



Town of New Castle, NH  
Settled 1623  
Incorporated 1693

## COVID19 Update December 18, 2020

This update has more detail for those who prefer this level of detail.

### **1) The FDA advisory committee voted to recommend an emergency use authorization for the Moderna COVID-19 vaccine December 17, 2020.**

This is a second mRNA vaccine. The FDA must again formally approve this, and then the vaccine may roll out and be given as early as Monday December 21, 2020. This also CANNOT cause a COVID infection, however, you may feel side effects of the vaccine as it causes the immune system to mount a protective response to potential future infection. The initial vaccine rollout is still planned to be given to phase people in category 1a.

More detail on this courtesy of Tony Coniglio:

Moderna Vaccine- Wednesday December 16 Moderna and the FDA released detailed information on their Phase 3 vaccine study of 30,351 people. Here are the highlights of the data, what to expect in the next few days, and Q&A:

**Efficacy** (see comparative data to Pfizer in table below. The efficacy data is overall very similar between the two).

The overall efficacy of the vaccine in the prevention of symptomatic COVID 19 infections was 94.1%.

The efficacy was 86.4% in people 65 yo and older.

In all other subgroups examined the efficacy was >90% including Communities of Color and People at Risk for Severe disease (e.g. Chronic lung disease, Cardiac disease, Severe obesity, Diabetes, Liver disease, or HIV).

The vaccine prevented Severe COVID 19 infections. There were 0 cases of severe infection in the vaccine group as compared to 30 in placebo.

Importantly, Moderna performed a nasopharyngeal swab and tested for the virus just before the second dose. There were 14 (0.1%) positive swabs in the vaccine group and 38 (0.3%) positive in the placebo group. This is some of the first encouraging data that the vaccine can prevent asymptomatic infection.

Also there were 2,075 volunteers who only received 1 dose of the vaccine. After 28 days, the efficacy rate was 80.2%. This is also encouraging for people who fail to return for their second dose although more data and longer follow-up are needed. Note the efficacy is higher in those who receive their second dose.

Safety (see table below for comparisons to the Pfizer data and the Shingrix vaccine).  
Qualitatively the side effects of Moderna as compared to Pfizer are very similar.

The median follow-up is approximately two months (53.6% of volunteers have 2 months of follow-up and 87.9% have 1 month of follow-up after the 2nd dose). This is very similar to the Pfizer follow-up. Data from other vaccine studies show most side effects occur within 6 weeks of dosing.

The most common side effects that are related to the Moderna vaccine, in order of highest to lower are:

Injection site reactions, for example pain, redness, swelling, enlarged lymph nodes  
Fatigue  
Headache  
Muscle Pain  
Joint Pain  
Chills/Shivering  
Nausea/Vomiting  
Fever

Side effects tended to start within 1-2 days of dosing, resolved within 2-3 days, occurred more frequently in younger vs. older people, and were more frequent after the 2nd dose than the first dose.

The severe side effects that occur in 2% or greater are Fatigue 9.6%, Myalgia (muscle pain) 8.6%, Headache 5.5% and Arthralgia (joint pain) 5.1%

Moderna did not see anaphylaxis or severe allergic reactions in their studies.

What to expect in the coming days:

Soon the FDA will likely officially approve the Emergency Use Authorization (EUA). The CDC Advisory Committee will meet over the weekend and also is expected to recommend approval.

Moderna will start shipping next week.

There will probably be further discussion on the allergic reactions reported with the Pfizer vaccine and the need for data on adolescents, pediatrics, pregnant and breast-feeding women, duration of protection, and determining whether the vaccine prevents asymptomatic infection and contagiousness/transmission.

Questions and Answers:

### **What are the similarities and differences between the Pfizer and Moderna vaccines?**

Similarities: two dose mRNA lipid nano particle vaccines; Consistent high efficacy in all subgroups tested. Efficacy starts about 14 days after the first dose. Side effects are similar and occur soon after dosing, are greater in younger than older people and are greater after the second dose.

Differences: Second dose on day 21 for Pfizer and day 28 for Moderna. Higher rate of some side effects with Moderna. Pfizer can be used in 16 and 17 yo whereas Moderna is restricted to 18 and above. Temperatures for shipping and storage are lower for Pfizer.

### **Was Bell's palsy (facial paralysis, drooping) also seen with Moderna?**

Yes, there were 3 in the Moderna vaccine group compared to 1 in the placebo.

### **Are there new data on infertility?**



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Yes, Moderna reported on their rat study of Development and Reproductive Toxicity (DART). This is a standard study done for new drugs and biologics. The vaccine is given prior to mating and during gestation (pregnancy) periods. At the same dose as the EUA, 100 micrograms, the vaccine did not have any adverse effects on female reproduction or fetal development. Also there were 6 volunteers who became pregnant in the vaccine clinical study and 7 in placebo. Adverse events were reported in two placebo volunteers and none of the vaccine group. Not only does the rat study show no adverse impact on reproduction, in both the Pfizer and Moderna studies, there were similar numbers of pregnancies in the vaccine compared to placebo groups.

#### **Do the vaccines work if you are already COVID 19 positive?**

Yes, the data from both the Moderna and Pfizer studies have some volunteers who were positive at the start of the study and, although the numbers are limited, the data are encouraging for efficacy.

#### **Is there anything unusual about the serious or medically significant side effects with Moderna?**

Moderna reported on three female volunteers who reported facial swelling or lip edema 1-2 days after vaccination. All of these volunteers had previous dermal filler or cosmetic filler injections in their face and/or lips. This may be due to an inflammatory reaction from the interaction of the immune response to the vaccine and the dermal filler.

**Table 1 COVID 19 vaccines**

	<b>Pfizer/BioNTech</b>	<b>Moderna</b>	<b>J&amp;J Janssen</b>	<b>AstraZeneca Oxford</b>
Number of Patients in Study	43, 661	27,817	40,000	40,051
Days of Dosing	0, 21 (two shots)	0, 28 (two shots)	0 (one shot)	0, 28 (two shots)
% Volunteers Black	10%	10%		
& Volunteers Hispanic	26.1%	20%		
Age Range in Study	16 yo and older	18 yo and older	18 yo and older	18 yo and older
Number of Infections (primary endpoint)	8	11		30

events) in vaccine group*				
Number of Infections (primary endpoint events) in the placebo group	162	185		101
Efficacy Rate	95%	94.1%		70%
Efficacy in Adults >65yo	94%	86.4%		
Number of Severe Infections in Vaccine group	1	0		0
Number of Severe infections in Placebo	9	30		
Shipping and storage temperature	-70 C	-20 C	-20 C	2-8 C
Days stable in refrigerator (2-8 C)	5	30	90	180

\*Note, the primary endpoint definition differed slightly between the two studies with Moderna's definition requiring more than one symptom (more stringent) for some symptom groupings

### Comparing Side Effects of Pfizer and Moderna COVID 19 vaccine to Shingrix shingles vaccine

	<b>Pfizer/BioNTech</b>	<b>Moderna</b>	<b>Shingrix 50-59 year olds</b>
Number of subjects	18,858	15,184	1,315
Pain	83.1%	91.6%	88.4%
Axillary Lymphadenopathy (pain/swelling in arm pit of the vaccinated arm)	0.3%	14.2%*	
Redness	5.9%	8.6%%	38.7%
Swelling	6.3%%	12.2%	30.5%
Myalgia (muscle aches)	38.3%	59.6%	56.9%
Fatigue	62.9%	68.5%	57.0%
Headache	55.1%	63.0%	50.6%
Shivering/Chills	31.9%	43.4%	35.8%
Fever	14.2%	15.5%	27.8%



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GI (nausea, vomiting, diarrhea or abdominal pain)	2.6%	19.0%*	24.3%
Arthralgia (Joint Pain)	23.6%	44.8%	1.7%
Severe/Grade 3 side effects occurring in >2% of volunteers	Fatigue 3.8%; headache 2.0%	Fatigue 9.6% Myalgia (muscle pain) 8.6% Headache 5.5% Arthralgia (joint pain) 5.1%	Pain 10.3%, Myalgia (muscle pain) 8.9%, Fatigue 8.5%, Headache 6.0%, Shivering 6.8%, GI 2.1%

\*May be higher than Pfizer data because Moderna “Solicited” this side effect (i.e. asked the volunteers)

2) The FDA has issued emergency authorization for the [first at-home coronavirus test](#).

### 3) Links for more information:

Link for Vaccine Group 1A

<https://www.dhhs.nh.gov/dphs/cdcs/covid19/documents/phase-1a-technical-assistance.pdf>

If you wish to volunteer for the AstraZeneca COVID-19 vaccine trial, you may phone 603-319-

8863, or go to <https://activmedresearch.com/>

Links to research studies:

<https://www.nih.gov/coronavirus>

[https://www.covidvaccinestudy.com/?utm\\_source=ct&utm\\_medium=ct&utm\\_campaign=ct&utm\\_term=ct&StudyID=C4591001](https://www.covidvaccinestudy.com/?utm_source=ct&utm_medium=ct&utm_campaign=ct&utm_term=ct&StudyID=C4591001)

Updated FAQ from the State of New Hampshire regarding COVID:

<https://www.dhhs.nh.gov/dphs/cdcs/covid19/documents/covid-19-faq.pdf>

COVID dashboard website- for daily positivity rate, school infections, graphics, etc.

<https://www.nh.gov/covid19/dashboard/overview.htm>

COVID numbers update by town:

[https://www.wmur.com/article/new-hampshire-town-by-town-covid-cases/34879297?utm\\_source=Sailthru&utm\\_medium=email&utm\\_campaign=Coronavirus%20Newsletter%202020-12-10&utm\\_term=wmur-coronavirus\\_COMBINED](https://www.wmur.com/article/new-hampshire-town-by-town-covid-cases/34879297?utm_source=Sailthru&utm_medium=email&utm_campaign=Coronavirus%20Newsletter%202020-12-10&utm_term=wmur-coronavirus_COMBINED)

CDC guidance for holiday celebrations:

<https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/holidays.html>

Yours in Health,

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