Vaccine Update
Moderna
01_14_2021

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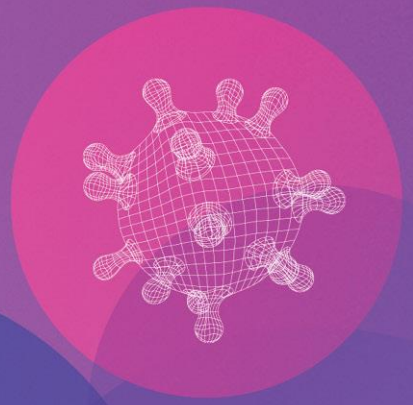


THE QUEEN'S HEALTH SYSTEMS

Moderna Vaccine

- On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Moderna COVID-19 (mRNA-1273) vaccine (ModernaTX, Inc; Cambridge, Massachusetts
- This vaccine is the second COVID-19 vaccine authorized under an EUA for the prevention of COVID-19 in the United States
- Vaccination with the Moderna COVID-19 vaccine consists of 2 doses (100 µg, 0.5 mL each) administered intramuscularly, 1 month (4 weeks) apart.
- (ACIP) issued an interim recommendation for use of the Moderna COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19

11,148,991 People have received a first dose of vaccine as of 01_14_2021

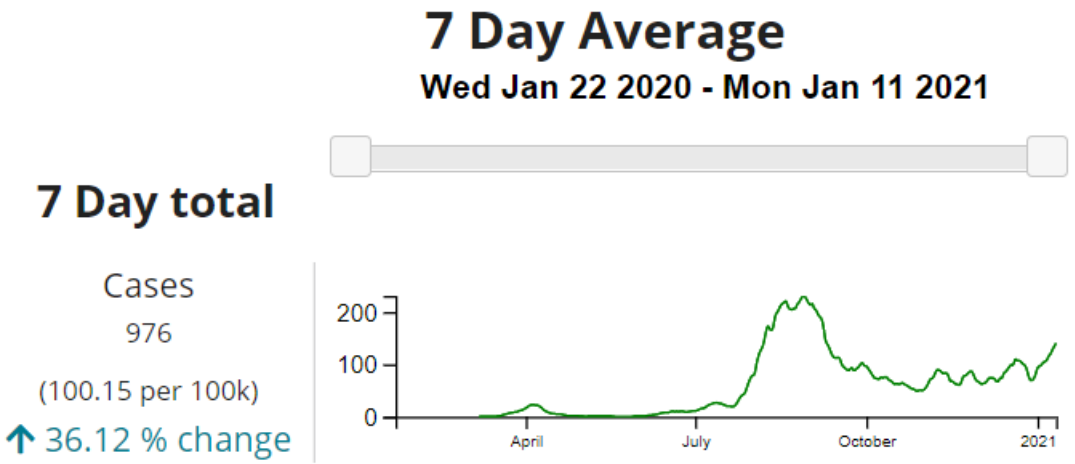
30,628,175 doses have been distributed

CDC recommends giving COVID-19 vaccine in phases, which may overlap:

1a: Healthcare personnel **and** Long-term care facility residents

1b: Frontline essential workers **and** People age 75 years and older

1c: People aged 65 through 74 years **and** People aged 16 through 64 years with underlying medical conditions **and** Other essential workers



Moderna COVID-19 Vaccine

- **General Information:**
  Multidose vial: 10 doses per vial
  Dosage: 0.5 mL
- Do NOT mix with a diluent.
  Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.
- **Age Indications:**
  18 years of age and older
- **Schedule:**
  2-dose series separated by 28 days
  A series started with COVID-19 vaccine (Moderna) should be completed with this product.
- **Administer:**
  Intramuscular (IM) injection in the deltoid muscle

Moderna COVID-19 Vaccine

- **General Information:**
  Vaccine may be thawed in the refrigerator or at room temperature.
- Refrigerator: Between 2°C and 8°C (36°F and 46°F) for 2 hours and 30 minutes
- Room temperature: Between 15°C and 25°C (59°F and 77°F) for 1 hour
- Vials that have not been punctured may be kept between 8°C and 25°C (46°F and 77°F) for up to 12 hours. Do **NOT** refreeze thawed vaccine.

- Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*
- Unpunctured vials: Check the expiration date.
  Never use expired vaccine.
  Punctured vials: Check the beyond-use time. Never use vaccine after the beyond-use time.
- With the vial upright, gently swirl the vaccine. Do NOT shake. If the vial is shaken, contact the manufacturer.
  Note: Gently swirl the vaccine before withdrawing subsequent doses.
- Examine the vaccine. It should be white to off-white in color and may contain white particles. Do not use if liquid contains other particulate matter or is discolored.
- Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.
- Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.

*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

- Withdraw 0.5 mL of vaccine into the syringe.[+] Ensure the prepared syringe is not cold to the touch.
- Note the date and time the vial was first punctured. Keep the vaccine between 2°C and 25°C (36°F and 77°F) for up to 6 hours. Discard any unused vaccine after 6 hours.
- Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.
- Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients older than 2 years of age (if tolerated).
- Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.
- Observe recipients after vaccination for an immediate adverse reaction:
  - **30 minutes**: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
  - **15 minutes**: All other persons

Contraindications:

- Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine
- Immediate allergic reaction* of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [(PEG]). See /Appendix B: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines.
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

Precautions:

- History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
- Moderate to severe acute illness

*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis, that occur within 4 hours following exposure to a vaccine or medication.

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine recommendations			
Recommended to receive 2nd dose of mRNA COVID-19 vaccine?	No	Yes	Yes

- Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called pegylation to improve the therapeutic activity of some medications (including certain chemotherapeutics).
- Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur.

"Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533-1540. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdfpdf icon

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

General Information

Interpretation of SARS-CoV-2 test results in vaccinated persons

- Prior receipt of an mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests). Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to one of two viral proteins: spike or nucleocapsid.
- a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination
- Antibody testing is not currently recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person.

Interpretation of tuberculosis test results in vaccinated persons

- Inactive vaccines do not interfere with tuberculosis (TB) test results. There is no immunologic reason to believe either a Tuberculin Skin Test (TST) (administered by intradermal placement of 0.1 cc of purified protein derivative) or blood draw for interferon gamma release assay (IGRA) would affect the safety or effectiveness of mRNA COVID-19 vaccines.
- We have no data to inform the impact of the COVID-19 mRNA vaccines on either TB test for infection (i.e., TST or IGRA).

General Information

Vaccine efficacy

Preliminary data suggest high vaccine efficacy in preventing COVID-19 following receipt of two doses of mRNA COVID-19 vaccine (Pfizer-BioNTech: 95.0% [95% CI: 90.3%, 97.6%]; Moderna: 94.1% [95% CI: 89.3%, 96.8%]). Limited data are currently available regarding the efficacy of a single dose. Patients should be counseled on the importance of completing the two-dose series (of the same vaccine product) to optimize protection.

Reactogenicity

Local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms. Depending on vaccine product (Pfizer vs. Moderna), age group, and vaccine dose, approximately 80–89% of vaccinated persons develop at least one local symptom and 55–83% develop at least one systemic symptom following vaccination.

General Information

- In clinical trials, hypersensitivity-related adverse events were observed in 0.63% of participants who received the Pfizer-BioNTech COVID-19 vaccine and 1.5% of participants who received the Moderna COVID-19 vaccine, compared to 0.51% and 1.1%, respectively, in the placebo groups.
- Anaphylaxis following vaccination was not observed in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials. However, anaphylactic reactions have been reported following receipt of mRNA vaccines outside of clinical trials.
- Antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.
- However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, as information on the impact of such use on mRNA COVID-19 vaccine-induced antibody responses is not available at this time.

Table 1. Local reactions in persons aged 18-64 years, Moderna COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Moderna Vaccine N=11401	Placebo N=11404	Moderna Vaccine N=10357	Placebo N=10317
Any Local, n (%)				
Any	9960 (87.4)	2432 (21.3)	9371 (90.5)	2134 (20.7)
Grade 3	452 (4.0)	39 (0.3)	766 (7.4)	41 (0.4)
Pain[a], n (%)				
Any	9908 (86.9)	2179 (19.1)	9335 (90.1)	1942 (18.8)
Grade 3	367 (3.2)	23 (0.2)	479 (4.6)	21 (0.2)
Redness[a], n (%)				
Any	345 (3.0)	46 (0.4)	928 (9.0)	42 (0.4)
Severe	34 (0.3)	11 (<0.1)	206 (2.0)	12 (0.1)
Swelling[b], n (%)				
Any	768 (6.7)	33 (0.3)	1309 (12.6)	35 (0.3)
Grade 3	62 (0.5)	3 (<0.1)	176 (1.7)	4 (<0.1)
Axillary Swelling/Tenderness[c], n (%)				
Any	1322 (11.6)	567 (5.0)	1654 (16.0)	444 (4.3)
Grade 3	36 (0.3)	13 (0.1)	45 (0.4)	10 (<0.1)

[a] Pain grade 3: any use of prescription pain reliever or prevented daily activity; grade 4: required emergency room visit or

- Pain grade 3: any use of prescription pain reliever or prevented daily activity; grade 4: required emergency room visit or hospitalization.
- Swelling grade 3: >100mm/>10cm; grade 4: necrosis/exfoliative dermatitis.
- Axillary swelling or tenderness was collected as a solicited local adverse reaction (i.e., lymphadenopathy: localized axillary swelling or tenderness ipsilateral to the vaccination arm); grade 3: any use of prescription pain reliever or prevented daily activity; grade 4: required emergency room visit or hospitalization.
- Note: No grade 4 local reactions were reported.

Table 2. Local reactions in persons aged ≥65 years, Moderna COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Moderna Vaccine N=3762	Placebo N=3746	Moderna Vaccine N=3587	Placebo N=3549
Any Local, n (%)				
Any	2805 (74.6)	566 (15.1)	3010 (83.9)	473 (13.3)
Grade 3	77 (2.0)	39 (1.0)	212 (5.9)	29 (0.8)
Pain[a], n (%)				
Any	2782 (74.0)	481(12.8)	2990 (83.4)	421 (11.9)
Grade 3	50 (1.3)	32 (0.9)	96 (2.7)	17 (0.5)
Redness[a], n (%)				
Any	86 (2.3)	19 (0.5)	265 (7.4)	13 (0.4)
Grade 3	8 (0.2)	2 (<0.1)	75 (2.1)	3 (<0.1)
Swelling[b], n (%)				
Any	166 (4.4)	19 (0.5)	386 (10.8)	13 (0.4)
Grade 3	20 (0.5)	3 (<0.1)	69 (1.9)	7 (0.2)
Axillary Swelling/Tenderness[c], n (%)				
Any	231 (6.1)	155 (4.1)	302 (8.4)	90 (2.5)
Grade 3	12 (0.3)	14 (0.4)	21 (0.6)	8 (0.2)

Serious Adverse Events

- Serious adverse events were defined as any untoward medical occurrence that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, or resulted in persistent disability or incapacity.
- The proportions of participants who reported at least one serious adverse event were 1% in the vaccine group and 1% in the placebo group. The most common serious adverse events occurring at higher rates in the vaccine group than the placebo group were myocardial infarction (5 cases in vaccine group vs. 3 cases in placebo group), cholecystitis (3 vs. 0), and nephrolithiasis (3 vs. 0).
- Three serious adverse events were considered by the U.S. Food and Drug Administration (FDA) as possibly related to vaccine: the one report of intractable nausea/vomiting and two reports of facial swelling in persons who had a previous history of cosmetic filler injections. The possibility that the vaccine contributed to the serious adverse event reports of rheumatoid arthritis (n=1), peripheral edema/dyspnea with exertion (n=1), and autonomic dysfunction (n=1) cannot be excluded.