COVID-19 Vaccines
The Facts, Risks, and Unknowns

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COVID-19 Vaccine – Latest Update

- Latest statistics
- Vaccine pipeline and frontrunners
- Clinical trial results
- Safety
- Cost Implications
- Distribution and Availability

Common Terms to Know

Term	Description
Operation Warp Speed	• Public–private partnership initiated by the U.S. government to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. • Promotes mass production of multiple vaccines and different types of vaccine technologies, based on preliminary evidence, allowing for faster distribution if clinical trials confirm safety and efficacy. • Advisory Committee on Immunization Practices (ACIP) makes recommendations to the CDC on who should receive the vaccine. Each states then makes the final decision on prioritizing who will receive the vaccine. • Billions of dollars from the CARES Act (Coronavirus Aid, Relief, and Economic Security) were passed by the United States Congress is an interagency program for vaccine development (Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, the National Institutes of Health, and the Biomedical Advanced Research and Development Authority (BARDA); the Department of Defense; private firms; and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs.
Emergency Use Authorization (EUA)	• FDA can allow unapproved medical products onto the market to be used in an emergency. • Benefits likely to outweigh risks ("substantial evidence" of safety and effectiveness for approval not required).
Herd Immunity	Herd immunity, or community immunity, is when a large part of the population of an area is immune to a specific disease. If enough people are resistant to the cause of a disease, such as a virus or bacteria, it has nowhere to go.
Natural Immunity	Immunity that an individual mounts to fight off a disease/condition because they have had the disease already or been exposed to the disease and have mounted sufficient antibodies to fight off or no longer able to contract the disease.

Executive Summary

- FDA has cleared Pfizer-BioNTech COVID-19 vaccine for EUA as a result of Operation Warp Speed:
  - "95% efficacy" in preventing infection.
  - Efficacy evaluated at least 7 days after 2nd dose.
- Moderna COVID-19 Vaccine is scheduled for FDA Advisory Panel review on December 17th for EUA.
  - "95% efficacy" in preventing infection.
  - Efficacy evaluated at least 14 days after 2nd dose.
- Knowns about both COVID-19 vaccines:
  - Prevents symptomatic COVID-19 within study parameters.
  - Most people will experience side effects, most prominent after 2nd dose (injection site pain, fatigue, headaches, and muscle pain).
  - Cannot cause COVID-19 and do not contain live virus.
  - Do not interact with or alter our genes (DNA) in any way.
- Unknowns about both COVID-19 vaccines:
  - Protection is not known after 2 months. [1, 2]
  - Additional data is needed for subpopulations.
  - Effectiveness if virus mutates.
  - Effectiveness against: asymptomatic infections, long-term effects of COVID-19, or transmission of COVID-19.
- Masks and social distancing will still be needed, pending CDC recommendations to say these measures can be discontinued and more is known about if the vaccine can prevent transmission and spread of COVID-19.
- Information will be constantly evolving.
- This webinar is designed to make you aware of the key facts and considerations to follow regarding current and future developments of COVID-19 vaccines.

1. VRBPAC-12.10.20-Meeting-Briefing-Document-FDA (Pfizer-BioNTech Covid-19 Vaccine, accessed 12/15/20)
2. VRBPAC-12.17.20-Meeting-Briefing-Document-FDA_0 (Moderna COVID-19 Vaccine, accessed 12/15/20)

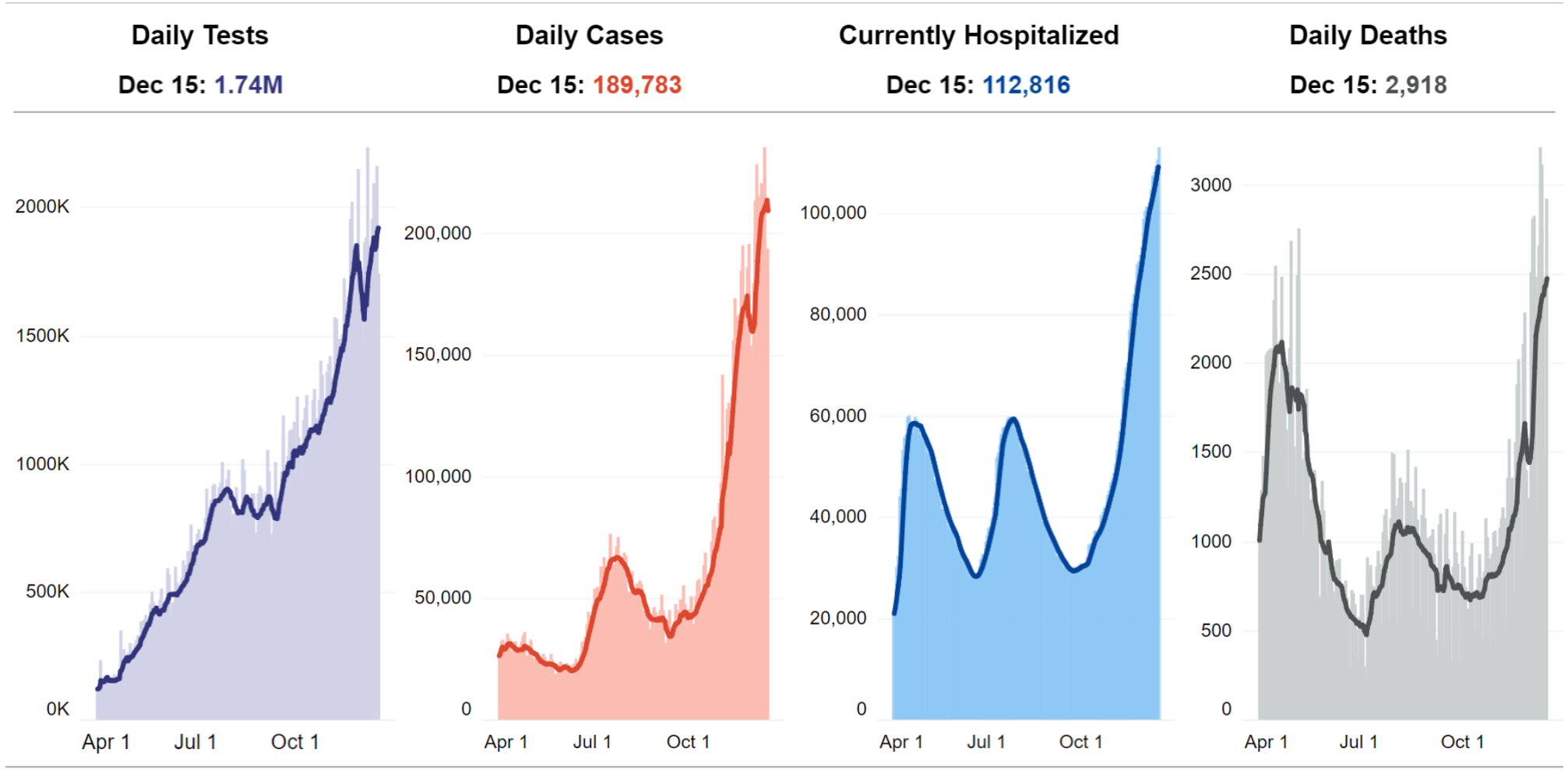
COVID 19 Pandemic - Statistics
Last updated as of December 14, 2020

Case Status	World-wide	United States
All Coronavirus Cases	72,778,115	16,741,470
- Active Cases	20,047,324	6,709,098
- Mild	20,047,234 (99.5%)	--
- Serious	106,223 (0.5%)	--
- Closed Cases	52,624,528	10,032,372
- Deaths	1,621,259 (3%)	306,464 (3%)
- Recovered	51,003,309 (97%)	9,725,908 (97%)

Source: United States Coronavirus Worldometer: https://www.worldometers.info/coronavirus/country/us/

John Hopkins University COVID-19 Tracking data

COVID-19: U.S. Statistics as of December 15, 2020

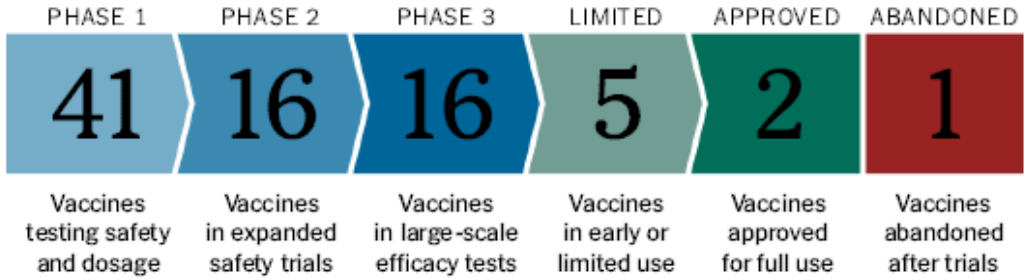


Source: The COVID Tracking Project: https://covidtracking.com/data/charts/us-all-key-metrics

COVID-19 Pipeline – Worldwide Snapshot

(as of December 14, 2020)

- Vaccines typically require years of research and testing
- 2020 has been a fast-paced year for COVID-19 vaccine development
- With over 200 vaccine candidates under development world-wide, an estimated **59 vaccines for COVID 19** are in human clinical trials - Phase 1, 2 (or Combined Phase 1 / 2) or Phase 3 trials*
- About 16 have reached or are ready for final stages of testing and/or review.



Source: COVID Vaccine Tracker: Latest Update NY Times; Clinical trials.gov.

Key:

Phase 1 Trials: Trials in a small # of people to test safety and dosage, as well as to confirm that it stimulates the immune system.

Phase 2 Trials: Trials conducted in hundreds of people split into groups, such as children, and the elderly to see if the vaccine acts differently in them. These trials further test the vaccine's safety.

Phase 3 Efficacy Trials: Thousands of people receive vaccine and wait to see how many become infected, compared with volunteers who received no vaccine (placebo). These trials can determine if the vaccine protects against COVID19, measuring what's known as the efficacy rate. Phase 3 trials are also large enough to reveal evidence of relatively rare side effects.

Limited (Early Approval): Britain and other countries have begun giving emergency authorization to vaccines based on preliminary evidence that they are safe and effective. China and Russia, on the other hand, have authorized vaccines without waiting for the results of Phase 3 trials, which experts say has serious risks.

Approved: Regulators review the complete trial results and plans for a vaccine's manufacturing and decide whether to give it full approval for marketing.

***Combined Phase:** One way to accelerate vaccine development is to combine phases. Some vaccines are now in Phase 1 / 2 trials, for example which this tracker would count as both Phase 1 and Phase 2.

Paused or Abandoned: If researchers observe worrisome symptoms in participants, they can temporarily pause the trial. After an investigation, the trial may resume or be abandoned.

U.S. Vaccine Pipeline - Frontrunners

Features	Pfizer/BionTech	Moderna (NIAID & NIH)	AstraZeneca/ Oxford University	Johnson & Johnson	Novavax	Merck/IAVI Merck/Vaxart	Sanofi/GSK
Product	Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)	Moderna COVID-19 Vaccine (mRNA-1273)	AZD1222 formerly ChAdOx1 nCoV-19	Ad26.COV2.S	NVX-CoV2373	V591 MK-4482	SARS-CoV2 Protein Antigen + AS03 Adjuvant
Vaccine type	mRNA	mRNA	Modified virus from chimpanzees that elicits spike protein production	Viral vector from an adenovirus	recombinant spike protein nanoparticle with adjuvant	Viral vector vaccine (similar to technologies used to make measles and ebola vaccine	Protein contains COVID-19 protein, but no genetic material (insect cell lines) with adjuvant
Target Dates FDA Advisory Review EUA Approval	 Dec 10, 2020 Dec 11, 2020	 Dec 17, 2020 --	 Likely early 2021 --	 Likely early 2021 -- (Company had to pause in Oct due to an undisclosed illness of a participant, but has since resumed)	 Likely mid-late 2021 --	 Still in early-stage clinical trials	 On Dec 11, 2020 – Sanofi announced delay until late 2021. Produced "insufficient immune response" in elderly people in Phase I/II trial
Phase III enrollment	43,998	30,000 +	60,000 (1 dose) 30,000 (2 doses)	60,000 (1 or 2 doses)	20,000+	Not available	40,000

Source: Covid-19 Vaccine Tracker: Latest Updates. https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

COVID-19 Vaccine Candidates
Front Runners Leading the Charge

Characteristics	Pfizer/BionTech	Moderna (NIAID & NIH)	AstraZeneca/ Oxford University	Johnson & Johnson	Novavax	Merck/IVAI	Sanofi/GSK
Product	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AZD1222 formerly ChAdOx1 nCoV-19	Ad26.COV2.S	NVX-CoV2373	V591	SARS-CoV2 Protein Antigen + AS03 Adjuvant
Dosage	30 mcg at 0 and 3 weeks (21 days apart)	100 mcg at 0 and 4 weeks (28 days apart)	Two shots spaced 4 weeks (28 days) apart	One shot regimen Two shot regimen (Day 0 & 57) running in parallel	Two doses spaced 3 weeks (21 days) apart	One shot, with booster on day 57 or day 169 Pill form	1 or 2 injections
Stability	15 days in thermal shippers, 6 months in ultra low temp freezer (-112° F to - 76° F) or 5 days in refrigerator (35° - 46° F). After dilution, use within 6 hours at 35° - 77° F	6 months in standard freezer (-4° F) or 30 days in refrigerator 36°-46°F	Standard refrigeration (36°-46°F) up to at least 6 months	Standard refrigeration (36°-46°F)	Standard refrigeration (36°-46°F)	Not available	Standard refrigeration (36°-46°F)

Pfizer's product needs to be shipped and stored at non-commercial freezer temperatures (colder than Antartica)

COVID-19 Vaccine - Key Highlights

- Pfizer/BioNTech and Moderna's vaccines are leading Operation Warp Speed, as the first two COVID-19 vaccines
  - "95% efficacy" in preventing infection
  - Both vaccines have met the FDA's minimum efficacy threshold (prevention of symptomatic COVID-19 by at least 50%) and safety threshold (two months of patient follow-up) for Emergency Use Authorization (EUA).
  - Pfizer's vaccine given thumbs up vote (17 - 4, 1 abstention) by FDA Advisory Panel (12/10/2020), EUA approval (12/11/2020)
- Distribution will require coordinated effort between the manufacturers, federal and state governments, pharmacies, and providers.
- Availability to be prioritized to those at highest risk.
- Whether the public will be receptive to COVID-19 vaccines remains a critical question
  - Herd immunity that can be achieved through immunization
  - Evolving safety profile

Phase III Clinical Trial Inclusion Criteria

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine
Age	Originally was ≥ 18 years of age; Pfizer later expanded to include ≥ 12 years of age	≥ 18 years of age

Health Status	• Healthy individuals
	• Individuals with stable chronic pre-existing medical conditions, including HIV, Hepatitis B, and Hepatitis C
		• Healthy individuals
		• Individuals with stable pre-existing medical conditions during past 3 months:
		  • No significant change in therapy
		  • No hospitalization(s), and
		  • No worsening of condition

Risk for COVID-19 Infection	High risk for COVID-19 infection (mass transportation, demographics, frontline essential workers, etc.)	High risk for COVID-19 infection, (adults whose locations or circumstances put them at appreciable risk of exposure to COVID-19)
Childbearing Potential	Included if negative pregnancy test	Included if negative pregnancy test, on adequate contraception, and not breastfeeding

Source: Clinicaltrials.gov

Phase III Clinical Trial Exclusion Criteria

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine
Previous COVID-19 History	Originally excluded if previous COVID-19 symptoms/signs with or without a positive COVID-19 test; Pfizer later expanded to include patients who previously had COVID-19	History of COVID-19
Immunocompromised	Except individuals with HIV, Hepatitis B, and Hepatitis C	Immunosuppressive or immunodeficient states (Individuals with HIV were not excluded)
Immunosuppressive Therapy	Immunosuppressive therapy, cytotoxic agents, or systemic corticosteroids	Systemic immunosuppressants
Immunoglobulins/Blood Products	Immunoglobulin(s) or receiving blood products	Immunoglobulin(s) or receiving blood products
Bleeding Disorders	Bleeding diathesis (tendency to bruise or bleed) or condition associated with prolonged bleeding	Contraindication to intramuscular injection or phlebotomy due to bleeding disorder
Pregnancy/Breast Feeding	Excluded	Excluded
Adverse Reactions to Vaccines	History of severe adverse reaction associated with vaccines or components	History of anaphylaxis, urticaria, or other significant adverse reaction after receipt of a vaccine
Other	Medical or psychiatric condition including suicidal ideation/behavior Lab abnormalities (investigator judgment) Receipt of medications intended to prevent COVID-19 Previous vaccination with any coronavirus vaccine	Acutely ill or fever 72 hours prior to or at screening Prior investigational coronavirus (SARS-CoV, Middle East Respiratory Syndrome [MERS]-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19 Received/plans to receive a vaccine within 28 days prior to the first dose or plans to receive a non-study vaccine within 28 days prior to or after any dose of investigational product (except for seasonal influenza vaccine

Source: Clinicaltrials.gov

Phase III Trial Results (Randomized, Placebo-Controlled)

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine
Participants enrolled	43,548 enrolled (43,448 received injections)	30,350 +
Study Sites	Global (76.7 % participants in U.S)	99 sites in U.S.
Age	Median: 51 years 75 years or greater: 4.3 % 65 years or greater: 21.4 % Over 55 years: 41.8 % 16 – 55 years: 57.9 % 16 – < 18 years: 0.4 %	Median: 52 years 18 – 65 years: 75.2 % 65 years or greater: 24.8 %
Gender	Female: 49.4 % Male: 50.6 %	Female: 47.3 % Male: 52.7 %
Race	White: 81.9 % African American: 9.8 % Asian: 4.4 % Other: < 3 %	White: 79.2 % African American: 10.2 % Asian: 4.6 % Other: 5.2 %
Hispanic/Latino	26.2 %	20.5 %
Comorbidities	Obesity: 35.0 % Diabetes: 8.4 % Chronic lung disease: 7.8 % Heart attack history: 1.0 % Peripheral vascular disease (circulation disorders): 0.6 % Liver disease: 0.6 % Heart failure (congestive): 0.4 % AIDS/HIV: 0.0 % (1 participant)	Diabetes: 9.4 % Obesity (severe): 6.5 % Cardiac disease (significant): 4.9 % Chronic lung disease: 4.8 % Liver disease: 0.6 % HIV: 0.6 %
Hypertension	24.5 %	Not reported

- VRBPAC-12.10.20-Meeting-Briefing-Document-FDA (Pfizer-BioNTech Covid-19 Vaccine, accessed 12/15/20)
- VRBPAC-12.17.20-Meeting-Briefing-Document-FDA_0 (Moderna COVID-19 Vaccine, accessed 12/15/20)

Phase III Trial Results (Randomized, Placebo-Controlled)

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	
Primary Endpoint (Key Measure)	Incidence of COVID-19 cases confirmed ≥ 7 days after 2nd dose of vaccine: • COVID-19 symptoms and • Positive COVID-19 test (PCR or other validated test)	Number of COVID 19 cases at least 14 days after the 2nd dose of vaccine determined by: • COVID-19 symptoms and • Positive COVID-19 test (PCR or other validated test)	
		Interim	**11/30/2020 update**
# of Confirmed COVID-19 Cases	**170**	**95**	**196**
Vaccine	8 (4.7%)	5 (5.6%)	11 (5.6%)
Placebo	162 (95.3%)	90 (94.5%)	185 (94.5%)
	95% Confidence Interval, 90.3% to 97.6%	p < 0.0001	
# of Severe COVID-19 Cases*	10	11	30
Vaccine	1	0	0
Placebo	9	11	30

* A severe COVID-19 case was defined as a case with at least one of the following: 1) Severe systemic illness (Respiratory rate > 30 breathes per minute, Heartrate > 125 beats per minute, Sp0O2 < 93% on room air at sea level, or PaO2/Fi02 < 300 mm Hg; 2) Respiratory failure requiring oxygen, ventilator assistance; 3) Evidence of shock (SBP < 90 mmHg; DBP < 60mmHg or requiring vasopressors; 4) Significant acute renal, hepatic or neurologic dysfunction; 5) Admission to an ICU; and/or 6) Death

References:
- EE Walsh et al. Safety and immunogenicity of two RNA-based Covid-19 vaccine candidates. N Engl J Med 2020 October 14 (epub).
- Pfizer-BioNTech COVID-19 Vacccine/BNT 162b2. Emergency Use Authorization (EUA) for an Unapproved Product. Review Memorandum. Rev December 11, 2020. Found at https://www.fda.gov/media/144416/download.
- Fact Sheet for Healthcare Providers. Emergency Use Authorization of Pfizer-Biotech COVID-19 Vaccine to prevent COVID-19. Found @https://www.fda.gov/media/144413/download.
- Press release. Moderna's COVID-19 vaccine candidate meets its primary efficacy endpoint in the first interim analysis of the phase 3 COVE study. Available at: https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy. Accessed November 17, 2020.

Safety

Patients were assessed within 7 days after receiving 1st and 2nd injections and 6 months after their second dose for adverse events.

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine
Adverse Effects	• Injection site reactions (pain, swelling, redness (84.1%) • Fatigue (62.9%) • Headaches (55.1%) • Muscle pain (38.3%) • Chills (31.9%) • Joint pain (23.6%) • Fever 14.2% • Small # with swollen lymph nodes (64 cases) and Bells Palsy (4 cases) • Local and systemic reactions were more frequent/prominent after the second dose	• Injection site pain (91.6 %) • Fatigue (68.5 %) • Headaches (63.0%) • Muscle pain (59.6%) • Joint pain (44.8%) • Chills (43.4%)
Severe Adverse Effects	While no serious adverse events reported in U.S. trial, severe allergic reactions reported in 2 patients receiving the vaccine in U.K. who both recovered in the hospital. These events prompted safety warnings of use in patients with history of serious allergies (food, eggs and other drug allergies)	The most common SAEs in the vaccine group which were numerically higher than the placebo group were myocardial infarction (0.03%), cholecystitis (0.02%), and nephrolithiasis (0.02%). Causal relationship not established.

Source: Pfizer Covid 19 Vaccine. fact-sheet-for-hcp-administering-vaccine-vaccination-providers-full-eua-prescribing-information.pdf (cvdvaccine-us.com)
Moderna press release. Moderna's COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the first interim analysis of the Phase 3 COVE Study. Nov 16 2020

Vaccine Distribution – Priority Setting

1

Phase 1

- Expected to begin in December 2020, when available doses will be limited and vaccination will be targeted to high-risk individuals, including those identified as members of a critical workforce. (Expect vaccine to be delivered to 636 sites across the U.S beginning 12/14/2020)
- Federal government is working directly with certain national chain pharmacies for on-site COVID-19 vaccination services for long-term care and assisted living facilities.
- States are strategically enrolling pharmacies to assist with vaccination of critical populations who are prioritized for early vaccination by the Advisory Committee on Immunization Practices (ACIP) (CDC).
- The CDC COVID-19 Vaccination Program Provider Agreement describes the program requirements for providers.

2

Phase 2 and beyond

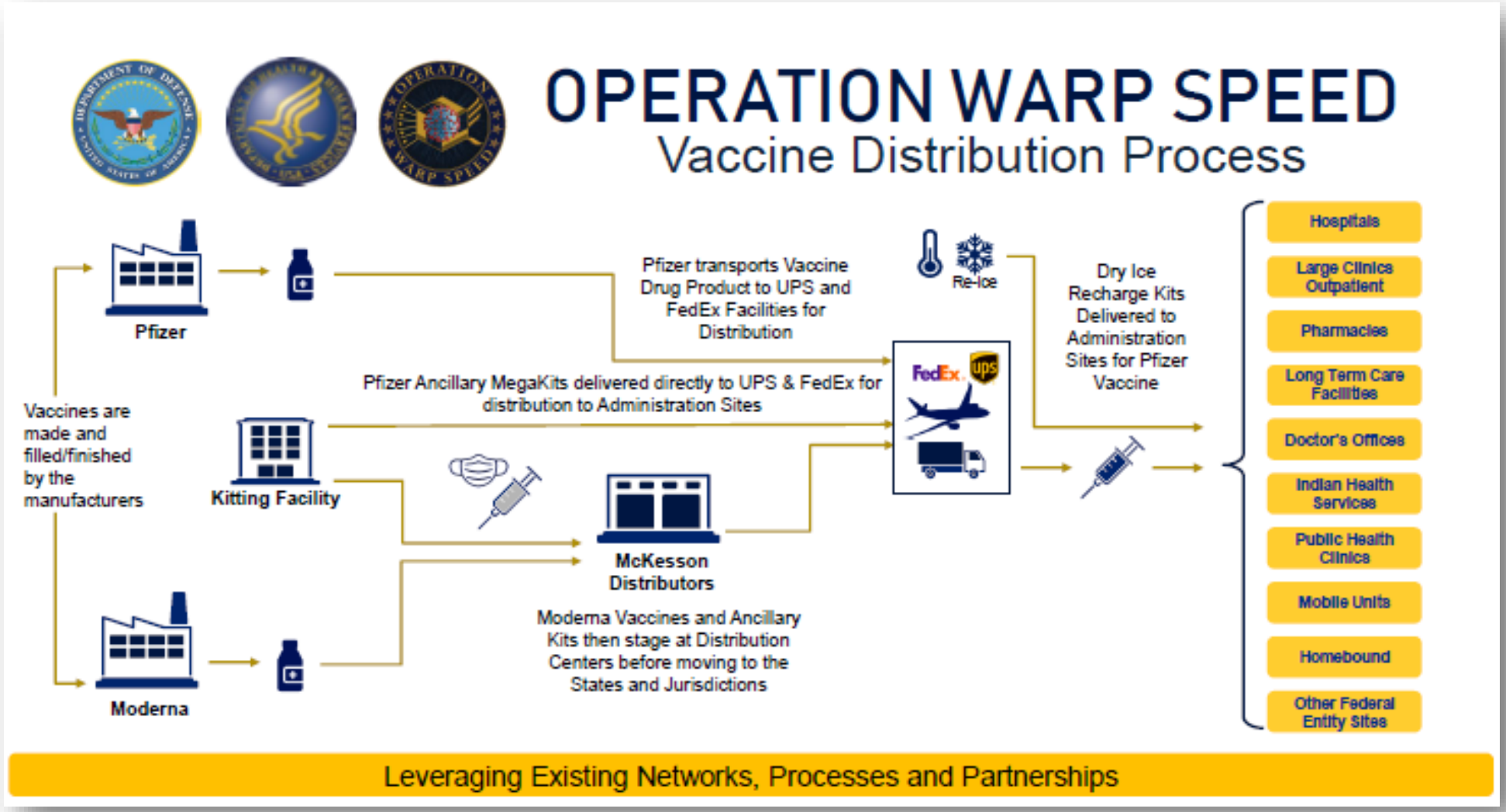
- Includes much larger quantities of doses and broad administration to the general public.
- Select national pharmacies will have the option to enroll directly with the federal government to receive COVID-19 vaccines through the Federal Pharmacy Partnership Strategy for COVID-19 Vaccination Program.
- Most community pharmacies will be eligible to receive COVID-19 vaccines.
- Pharmacies that are participating in the Federal Pharmacy Partnership are not required to enroll with the state program.
- The CDC COVID-19 Vaccination Program Provider Agreement* describes the program requirements for providers.

*CDC COVID-19 Vaccination Program Provider Agreement: https://scdhec.gov/sites/default/files/media/document/COVID19-Vaccination_Program_Provider_Agreement_and_Profile_Form.pdf

Distribution – How/Where Will People Get Vaccines

- Pandemic vaccination planning is a combined state, territorial, tribal, and local responsibility that requires close collaboration between public health, external agencies, and community partners.
- Plans are in works for availability and to be administered to patients at hospitals, community/local health centers, and private medical offices.
- Pharmacies, including CVS, Walgreens, Walmart, and OSCO, will also have access to the vaccine and will be able to vaccinate their customers. See list on next slide for those that have signed up since 11/6/2020.
- McKesson is contracted with the government to be the central distributor for COVID 19 vaccines. However, Pfizer has decided to forego using McKesson and do its own direct shipping for now due to strict temperature control needed for product stability.
- The expectation is that the vaccine will be available to more health care settings “as the vaccine infrastructure ramps up.”

Source: CDC.gov 8 Things to Know about Vaccine Planning | CDC: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/8-things.html
COVID-19-Vaccination-Program-Interim_Playbook.pdf (cdc.gov): https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.



Source: HHS.gov

Chain and Community Pharmacy Networks Signed on to Receive & Administer COVID 19 Vaccines (as of November 2020)

- Albertsons Companies, Inc. (incl., Osco, Jewel-Osco, Albertsons, Albertsons Market, Safeway, Tom Thumb, Star Market, Shaws, Haggen, Acme, Randalls, Carrs, Market Street, United, Vons, Pavilions, Amigos, Lucky's, Pak n Save, Sav-On)
- Costco Wholesale Corp.
- CPESN USA, LLC
- CVS Pharmacy, Inc. (incl. Long's)
- Good Neighbor Pharmacy and AmerisourceBergen Drug Corporation's PSAO, Elevate Provider
- Health Mart Systems, Inc.
- H-E-B, LP
- Hy-Vee, Inc.
- LeaderNET and Medicine Shoppe, Cardinal Health's PSAOs
- Managed Health Care Associates (MHA)
- Meijer Inc.
- Publix Super Markets, Inc.
- Retail Business Services, LLC (incl., Food Lion, Giant Food, The Giant Company, Hannaford Bros Co, Stop & Shop)
- Rite Aid Corp.
- The Kroger Co. (incl., Kroger, Harris Teeter, Fred Meyer, Frys, Ralphs, King Soopers, Smiths, City Market, Dillons, Marianos, Pick-n-Save, Copps, Metro Market)
- Topco Associates, LLC (incl. Big-Y Pharmacy and Wellness Center, Brookshire's Pharmacy, Super One Pharmacy, FRESH by Brookshire's Pharmacy, Coborn's Pharmacy, Cash Wise Pharmacy, MarketPlace Pharmacy, Hartig Drug Company, King Kullen, Food City Pharmacy, Ingles Pharmacy, Raley's, Bel Air, Nob Hill Pharmacies, Save Mart Pharmacies, Lucky Pharmacies, SpartanNash, Price Chopper, Market 32, Tops Friendly Markets, ShopRite, Wegmans, Weis Markets, Acme Fresh Markets)
- Walgreens (incl. Duane Reade)
- Walmart, Inc. (incl. Sam's Club)
- Winn-Dixie Stores Inc. (incl. Winn-Dixie, Harveys, Fresco Y Mas)

Prioritization of Populations - What could this look like?

The number of individuals needed to achieve herd immunity is not known and varies by disease (CDC.gov)

Some experts speculate that achieve herd immunity, roughly 70% of the population may need to be vaccinated or have natural antibodies."

Based on 2020 U.S population of 331 Million:

- 462 million doses (0.7 x 331M x 2 doses) needed for herd immunity
- 662 million (2 x 331 million doses) for everyone in the U.S.

December 2020 – January 2021 (in order of priority)

- Health care workers (~ 19.7 M)*
- Long-term care facilities, rest homes, and assisted living facilities (~ 2.0 M)*
- Police, fire, and emergency medical services
- Congregate care settings, including homeless shelters, corrections facilities and the staff who work there
- Home-based health care workers
- Health care workers doing non-COVID-19-facing care

February 2021 – April 2021 (in order of priority)

- Individuals with 2+ comorbidities (high risk for COVID-19 complications)
- Early education, K-12, transit, grocery, utility, food and agriculture, sanitation, public works, and public health workers
- People age 65 and older
- People with one comorbidity

April 2021 and after

General public

- Vaccine being available for people under 65 without risk factors is still "months away" and "many variables being worked out" to say when this stage would get under way, but estimated for "sometime in the spring/summer if all priorities before these are achieved."
- Distribution of the vaccine will be a long process that plays out over several months, and the timeline could change based on production.

*Kaiser Family Foundation, December 10, 2020. Found at https://www.kff.org/2a7c731/

The Advisory Committee on Immunization Practices (ACIP) to the Centers for Disease Control and Prevention (CDC) recommends that first shots go to health care workers and people living in long-term care facilities, who are considered at very high risk of contracting COVID-19. However, individual states, will have the final say.

Cost Implications – The forecast

- U.S. Government has contracted with various manufacturers for the first one hundred million vaccine doses, if approved by the FDA, with options to purchase additional doses at a negotiated price.
- With the exception of deal with AstraZeneca, which offered a lower price per drug in exchange for upfront research and development costs, all the deals price COVID-19 vaccines between $20 to $42 for a two- dose course of treatment.
- No out-of-pocket cost to be incurred by patient for vaccine.
- As is customary with government-purchased vaccines, healthcare professionals or providers can charge for administering the vaccine.

	Pfizer/BionTech	Moderna (NIAID & NIH)	Johnson & Johnson	AstraZeneca/Oxford University	Novavax	Merck/IAVI	Sanofi/Glaxo Smith Kline
Product	BNT162	mRNA-1273	Ad26.COV2.S	AZD1222	NVX-CoV2373	V590	SARS-CoV2 Protein Antigen + AS03 Adjuvant
Operation Warp Speed Funding &/or Contract for first 100 Million doses	$1.95 Billion	$1.5 Billion (an additional $1 Billion was provided to fund research efforts)	$1 Billion	$1.2 Billion* (300 Million doses)	$1.6 Billion	$38 Million (funding toward preclinical research)	$2.1 Billion
Estimated Cost per Dose	$19.50	$15 - $25	$ 10	$4*	$16	--	$21
Option to purchase	500 Million more doses	Information not readily available	Information not readily available	Information not readily available	Information not readily available	Information not readily available	Information not readily available

*AstraZeneca signed a $1.2 billion agreement with the U.S. government to produce up to 300 million doses of the vaccine. But the funding will support both the vaccine's phase 3 trials and manufacturing, so per dose cost isn't clear.

Source: Fact Sheet: Explaining Operation Warp Speed | HHS.gov. https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html. Accessed 12/11/2020

BARDA, Biomedical Advanced Research and Development Authority

BARDA, Medical Counter Measures Portfolio, https://medicalcountermeasures.gov/App/barda/coronavirus/COVID19.aspx

Payment Allowances for COVID-19 Vaccines and Administration during the Public Health Emergency:

- Medicare Part B Payment for COVID-19 Vaccines during the Public Health Emergency for Vaccine and Administration have been published.
- CMS has released a set of toolkits for providers, states and insurers to help the health care system prepare and assist in swiftly administering these products once they become available.
- Resources are designed to increase the number of providers that can administer the products and ensure adequate reimbursement for administration in Medicare, while making it clear to private insurers and Medicaid programs their responsibility to cover these products at no charge to beneficiaries.
- Webpage provides the payment allowances and other related information for these products.

CODE	CPT SHORT DESCRIPTOR	LABELER NAME	VACCINE/PROCEDURE NAME	PAYMENT ALLOWANCE	EFFECTIVE DATES
91300	SARSCOV2 VAC 30MCG/0.3ML IM	Pfizer	Pfizer-Biontech Covid-19 Vaccine	$0.010*	xx/xx/xxxx – TBD
0001A	ADM SARSCOV2 30MCG/0.3ML 1ST	Pfizer	Pfizer-Biontech Covid-19 Vaccine Administration – First Dose	$16.940	xx/xx/xxxx – TBD
0002A	ADM SARSCOV2 30MCG/0.3ML 2ND	Pfizer	Pfizer-Biontech Covid-19 Vaccine Administration – Second Dose	$28.390	xx/xx/xxxx – TBD
91301	SARSCOV2 VAC 100MCG/0.5ML IM	Moderna	Moderna Covid-19 Vaccine	$0.010*	xx/xx/xxxx – TBD
0011A	ADM SARSCOV2 100MCG/0.5ML1ST	Moderna	Moderna Covid-19 Vaccine Administration – First Dose	$16.940	xx/xx/xxxx – TBD
0012A	ADM SARSCOV2 100MCG/0.5ML2ND	Moderna	Moderna Covid-19 Vaccine Administration – Second Dose	$28.390	xx/xx/xxxx – TBD

*Note: CMS anticipates that providers and/patients, initially, will not incur a cost for the vaccine. Therefore, CMS plans to update the payment allowance for vaccine at a later date. Providers should not bill for the product, if they received it for free.

References:

Coronavirus (COVID-19) Partner Toolkit | CMS: https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-toolkit
COVID-19 Vaccines and Monoclonal Antibodies | CMS: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies
Laboratories: CMS Flexibilities to Fight COVID-19: https://www.cms.gov/files/document/covid-19-laboratories.pdf

Knowns vs Unknowns about COVID-19 Vaccines

	Knowns	Unknowns
Efficacy	• Likely to prevent symptomatic COVID-19 • Adverse effects immediately after 1st and 2nd dose.	• What is the spectrum that the disease can prevent (prevent people from showing no symptoms or only very mild symptoms)? • How well the vaccine works in different populations that need it the most (elderly) – those included in Pfizer's study were included but few. Difficult to generalize. • Other vulnerable populations (pregnancy/lactation, adolescents/children) • How long will the vaccine's effectiveness last? Is one or even two doses enough? • Right now, experts aren't sure how long people are immune to COVID-19 (e.g., natural immunity) after being infected.
Safety	• Healthy individuals age 16 and over • Cautionary use in those with history of allergies • Patients who have had COVID-19 should still get the vaccine. There's no evidence that it's harmful in any way. Right now, experts aren't sure how long people are immune to virus that causes COVID-19, after being infected.	• Long term safety profile (after 2 months) • Does the vaccine prevent transmission and spread of the disease (masking and social distancing will still be encouraged/required)? • Risk in patients with multiple comorbidities
Distribution	• Prioritized to those high risk	• How long before vaccine is made available for general public
Cost	• Vaccines purchased by U.S. government with U.S taxpayer dollars to be given to Americans at no cost • Vaccination fee for administration (likely reimbursed by patient's public/private insurance company or for uninsured, by the Health Resources and Services Administration's Provider Relief fund (www.HHS.gov) • Cost of COVID testing will continue to be financial burden incurred by payers and in certain cases, by the patient.	

Thank you

Questions

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25+ year professional commitment on advancing sound medication management principles and strategies based on a strong scientific and value-based foundation for healthcare decision-making. Served in direct patient care (retail, clinic, hospital, home infusion services) and executive roles in health plans, national pharmacy benefit managers, and startup healthcare companies.

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