



Town of New Castle, NH
Settled 1623
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COVID Update February 5, 2021

1. Second Dose Vaccines:

The state is changing from the federal scheduling system to its own in the next several weeks. Additionally, Governor Sununu has guaranteed that residents who have received their first dose of vaccine via the phase 1B of the COVID-19 distribution will be able to receive their second dose within a week of the recommended intervals for both the Moderna and Pfizer vaccines. This is supposed to be available by the start of next week. It is adding tens of thousands of second-shot appointment slots per day per state officials in the Portsmouth Herald.

2. J and J vaccine (likely the next vaccine that will become available in the US)

The J&J Janssen single shot vaccine Phase 3 data from a study of 43,783 participants is out. **The study shows that this vaccine was 100% effective in preventing hospitalization and/or death from COVID-19.** The efficacy for preventing severe infections was 85%. When examining only US sites the efficacy was 72%. Internationally it showed an overall efficacy of 66% in preventing COVID-19 infections within 28 days after receiving vaccination. The onset of protection was as early as 14 days. Although the efficacy for preventing infections compared to Pfizer or Moderna is lower, this vaccine is one shot rather than two and can be stored in the refrigerator for up to 90 days. Expect that J&J has submitted the data to the FDA with anticipated approval of the Emergency Use Authorization in several weeks.

3. Efficacy against South African Variant:

Two vaccines in US development have reported efficacy rates from studies in South Africa.

J&J Janssen reported data on efficacy in 6,756 participants from South Africa. 95% of the infections in either the placebo or vaccine groups were with the South African variant. **Efficacy was 57%.** This compares to the 72% efficacy seen with the J&J vaccine in the US.

Novavax reported on efficacy in 4,400 participants from South Africa. 90% of the infections in either the placebo or vaccine groups were with the South African variant. **Efficacy was 49.4%.** This compares to 89.3% efficacy in the UK study of the Novavax vaccine.

4. Other vaccines:

Astra Zenica: Health officials across the world looking to stretch their vaccine supplies got some encouraging news. New data from Oxford and AstraZeneca suggests that a single dose of

their vaccine provides strong protection in clinical trials, [even when second shots are delayed by at least three months](#). It is reported to be **72% effective three weeks after the first dose**.

Also, very importantly, **the vaccine developed by the University of Oxford and AstraZeneca has the potential to slow the transmission of the virus**.

In more detail: Researchers measured the impact on transmission by swabbing participants every week seeking to detect signs of the virus. If there is no virus present, even if someone is infected, it cannot be spread. And they found [a 67 percent reduction in positive swabs](#) among those vaccinated.

This means that if the conclusions are confirmed, there is a large chance that the vaccine not only decreases one's chance of getting COVID, it also decreases one's ability to transmit the virus to others.

“While this would be extremely welcome news, we do need more data before this can be confirmed and so it's important that we all still continue to follow social distancing guidance after we have been vaccinated,” said Dr. Doug Brown.

Studies in the US are ongoing on the Astra Zenica vaccine, with attention to people age 65 and older, as some countries have stated there are not enough data present to support giving it to those 65 years old or older.

Sputnik V: A vaccine developed in Russia, known as Sputnik V, has exceeded expectations in a new study that showed it to [have a 91.6 percent efficacy rate against the coronavirus](#) without serious side effects. The vaccine is cheap, costing approximately \$20 for 2 shots, and it does not need to be stored at ultracold temperatures. It was developed quickly.

4. Current State of Vaccination in the US:

As of Feb 2, 26 Million people have received at least 1 dose and 6 million have received two doses. The CDC studied the distribution of vaccine over the first month. Among over 12 million vaccine recipients 63.0% were women and 37.0% were men; 55.0% were aged ≥ 50 years, 16.8% were aged 40–49 years, and 28.2.% were aged 18–39 years; 60.4% were White and 39.6% represented racial and ethnic minorities, including 14.4% categorized as multiple or other race/ethnicity, 11.5% Hispanic/Latino, 6.0% Asian, 5.4% Black, 2.0% AI/AN, and 0.3% NH/PI. Among 11,460 Skilled Nursing Facilities with at least one vaccination clinic conducted during the first month of the CDC Pharmacy Partnership for Long-Term Care Program, a median of 77.8% of residents and 37.5% of staff members received ≥ 1 vaccine dose through the program.

We need to do a better job vaccinating groups at high risk of COVID 19 infections including Hispanic/Latinos, Blacks, and staff members at Skilled Nursing Facilities.

5. Vaccine availability nationally:



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This week Pfizer announced that the US delivery of 200 million doses of their vaccine will be complete by the end of May. This is 2 months earlier than previously expected. Also the US announced that beginning next week some shipments of vaccine will go directly to retail pharmacies. I do not know currently that this changes any dosing sites in New Hampshire.

Moderna is asking regulators for approval [to increase the number of doses in each vial to 15 from 10](#), arguing that the lower threshold is hampering its output.

5. FAQs

A. If we need to change the current vaccines to address the new variants, we will have to wait for full development and Phase 3 studies?

No, it shouldn't require as much time as the original vaccine development. The Pfizer and Moderna mRNA vaccines can be adjusted in the lab to address new variants within 6-8 weeks if needed. Rather than full efficacy studies in 30-40 thousand participants, it should be possible to study a much smaller number of participants and rather than measuring efficacy, the antibody production in blood could be used as an endpoint. This should shorten the availability of a new vaccine by several months and is sometimes called a "bridging" strategy.

B. Is the AstraZeneca vaccine effective in people 65 and older?

The German vaccine committee recently indicated that there was insufficient data to support efficacy in those over 65. However this was not based on the US study. The US trial completed enrollment and has 23.6% of the study population 65 and older. Therefore it is anticipated when AstraZeneca applies for EUA at FDA, there should be sufficient data to support efficacy in this age group.

C. Can patients with cancer, transplants or autoimmune diseases receive the vaccine? Are there data supporting efficacy and safety? Are there concerns?

Patients with these conditions were not enrolled in the Phase 3 trials however they are at high risk for complications from COVID 19 infection and therefore should speak with their doctor and pursue vaccination. Many Medical Societies supporting these groups have advocated for vaccination. The mRNA vaccines are not live or attenuated virus so there is not a concern over viral infection. There is a chance that the antibody production and therefore efficacy may be less but this shouldn't preclude vaccination.

D. For those who are detail oriented, here is a repeat table of vaccines in late development in the US:

COVID 19 vaccines in the US in 2021

	Pfizer/BioNTech	Moderna	J&J Janssen	AstraZeneca Oxford	Novavax
Names	BNT162b2 Comirnaty (tozinameran)	mRNA-1273	JNJ-78436735 (formerly Ad26.COV2.S)	AZD1222 (ChAdOx1-S* recombinant)	NVX-CoV2373
Type of Vaccine	mRNA	mRNA	Non-replicating viral vector (adenovirus)	Replication-deficient viral vector vaccine (adenovirus from chimpanzees)	full-length, prefusion spike protein Nanoparticle saponin-based Matrix-M™ adjuvant
Number of Patients in Study	43, 661	27,817	43,783	40,051 (efficacy data based on interim analysis of 11,636)	30,000 (2:1 randomization vaccine:placebo)
Days of Dosing	0, 21 (two shots)	0, 28 (two shots)	0 (one shot)	0, 28 (two shots)	0, 21 (two doses)
% Volunteers Black	10%	10%	19%	4.4%	
% Volunteers Hispanic	26.1%	20%	45%		
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 events) in vaccine group*	8	11		30	
Number of Infections (primary endpoint events) in the placebo group	162	185		101	
Efficacy Rate	95%	94.1%	66%	70.4%	
Efficacy in Adults >65yo	94%	86.4%			



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Number of Severe Infections in Vaccine group	1	0		0	
Number of Severe infections in Placebo	9	30		1	
Shipping and storage temperature	-70 C	-20 C	-20 C	2-8 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

Many thanks again to Tony and Diane Coniglio for their contributions to this update.
Yours in Health,

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