

COVID-19 Safety Update and Vaccine Information

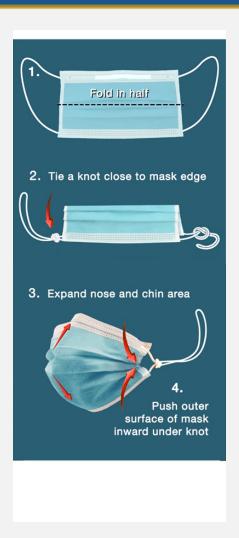
Jessica McCormick-Ell, Ph.D., SM (NRCM), CBSP, RBP Director, NIH Division of Occupational Health and Safety

Fit is critical- focus should be on improving fit

- Knot and tuck (brief demonstration)
- Mask fitters/ braces

Recommendations about Double Masking

- Indoor settings where physical distancing is not feasible, and personnel will work in close proximity for more than 15 minutes
- Where population densities will briefly (less than 30 minutes) exceed 1 person per 200 to 250 square feet
- When work requires travel in a shared vehicle (e.g., animal transport)
- Public settings such as public transportation or grocery stores



Post Vaccination Safety

- Safety Guidance still applies!
- Face coverings, distancing and density measures are all important
- Vaccines are meant to prevent serious disease and hospitalization. Persons can still get COVID diseasealthough will likely be mild or asymptomatic testing
- Asymptomatic testing is recommended, especially since post vaccine infections can be very mild

NIH COVID-19 Vaccination Program

- The goal of the NIH COVID-19 Vaccination Program is to minimize workplace transmission of SARS-CoV-2, the virus that causes COVID-19.
- NIH frontline staff who work onsite at NIH facilities in clinical or essential operation positions are being prioritized to receive the COVID-19 vaccine first.
- The NIH is currently offering the Moderna COVID-19 Vaccine to prevent COVID-19 illness among staff.
- Additional vaccines may be offered in the future based on safety and availability.

Vaccination Program Stats

As of 2/25/2021	Maryland	Montana	North Carolina	Total
Dose 1 Appointments Tomorrow	240	27	-	267
Dose 1 Appointments Available	240	40	-	280
Dose 2 Appointments Tomorrow	107	-	-	107
Dose 2 Appointments Available	240	-	-	240
Eligible Staff	11,961	397	-	12,358
Staff Responses	8,382	361	-	8,743
Response Rate	70%	91%	#N/A	71%
Upcoming Dose 1 Appointments	1,068	41	-	1,109
Upcoming Dose 2 Appointments	730	163	-	893
Declinations	322	52	-	374
Deferrals	230	38	-	268
Vaccinated Elsewhere	879	-	-	879
Dose 1 Administrations To Date	6,416	224	-	6,640
Dose 2 Administrations to Date	4,451	24	-	4,475
Medical Attestations Received	2,139			2,139



COVID-19 Vaccines in Development: Status as of February 25, 2021





mRNA



Phase 3 Launch July 2020

EUA Dec 18, 2020





mRNA

Phase 3 Launch **July 2020**

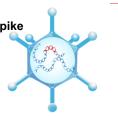
EUA Dec 11, 2020





Adenovirus wT spike vector





Phase 3 Launch August 2020

Phase 3 Launch Sept 1 dose 2020

Enrollment completing

EUA meeting 2/26/2021likely approved

Enrollment completed





Recombinant protein + adjuvant _{S2}

Recombinant protein + adjuvant S2P



Phase 3 Launch Dec 2020

Phase 3 Launch 2021

Courtesy: AS Fauci/NIAID



Vaccines with FDA EUA

- Two vaccines have received FDA Emergency Use Authorizations (EUAs):
 - Pfizer/BioNTech (BNT162b2) 95% effective (manufacturer data)
 - Moderna (mRNA-1273) 94.5% effective (manufacturer data)
- Both are mRNA vaccines with a 2-dose schedule. People being vaccinated should complete the two-dose series with the same vaccine product.
- Duration of protection is not yet known.
- For the latest information about authorized vaccines, visit the FDA COVID-19 Vaccine Website at: www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

Sources: https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy



Explanation of a Vaccine Trial

Phase 1 20-100 Healthy Volunteers



Researchers try to answer these questions:

- · Is this vaccine safe?
- Are there any serious side effects?
- How does the vaccine dose relate to any side effects?
- Is the vaccine causing an immune response?

Phase 2 Several Hundred Volunteers



Researchers try to answer these questions:

- What are the most common short-term side effects?
- What's the body's immune response?
- Are there signs that the vaccine is protective?

Phase 3 1000+ Volunteers



Researchers try to answer these questions:

- How do disease rates compare between people who get the vaccine and those who do not?
- How well can the vaccine protect people from disease?

Phase 4 Vaccine is Approved



Researchers try to answer these questions:

- FDA approves a vaccine only if it's safe, effective, and benefits outweigh the risks.
- Researchers continue to collect data on the vaccine's long-term benefits and side effects.

Source: https://covid19community.nih.gov/resources/understanding-clinical-trials

Updates on Numbers in Vaccine Trials

Pfizer/BioNTech

- 45,302 enrolled
 - **43,125** received 2nd dose
- 150 clinical sites
 - **39** U.S. states
- Racial/ethnic distribution
 - **70%** White
 - **13%** Hispanic
 - 10% African American
 - **6%** Asian
 - 1% Native American
- **40%** ages 56-85

Sources: https://www.pfizer.com/science/coronavirus/vaccine; https://www.modernatx.com/cove-study

For more information, visit <u>www.clinicaltrials.gov</u>

Moderna

- 30,000 enrolled
 - **25,654** received 2nd dose
- 89 clinical sites
 - **32** U.S. states
- Racial/ethnic distribution
 - 63% White
 - **20%** Hispanic
 - 10% African American/Black
 - 4% Asian
 - **3%** All others
- 64% ages 45 and older
 - 39% ages 45-64
 - 25% ages 65+



What is the Moderna Vaccine?

- The Moderna COVID-19 Vaccine (mRNA-1273) is an mRNA vaccine developed to prevent Coronavirus Disease 2019 caused by SARS-CoV-2.
- The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19. It contains one gene from the virus, which is the protein that binds cells in the human body. This will generate an immune response.
- The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the arm muscle. You will need to return for dose 2, 28 days after Dose 1. You will receive a reminder at the time of administration.
- The duration of protection is currently unknown.

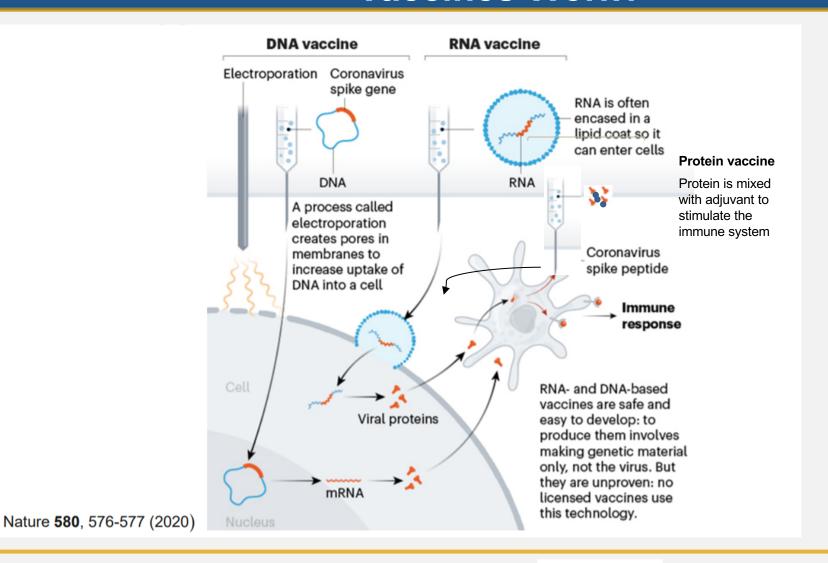


What is the Pfizer-BioNTech Vaccine?

- The Pfizer-BioNTech COVID-19 vaccine is not currently offered at NIH but may be in the future. It is an mRNA vaccine developed to prevent Coronavirus Disease 2019 caused by SARS-CoV-2
- The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19. It contains one gene from the virus, which is the protein that binds cells in the human body. This will generate an immune response.
- The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.
- The duration of protection is currently unknown.



How do DNA, RNA and Protein Vaccines Work?





How do COVID-19 mRNA vaccines work?

- COVID-19 mRNA vaccines give instructions for our cells to make a harmless piece of what is called the "spike protein." The spike protein is found on the surface of the virus that causes COVID-19.
- COVID-19 mRNA vaccines are given in the upper arm muscle. Once the instructions (mRNA) are inside the immune cells, the cells use them to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them.
- Next, the cell displays the protein piece on its surface. Our immune systems
 recognize that the protein doesn't belong there and begin building an immune
 response and making antibodies, like what happens in natural infection against
 COVID-19.
- At the end of the process, our bodies have learned how to protect against future infection. The benefit of mRNA vaccines, like all vaccines, is those vaccinated gain this protection without ever having to risk the serious consequences of getting sick with COVID-19.



Who should get the vaccine?

	Moderna	Pfizer-BioNTech
Who should get the vaccine?	18 years and older	16 years and older
Who should not get the vaccine?	Prior history of severe allergic reaction to this vaccine or any product in this vaccine	Prior history of severe allergic reaction to this vaccine or any product in this vaccine
Ingredients	Messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.	Messenger ribonucleic acid (mRNA), lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.



Possible Side Effects

- The data show common side effects among those vaccinated and should be expected.
- Indicative of immune response
- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, hardness, and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

Possible Side Effects- Moderna

 Percentage of Participants with Solicited Local and Systemic Adverse Reactions Within 7 Days After Each Dose in Participants 18-64 Years

	Moderna Dose 1	Moderna Dose 2
Pain	86.9 %	89.9%
Fatigue	38.4%	67.6%
Headache	35.3%	62.8%
Muscle pain	23.7%	61.6%
Joint pain	16.6%	45.5%
Swelling/Tenderness	11.6%	16.2%
Chills	9.2%	48.6%
Nausea / Vomiting	9.4%	21.4%
Fever	0.9%	17.4%



Possible Side Effects-Moderna

 Percentage of Participants with Solicited Local and Systemic Adverse Reactions Within 7 Days After Each Dose in Participants 65 Years and Older

	Moderna Dose 1	Moderna Dose 2
Pain	74.0%	83.2%
Fatigue	33.3%	58.3%
Headache	24.5%	46.2%
Muscle pain	19.7%	47.1%
Joint pain	16.4%	35.0%
Swelling/Tenderness	6.1%	8.5%
Chills	5.4%	30.9%
Nausea / Vomiting	5.2%	11.8%
Fever	0.3%	10.0%



Possible Side Effects-Pfizer

Percentage of Participants with Solicited Local Reactions Within 7
 Days After Each Dose in Participants 18-55 Years

	Pfizer-BioNTech Dose 1	Pfizer-BioNTech Dose 2
Redness	4.5%	5.9%
Swelling	5.8%	6.3%
Pain at Injection Site	83.1%	77.8%
Fever	3.7%	15.8%
Fatigue	47.4%	59.4%
Headache	41.9%	51.7%
Chills	14.0%	35.1%
Vomiting	1.2%	1.9%
Diarrhea	11.1%	10.4%
Muscle pain	21.3%	37.3%
Joint pain	11.0%	21.9%



Possible Side Effects-Pfizer

Percentage of Participants with Solicited Local Reactions Within 7
 Days After Each Dose <u>in Participants 55 Years and Older</u>

	Pfizer-BioNTech Dose 1	Pfizer-BioNTech Dose 2
Redness	4.7%	7.2%
Swelling	6.5%	7.5%
Pain at Injection Site	71.1%	66.1%
Fever	1.4%	10.9%
Fatigue	34.1%	50.5%
Headache	25.2%	39.0%
Chills	6.3%	22.7%
Vomiting	0.5%	0.7%
Diarrhea	8.2%	8.3%
Muscle pain	13.9%	28.7%
Joint pain	8.6%	18.9%



Robust vaccine safety monitoring

- Existing systems and data sources are used to monitor safety of vaccines post-authorization and post-licensure, such as:
 - Vaccine Adverse Event Reporting System (VAERS)
 - Vaccine Safety Datalink (VSD)
 - Clinical Immunization Safety Assessment (CISA)
 - Biologics Effectiveness and Safety System (BEST)
- New systems have been developed to monitor COVID-19 vaccine safety, such as v-safe:
 - Active surveillance that uses text messaging to initiate web-based survey monitoring.
 - Will provide telephone follow up to anyone who reports medically significant adverse events.



Reported Adverse Events Since Trials

 Most commonly reported adverse events to Vaccine Adverse Event Reporting System (VAERS) after COVID-19 vaccines

Pfizer-BioNTech COVID-19 vaccine (N= 7,307)

Moderna	COVID-19	vaccine	(N = 1.786)
WIOGETTIA		vaccinc	(1 1 1 - 1.7007

Adverse Event	N (%)
Headache	1,550 (21.2)
Fatigue	1,192 (16.3)
Dizziness	1,113 (15.2)
Nausea	1,014 (13.9)
Chills	983 (13.5)
Fever	962 (13.2)
Pain	958 (13.1)
Injection Site Pain	716 (9.8)
Pain in Extremity	610 (8.4)
Difficulty breathing	536 (7.3)

Adverse Event	N (%)
Headache	430 (24.1)
Fever	333 (18.6)
Chills	315 (17.6)
Pain	290 (16.2)
Dizziness	289 (16.2)
Fatigue	287 (16.1)
Nausea	281 (15.7)
Injection Site Pain	208 (11.6)
Pain in Extremity	189 (10.6)
Difficulty breathing	172 (9.6)



Reported Adverse Events Since Trials-VSAFE

Local and Systemic Reactions, day 0-7	All vaccines %	Pfizer- BioNTech Dose 1 %	Pfizer- BioNTech Dose 2 %	Moderna Dose 1 %
Pain	70.7	67.7	74.8	70.1
Fatigue	33.4	28.6	50.0	29.7
Headache	29.4	25.6	41.9	26.0
Myalgia	22.8	17.2	41.6	19.6
Chills	11.5	7.0	26.7	9.3
Fever	11.4	7.4	25.2	9.1
Sweating	11.0	6.8	26.7	13.4
Joint pain	10.4	7.1	21.2	8.6
Nausea	8.9	7.0	13.9	7.7



Risk of Allergic Reactions

- The risk of experiencing any allergic reaction is low. The vast majority of reported allergic reactions are mild.
- The most common allergic reactions are rash at the injection site and injection site urticaria (raised itchy red bumps).
- According to Moderna's EUA submission, allergic reactions were only reported in 1.5% vaccine recipients and 1.1% of placebo recipients.

Risk of Anaphylaxis

- The risk of severe allergic reaction (anaphylaxis) is extremely low.
- Estimated anaphylaxis reporting rates following COVID-19 vaccines based on VAERS reports and reported doses administered

Reported vaccine doses administered	Anaphylaxis cases	Reporting rate (analytic period Dec 12-Jan 18)
Pfizer-BioNTech: 9,943,247	50	5.0 per million doses admin.
Moderna: 7,581,429	21	2.8 per million doses admin.



Risk of Anaphylaxis

- The majority of those who experienced anaphylaxis had a prior history of allergies or allergic reactions
- 64 / 71 (90%) presented in 30 minutes or less



Risk of Anaphylaxis

Anaphylaxis reports to VAERS following COVID-19 vaccines

Characteristics	Pfizer-BioNTech (N = 50)	Moderna (N = 21)
Median age, years (range)	38.5 (26-63)	39 (24-63)
Female (%)	47 (94)	21 (100)
Minutes to symptom onset, median (range)	10 (<1-1200 [20hrs])	10 (<1-45)
Symptom onset ≤15 minutes (%)	37 (74)	18 (86)
Symptom onset ≤30 minutes (%)	45 (90)	19 (90)
Documented h/o allergies or allergic rxns (%)	40 (80)	18 (86)
Documented h/o prior anaphylaxis	12 (24)	5 (24)
Dose number (1 st , 2 nd , unknown)	42, 3, 5	19, 1, 1



Tell OMS If You Have Any of the Following

- Tell the vaccination provider about all of your medical conditions, including if you:
 - have any allergies
 - have a fever
 - have a bleeding disorder or are on a blood thinner
 - are immunocompromised or are on a medicine that affects your immune system
 - are pregnant or plan to become pregnant
 - are breastfeeding
 - have received another COVID-19 vaccine



Additional Information

- OMS: 301-496-4411
- Email: <u>OMSCovidVaccineProgram@mail.nih.gov</u>
- DOHS: 301-496-2960
- CDC FAQs: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/moderna-faqs.html
- NIH FAQs: <u>https://employees.nih.gov/pages/coronavirus/frequent</u> <u>ly-asked-questions.aspx</u>

What is my risk of experiencing an allergic reaction after vaccination?

- The risk of experiencing any allergic reaction is low. The vast majority of reported allergic reactions are mild.
- According to Moderna's EUA submission, allergic reactions were only reported in 1.5% vaccine recipients and 1.1% of placebo recipients.
- The most common allergic reactions are rash at the injection site and injection site urticaria (raised itchy red bumps). Two individuals in the Moderna trial, out of thousands, experienced a severe allergic event.
- To date, there have been no reported allergic fatalities from receiving either the Moderna vaccine or Pfizer-BioNTech vaccine.

Was the vaccine developed too fast?

- This vaccine initiative was conducted with unprecedented collaboration, financing and rigor to help support its successful production.
- The NIH chartered an independent Data and Safety Monitoring Board to review clinical trial data by Moderna.
- The Food and Drug Administration has independently approved the use of both the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine.
- Data reporting has been transparent.



Can we wait to see how other people do with the vaccine before we take it?

- The data show both the Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine are safe and effective at preventing COVID-19 illness.
- Over 34,000 subjects received an mRNA vaccine from the Moderna and Pfizer-BioNTech in initial studies. In the Moderna trial, no vaccinated individual presented with severe COVID-19 illness and only one person in the Pfizer study.
- The overall efficacy rate for both vaccines was greater than 94%.
- Since approval, over 24 million doses have been administered in the US alone,
 71 million globally. No deaths have been reported as a result of the vaccine.

I don't take the flu shot, why should I take this shot?

- COVID-19 illness is not the same as seasonal influenza infection. SARS-CoV-2 has higher infectivity rates and higher mortality rates compared to seasonal influenza virus.
- In one year, there have been 25.5 million reported cases of SARS-CoV-2 and 425,000 deaths in the US. This is much higher than metrics reported from the last three influenza seasons.

Influenza	Symptomatic Illnesses	Deaths
Season	Estimate	Estimate
2017-2018*	45,000,000	61,000
2018-2019*	36,000,000	34,000
2019-2020*	38,000,000	22,000

 SARs-CoV-2 can often result in chronic and unpredictable medical outcomes that often present long after the infection has been cleared.



I don't want to feel sick after getting vaccinated.

- Both vaccines greatly reduce the risk of becoming ill with COVID-19.
- The vaccine is designed to trigger a protective immune response to prevent COVID-19 infection.
- Mild side effects are expected and usually resolve in 1-2 days.
- The mild side effects that may be experienced are a sign that your body is building immunity against the actual SARS-CoV-2 virus.

I have heard people die after getting vaccinated.

- After millions of delivered doses, there have been no deaths proven to to be the result of receiving the Moderna or Pfizer-BioNTech vaccines.
- Clinical trials for the vaccines met stringent safety standards. The death of any participant, vaccinated or unvaccinated, was reported and investigated. No death was attributed to the vaccine.

I'm worried about getting vaccinated because I don't want to risk unpaid leave from work.

- Those who get vaccinated lower their risk of both mild and severe COVID illness.
- Most side effects from vaccination resolve in 1-2 days. In contrast, COVID-18 infection can result in severe and chronic health conditions lasting months.
- Individuals are allowed to work after vaccination as long as they are not COVID-positive and don't have any recent known exposures.
- Getting vaccinated will protect you, others, and is essential to ending the pandemic.



The vaccine doesn't excuse someone from a COVID contact quarantine?

- The vaccine will reduce the risk of COVID-19 illness, but it is currently unknown whether COVID-19 vaccines prevent transmission of COVID-19 (i.e. sterilizing immunity).
- Even after vaccination, individuals must follow proper public health guidance to prevent potential viral transmission to others.
- Keep wearing face coverings, practice physical distancing, frequently washing your hands.
- Anyone who had close contact with someone with COVID-19 should stay home for 14 days after their last exposure to that person to prevent potential transmission to others.



Has the Federal Government stopped providing assistance to individuals losing jobs or away from work due to a COVID case or contact trace isolation?

 Please contact your supervisor or administrative officer to discuss any human resource concerns you may have as a result of the COVID-19 pandemic.

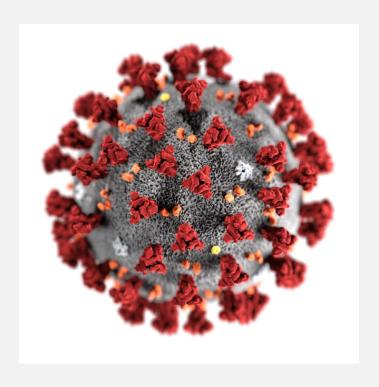


References

Miller, J (2020). Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation -Emergency Use Authorization (EUA) Application for mRNA-1273 :mRNA- 1273 Efficacy [PowerPoint slides]. FDA. https://www.fda.gov/media/144583/download.



Parts of the Coronavirus



RNA – the molecular message that enables production of the proteins needed for other parts of the virus

Nucleoproteins – proteins that help give the virus its structure and enable it to replicate

Viral Envelope – protects the virus, made from lipids, anchors the different structural protein needed for the virus to infect cells

Envelope proteins – embedded in lipid layer, help the virus infect cells

Spike proteins – act as hooks to allow the virus to attach to host cells



Moderna Efficacy by Subgroup

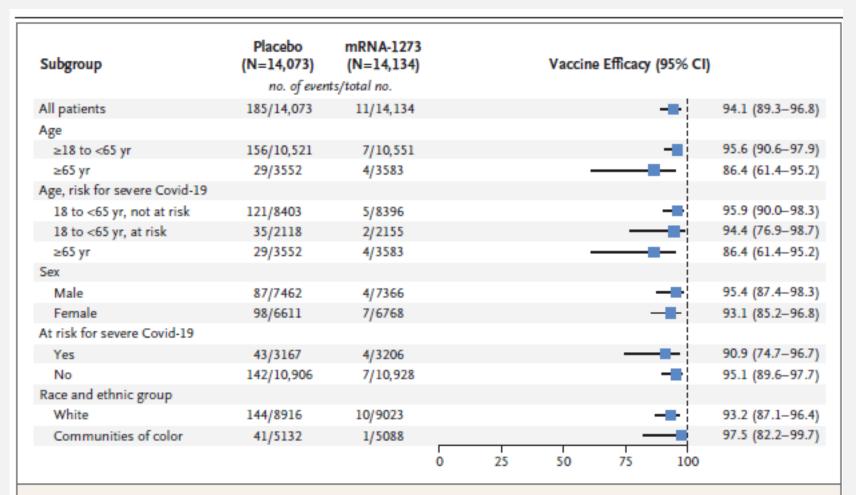
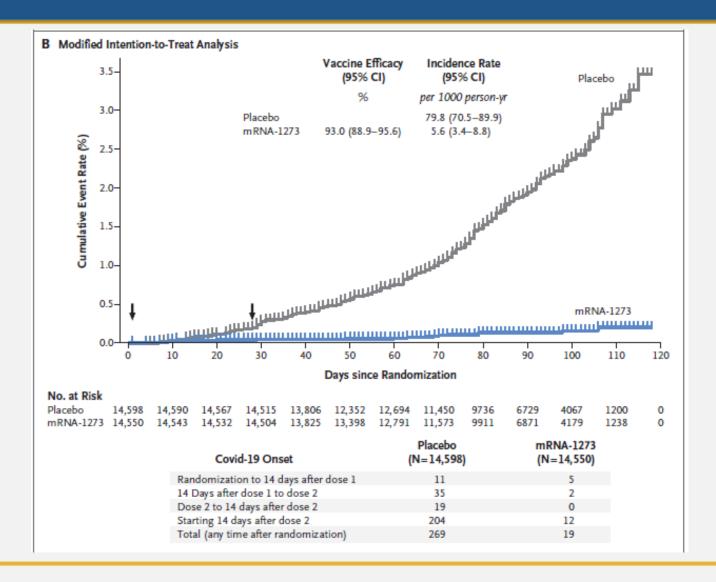


Figure 4. Vaccine Efficacy of mRNA-1273 to Prevent Covid-19 in Subgroups.

Baden & Sahly et al, NEJM Dec 30, 2020

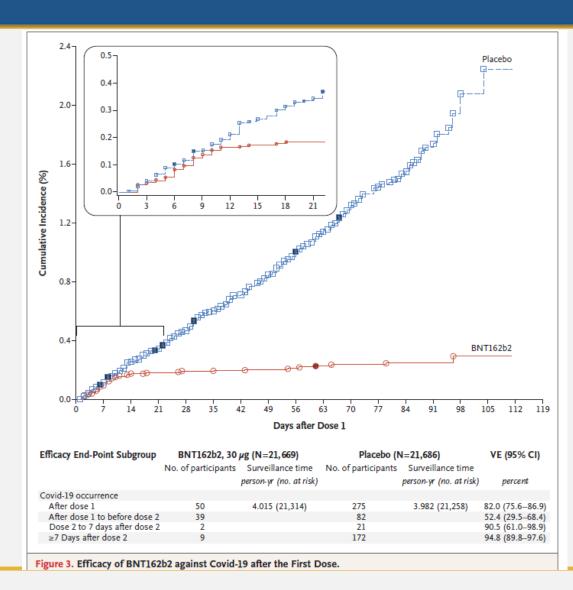


Moderna Efficacy: Cumulative Incidence Rate





Pfizer Efficacy: Cumulative Incidence Rate



Polack et al, NEJM Dec 10, 2020



Pfizer Efficacy by Subgroup

Efficacy End-Point Subgroup		BNT162b2 (N=18,198)		Placebo =18,325)	Vaccine Efficacy, % (95% CI)†
	No. of Cases	Surveillance Time (No. at Risk)*	No. of Cases	Surveillance Time (No. at Risk)*	
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0-97.9)
Age group					
16 to 55 yr	5	1.234 (9,897)	114	1.239 (9,955)	95.6 (89.4-98.6)
>55 yr	3	0.980 (7,500)	48	0.983 (7,543)	93.7 (80.6-98.8)
≥65 yr	1	0.508 (3,848)	19	0.511 (3,880)	94.7 (66.7-99.9)
≥75 yr	0	0.102 (774)	5	0.106 (785)	100.0 (-13.1-100.0)
Sex					
Male	3	1.124 (8,875)	81	1.108 (8,762)	96.4 (88.9-99.3)
Female	5	1.090 (8,536)	81	1.114 (8,749)	93.7 (84.7-98.0)
Race or ethnic group‡					
White	7	1.889 (14,504)	146	1.903 (14,670)	95.2 (89.8-98.1)
Black or African American	0	0.165 (1,502)	7	0.164 (1,486)	100.0 (31.2-100.0)
All others	1	0.160 (1,405)	9	0.155 (1,355)	89.3 (22.6-99.8)
Hispanic or Latinx	3	0.605 (4,764)	53	0.600 (4,746)	94.4 (82.7-98.9)
Non-Hispanic, non-Latinx	5	1.596 (12,548)	109	1.608 (12,661)	95.4 (88.9-98.5)
Country					
Argentina	1	0.351 (2,545)	35	0.346 (2,521)	97.2 (83.3-99.9)
Brazil	1	0.119 (1,129)	8	0.117 (1,121)	87.7 (8.1-99.7)
United States	6	1.732 (13,359)	119	1.747 (13,506)	94.9 (88.6-98.2)

Polack et al, NEJM Dec 10, 2020

