COVID Town Hall Vaccine Updates
Moderna Vaccine

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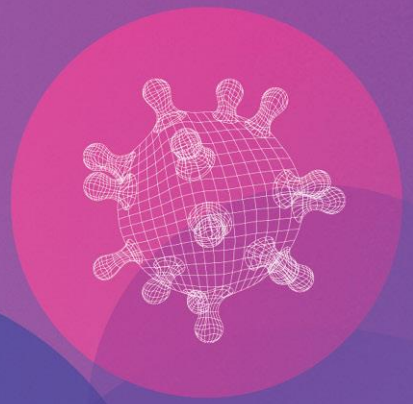

THE QUEEN'S HEALTH SYSTEMS

Vaccines Currently Under EUA

Pfizer BioNTech COVID-19 Vaccine and Moderna

- Moderna is a biotechnology company founded in 2010 in Cambridge, Massachusetts with a primary focus on the class of medications based on messenger RNA (mRNA).
- Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) in individuals 18 years of age and older.
- Similar technology is used by formulating the vaccine in lipid particles which same allows the delivery of the modified mRNA into host cells. This in turn allows expression of the SARS-CoV-2 Spike antigen leading to eliciting an immune response to the Spike antigen, which protects against COVID-19.
- **Reminder: vaccines based on messenger RNA (mRNA) technology do not use inactivated virus, attenuated virus, or any other kind of virus.**

Efficacy Analysis

- The primary efficacy analysis population (referred to as the Per-Protocol Set), included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073). All were negative for SARS-CoV-2 at baseline.
- Median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).
- Cases of COVID-19, starting 14 days after Dose 2, were defined as symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom.
- 0 cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group

Safety Analysis

Safety was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older and is ongoing in the United States (NCT04470427). This involved 30,351 participants. Reported AE were as follows:

- Pain at the injection site (92.0%)
- Fatigue (70.0%)
- Headache (64.7%)
- Myalgia (61.5%)
- Arthralgia (46.4%)
- Chills (45.4%)
- Nausea/vomiting (23.0%)
- **Axillary swelling/tenderness (19.8%)**
- Fever (15.5%)
- Swelling at the injection site (14.7%)
- Erythema at the injection site (10.0%).

Adverse Events Reported

- As of November 25, 2020, 1.0% or 147 participants reported serious adverse events and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell's palsy which occurred 32 days following receipt of vaccine.
- Two serious adverse events of facial swelling in vaccine recipients with a history of injection of **dermatological fillers**. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and felt to be related. This included facial and lip swelling.
- There was **one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization.** This event occurred 1 day after vaccination and was likely related to vaccination.
- There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Vaccine Storage and Administration

- Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25º to -15ºC (-13º to 5ºF), in the original carton and not on dry ice or below -40ºC (-40ºF).
- Can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use
- Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours.
- A carton of Moderna COVID-19 Vaccine contains 10 multiple-dose vials. Each vial contains 10 doses. A case includes 12 cartons, or a total of 120 vials providing 1,200 doses. A shipping pallet may include up to 192 cases.
- The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.
- Full prescribing the EUA can be found here https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

Additional Information

- Among trial participants in the safety analysis, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, **4.6% were Asian**, 0.8% were American Indian or Alaska Native, **0.2% were Native Hawaiian or Pacific Islander**, 2.1% were Other, and 2.1% were Multiracial.
- The clinical considerations for both Pfizer and Moderna are similar and are listed on the CDC website: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
- Hypersensitivity-related adverse events were observed in 0.63% of Pfizer-BioNTech and 1.5% of Moderna COVID-19 vaccine clinical trial participants who received the vaccine, compared to 0.51% and 1.1%, respectively, in the placebo groups.
- As stated previously 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, however, **routine use 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.
- https://www.modernatx.com/covid19vaccine-eua/providers/faq

Additional Information

- Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine is a contraindication to vaccination for both the Pfizer-BioNTech external and Moderna external COVID-19 vaccines.
- 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 additional medications (including some injectable contraceptives and steroids).
- CDC considers a history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a **precaution but not a contraindication** to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines (as these vaccines contain ingredients in common).
- Allergic reactions (including severe allergic reactions) not related to vaccines or injectable therapies (e.g., food, pet, venom, or environmental allergies; allergies to oral medications [including the oral equivalents of injectable medications]) are not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine.

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	Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)
	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 (Proprietary to Moderna)
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

Suspicions grow that nanoparticles in Pfizer's COVID-19 vaccine trigger rare allergic reactions

By Jop de Vrieze Dec. 21, 2020, 5:10 PM

Anaphylactic reactions can occur with any vaccine, but are usually extremely rare – about one per 1 million doses. As of 19 December, the United States had seen six cases of anaphylaxis among 272,001 people who received the COVID-19 vaccine, according to a recent presentation by Thomas Clark of the U.S. Centers for Disease Control and Prevention (CDC); the United Kingdom has recorded two.

PEGs are also used in everyday products such as toothpaste and shampoo as thickeners, solvents, softeners, and moisture carriers, and they've been used as a laxative for decades

As much as 72% of people have at least some antibodies against PEGs, according to a 2016 study led by Samuel Lai, a pharmaco-engineer at the University of North Carolina, Chapel Hill, presumably as a result of exposure to cosmetics and pharmaceuticals.

complement activation-related pseudoallergy (CARPA), a nonspecific immune response to nanoparticle-based medicines, often PEGylated, that are mistakenly recognized by the immune system as viruses.

Ref https://www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

FIGHT COVID-19 | GET VACCINATED

THE QUEEN'S HEALTH SYSTEMS

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15 minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** • History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies • History of allergy to oral medications (including the oral equivalent of an injectable medication) • Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) • Family history of anaphylaxis • Any other history of anaphylaxis that is not related to a vaccine or injectable therapy **ACTIONS** • 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause • 15 minute observation period: Persons with allergic reaction, but not anaphylaxis	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine) • History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy **ACTIONS:** • Risk assessment • Potential deferral of vaccination • 30 minute observation period if vaccinated	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine **ACTIONS** • Do not vaccinate

* See Special Populations section for information on patient counseling in these groups

Stay Tuned for Next Steps