Johnson & Johnson (Janssen) COVID-19 vaccine. Although they are not mandated to stop giving it, several states and vaccine sites are following this guidance while the CDC's Advisory Committee on Immunization Practices (ACIP) investigates data surrounding rare, but severe blood clots following the vaccine. To date, 7.2 million people in the U.S. have received the vaccine. Six female patients, ages 18 years to 48 years, have developed a cerebral venous sinus thrombosis (CVST), which is a blood clot in the brain, along with thrombocytopenia (low platelet levels) six to thirteen days post-vaccine. Another possible seventh case involving a 59-year-old female who had a different type of clot was brought to the attention of the committee, as well. In clinical trials, a few thromboembolic events were reported, but no link was found to the vaccine at that time. The ACIP met on April 14, 2021. However, they need more information to make evidence-based recommendations. The committee will move as quickly as possible over the next week or two – likely before their next scheduled meeting on May 5, 2021. Anyone who develops a headache, abdominal pain, leg pain or shortness of breath within three weeks of receiving the Janssen COVID-19 vaccine is advised to contact their health care provider. For the CDC and FDA statement, see here. Johnson & Johnson Statement on Pause
4.23.2021	Janssen COVID-19 Vaccine Resumes	On April 23, 2021, the Advisory Committee on Immunization Practices (ACIP), an independent group of experts, voted 10 to 4 with 1 abstention in favor of resuming the Emergency Use Authorization (EUA) for the Johnson & Johnson (Janssen) COVID-19 vaccine for all adults 18 years of age and older. The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) agreed that giving the vaccine may resume after a temporary pause while the agencies reviewed safety data. Out of nearly 8 million doses administered, a total of 15 cases of cerebral venous sinus thrombosis (CVST) currently have been reported among recipients of the vaccine. Also, the FDA and CDC wanted time to assure that healthcare providers can recognize and properly treat these rare forms of brain blood clots that are accompanied by low platelet levels, or thrombosis thrombocytopenia syndrome (TTS). The agencies reinforced that the vaccine is effective at preventing COVID-19 with a very low chance of CVST or TTS occurring. However, all recipients, especially women younger than 50 years old, should be made aware by providers administering the vaccine of the increased risk for this adverse event (AE). An updated fact sheet for patients and caregivers can be found here. Healthcare providers have an updated fact sheet, here.

		FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review
5.7.2021	Pfizer and BioNTech File for Full Approval	On May 7, 2021, Pfizer and BioNTech announced they are seeking full approval for their vaccine after announcing they had submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the prevention of COVID-19 in patients 16 years of age and older. The request is on a rolling basis with a Priority Review voucher. A Prescription Drug User Fee Act (PDUFA) date has not been officially set, but it should come in the 4th Quarter of 2021. Pfizer and BioNTech File for Full U.S. Approval
5.13.2021	Age Lowered for Emergency Use Authorization of Pfizer/BioNTech COVID-19 Vaccine	On May 12, 2021, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted 14 to 0 with one recusal to recommend the use of the Pfizer/BioNTech COVID-19 vaccine starting right away in adolescents as young as 12 years old. The vote came just days after the U.S. Food and Drug Administration (FDA) extended the vaccine's Emergency Use Authorization (EUA) to individuals who are 12 years to 15 years of age. It still will be given in two doses, separated by at least three weeks, at the same dose as is administered for adults. The clinical trial that led to its new authorization was conducted with over 2200 participants between the ages of 12 and 15 years. It showed 100% efficacy at preventing COVID-19 – with 18 COVID-19 positive cases observed in the placebo group compared to zero in the vaccinated group. The vaccine was generally well tolerated with no serious adverse events (AEs). Most AEs, which generally lasted one to three days and followed the second dose, included injection site pain, fever, headache, chills, fatigue and joint pain. Trials for the vaccine are ongoing in patients six months to 11 years of age. The FDA has scheduled an advisory committee in June to discuss the vaccine's use in patients under 12 years of age. Pfizer anticipates filing by September for an EUA expansion to children two years to 11 years of age. Updated fact sheets can be found here for healthcare workers administering the vaccine and here for recipients and caregivers. Pfizer and BioNTech Receive Emergency Use for Adolescents 12 Years to 15 Years of Age

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