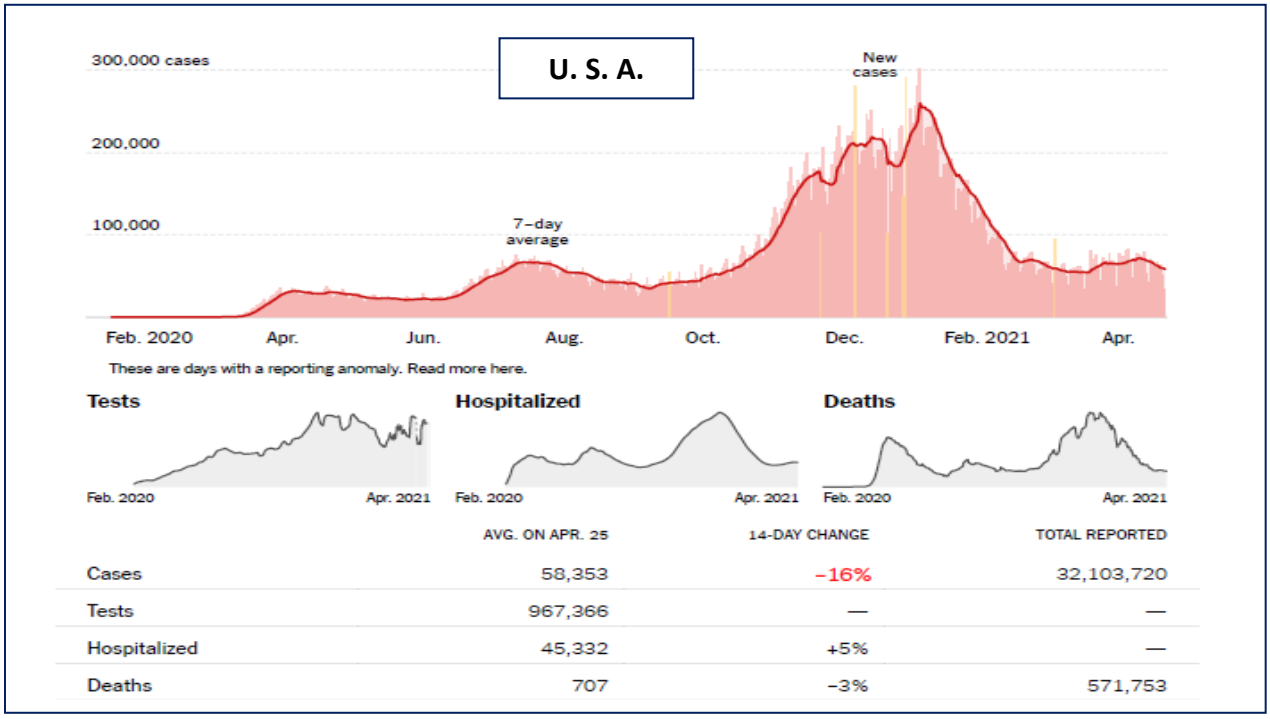
COVID-19 UPDATE – MONDAY, APRIL 26, 2021

Dear Members of the DoM Community,

Good morning to you. Here are what's happening in the COVID-19 pandemic last week. I hope the information keeps you updated on the status of the pandemic.

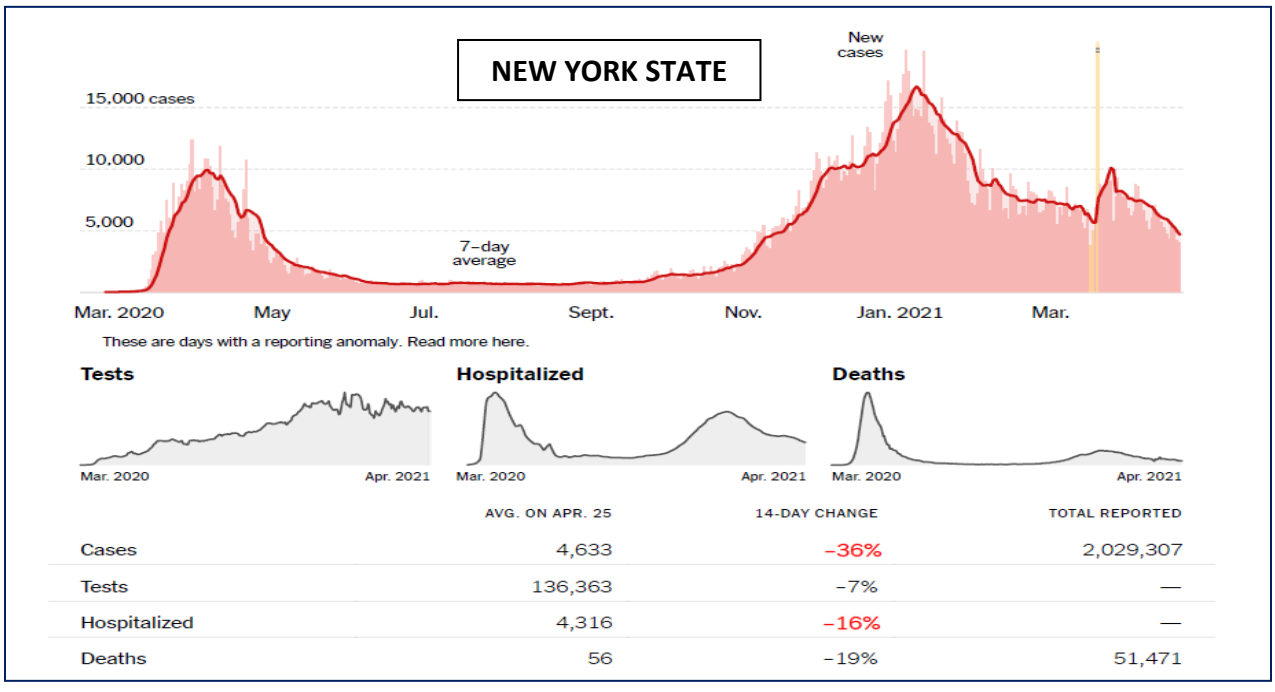
1. Nationwide COVID-19 Data

Finally, the daily new case numbers in the U.S. have started to decline.



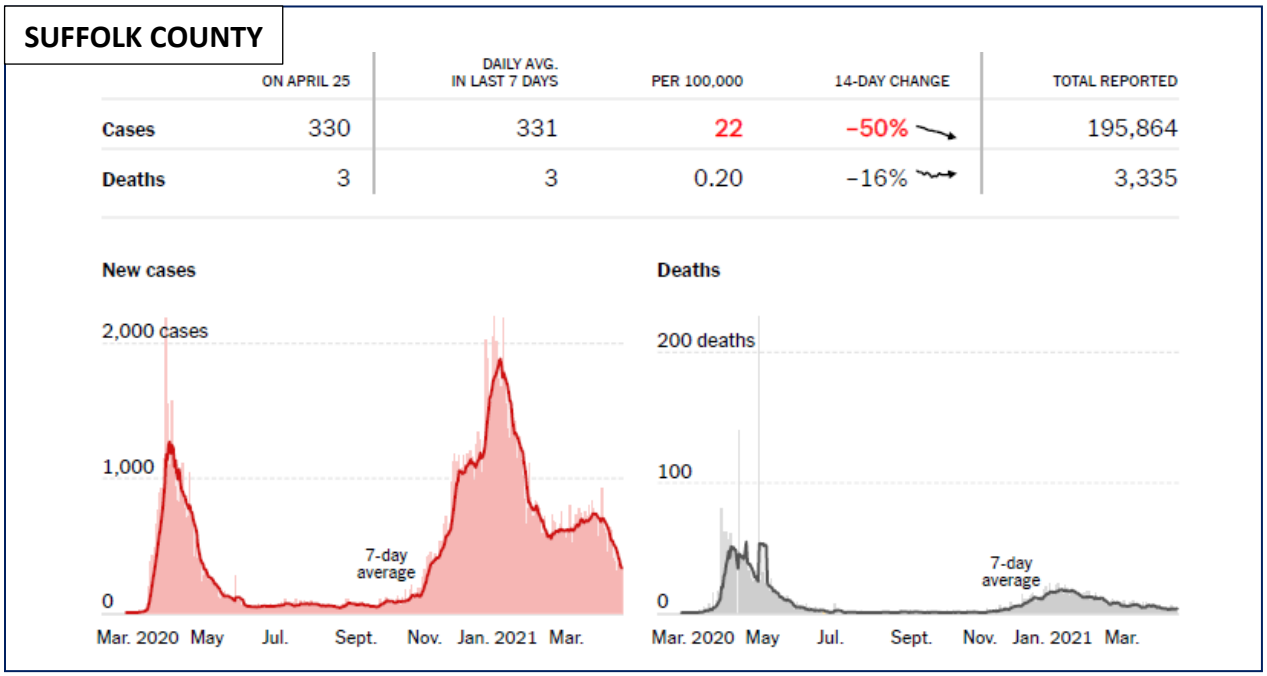
	AVG. ON APR. 25	14-DAY CHANGE	TOTAL REPORTED
Cases	58,353	-16%	32,103,720
Tests	967,366	—	—
Hospitalized	45,332	+5%	—
Deaths	707	-3%	571,753

2. New case numbers and numbers of hospitalized patients in New York State continue to decrease.



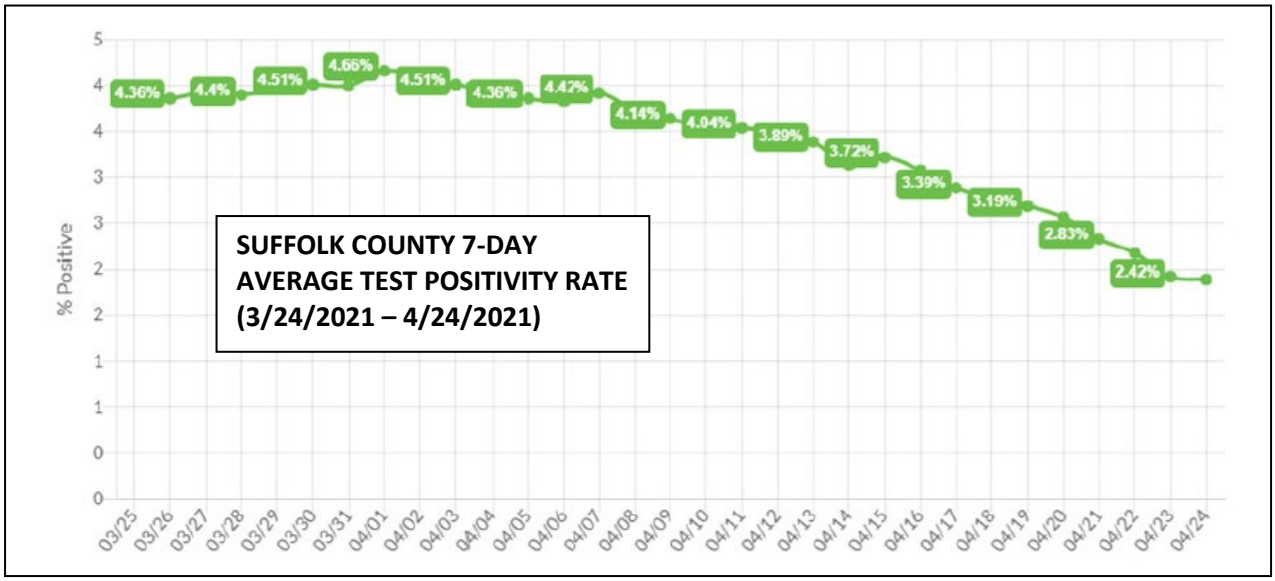
	AVG. ON APR. 25	14-DAY CHANGE	TOTAL REPORTED
Cases	4,633	-36%	2,029,307
Tests	136,363	-7%	—
Hospitalized	4,316	-16%	—
Deaths	56	-19%	51,471

3. ***Case numbers in Suffolk County have also declined significantly, now at a 7-day average of 22 per 100,000 population. This is a decrease of 12 per 100,000 from a week ago.***



COVID-19 Testing in Suffolk County on April 24:

- 14,738 COVID-19 tests were administered.
- 330 new cases were reported.; 7-day average = 339, a **decrease of 166** from one week ago.
- 195,864 total cases have been reported since March of 2020.
- Seven-day average test positivity rate = 2.4%, a **decrease of 1%** from a week before (see 4-week trend below).



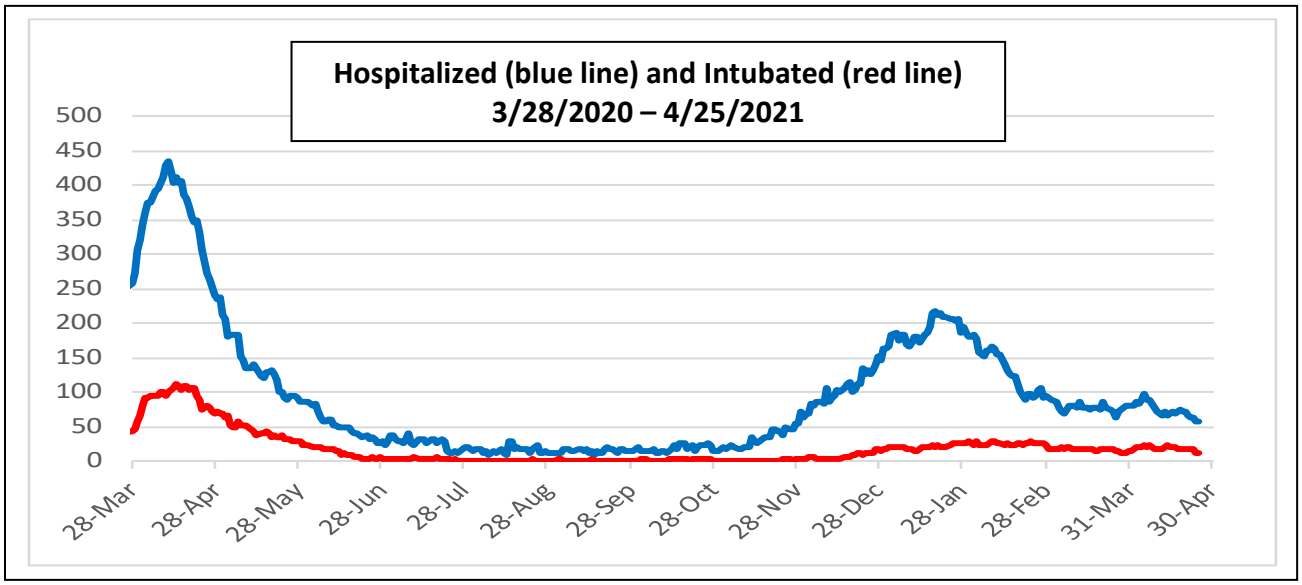
Fatalities:

- 3,335 total fatalities, an **increase of 21** from one week before.

COVID-19 Hospitalizations:

- 244 individuals were hospitalized, a **decrease of 38** from one week before.
- 61 patients were in the Intensive Care Unit (ICU), a **decrease of 10** from a week ago.

4. Daily COVID-19 Hospitalization Data in SBUH



At midnight Sunday, April 25, SBUH census is as follows (see figure above for all-time trend of hospitalization).

- 56 COVID + inpatients; 7-day average = 64, a **decrease of 7** from one week before.
  - 16 patients were in ICU level of care; 11 on ventilators; 11 in ICR.
  - COVID admissions on Sunday = 1.
  - COVID live discharges =1.
  - COVID-related deaths = 0.
- Total hospital census = 607; Med/Surg = 484 (110%).

5. SARS-CoV-2 Viral Variants Update (source = CDC; NYC Health Department)

- The Health Department in New York City has identified multiple variants of interest and variants of concern, notably the **B.1.1.7** and the **B.1.526** variants:

Specimen collection date, week	Total specimens sequenced by PRL	B.1.1.7 (N, %)	B.1.351 (N, %)	B.1.429 (N, %)	B.1.427 (N, %)	P.1 (N, %)	B.1.526 (N, %)+		B.1.525 (N, %)	P.2 (N, %)
							S:E484K+ (N, %)	S:E484K- (N, %)		
Feb 8 - 14	734	52 (7.1%)	0 (0%)	9 (1.2%)	4 (0.5%)	0 (0%)	111 (15.1%)	103 (14%)	1 (0.1%)	3 (0.4%)
Feb 15 - 21	826	69 (8.4%)	2 (0.2%)	5 (0.6%)	8 (1.0%)	0 (0%)	133 (16.1%)	121 (14.6%)	1 (0.1%)	0 (0%)
Feb 22 - 28	990	118 (11.9%)	0 (0%)	12 (1.2%)	4 (0.4%)	0 (0%)	207 (20.9%)	178 (18%)	4 (0.4%)	2 (0.2%)
March 1 - 7	715	125 (17.5%)	0 (0%)	14 (2.0%)	3 (0.4%)	0 (0%)	168 (23.5%)	153 (21.4%)	1 (0.1%)	0 (0%)
March 8 - 14	1481	141 (9.5%)	0 (0%)	13 (0.9%)	2 (0.1%)	1 (0.1%)	227 (15.3%)	254 (17.2%)	0 (0%)	0 (0%)
March 15 - 21	698	183 (26.2%)	2 (0.3%)	8 (1.1%)	5 (0.7%)	4 (0.6%)	195 (27.9%)	105 (15.0%)	2 (0.3%)	0 (0%)
March 22 -28	1496	441 (29.5%)	4 (0.3%)	17 (1.1%)	5 (0.3%)	19 (1.3%)	381 (25.5%)	295 (19.7%)	3 (0.2%)	0 (0%)
March 29-April 4	1195	425 (35.6%)	4 (0.3%)	6 (0.5%)	9 (0.8%)	15 (1.3%)	305 (25.5%)	201 (16.8%)	6 (0.5%)	0 (0%)
April 5-11	1831	665 (36.3%)	4 (0.2%)	7 (0.4%)	7 (0.4%)	47 (2.6%)	463 (25.3%)	276 (15.1%)	5 (0.3%)	0 (0%)

- **B.1.1.7** (first identified in the UK) is classified by CDC as a **variant of concern**, which means that there is evidence that it increases transmissibility and the severity of disease. Specifically, B.1.1.7 has been found to be 50% more transmissible and cause more severe infections.
- **B.1.526** (first identified in NYC) is classified by CDC as a **variant of interest**, because there are signs that it increases transmissibility. Studies are ongoing regarding the impact of B.1.526 on disease severity, reinfection, and vaccine effectiveness.

- **Study showed that vaccine-elicited and therapeutic monoclonal antibodies can neutralize B.1.526 variants** (see https://www.biorxiv.org/content/10.1101/2021.03.24.436620v1 for preprint).

  B.1.526 SARS-CoV-2 variants identified in New York City are neutralized by vaccine-elicited and therapeutic monoclonal antibodies

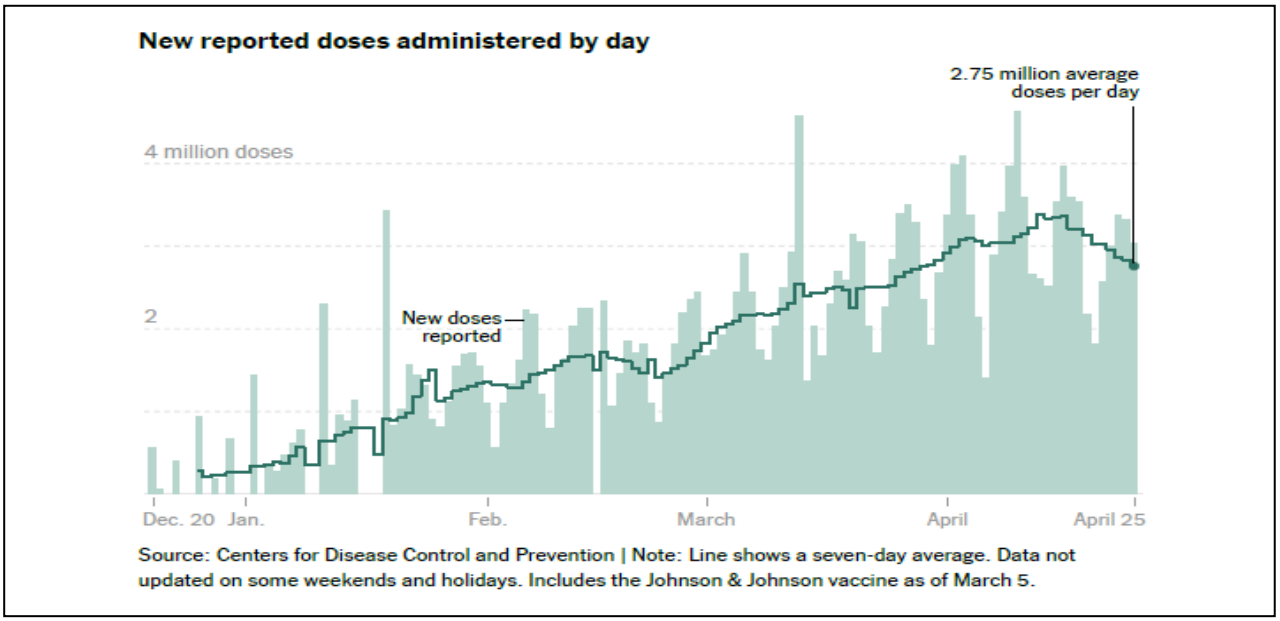
  ABSTRACT
  DNA sequence analysis recently identified the novel SARS-CoV-2 variant B.1.526 that is spreading at an alarming rate in the New York City area. Two versions of the variant were identified, both with the prevalent D614G mutation in the spike protein together with four novel point mutations and with an E484K or S477N mutation in the receptor binding domain, raising concerns of possible resistance to vaccine-elicited and therapeutic antibodies. We report that convalescent sera and vaccine-elicited antibodies retain full neutralizing titer against the S477N B.1.526 variant and neutralize the E484K version with a modest 3.5-fold decrease in titer as compared to D614G. The E484K version was neutralized with a 12-fold decrease in titer by the REGN10933 monoclonal antibody but the combination cocktail with REGN10987 was fully active. The findings suggest that current vaccines and therapeutic monoclonal antibodies will remain protective against the B.1.526 variants. The findings further support the value of wide-spread vaccination.

- For more information on variants of concern and variants of interest, visit cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html.

6. **Vaccination Program Update** (sources = CDC, NYS DOH, and NYT)

- On April 25, the 7-day average of COVID vaccine administered in the U.S. was 2.75 million. This was 330,000 fewer than that of a week ago. A total of 225 million+ doses have been administered since the beginning of the rollout.

- **42% of the U.S. population have received at least one dose (NY state is at 46% and Suffolk County is 44%).**



7. FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review

Following a thorough safety review, including two meetings of the CDC's Advisory Committee on Immunization Practices, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention have determined that the recommended pause regarding the use of the Johnson & Johnson (Janssen) COVID-19 Vaccine in the U.S. should be lifted and use of the vaccine should resume.

The pause was recommended after reports of six cases of a rare and severe type of blood clot in individuals following administration of the Janssen COVID-19 Vaccine. During the pause, medical and scientific teams at the FDA and CDC examined available data to assess the risk of thrombosis involving the cerebral venous sinuses, or CVST (large blood vessels in the brain), and other sites in the body (including but not limited to the large blood vessels of the abdomen and the veins of the legs) along with thrombocytopenia, or low blood platelet counts. The teams at FDA and CDC also conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots and low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS).

The two agencies have determined the following:

- Use of the Janssen COVID-19 Vaccine should be resumed in the United States.
- The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- The FDA has determined that the available data show that the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.
- At this time, the available data suggest that the chance of TTS occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk.
- Health care providers administering the vaccine and vaccine recipients or caregivers should review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers, which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

8. Mass Vaccination Sites to Set Aside Allocation for New Yorkers 60 Years of Age and Older to Walk-in and Get Vaccinated
https://www.governor.ny.gov/news/governor-cuomo-announces-16-mass-vaccination-sites-new-york-state-will-accommodate-walk

Governor Andrew M. Cuomo announced that beginning Friday, April 23, sixteen mass vaccination sites will accept walk-in appointments for individuals age 60 and older. New York State will set aside a vaccine allocation to facilitate this expanded vaccination access. There may be a wait for those opting to walk-in at some sites depending on demand. Additionally, all proof of identity and insurance information, if applicable, will be needed.

Two of the mass vaccination sites are located on Long Island:

SUNY Old Westbury
Clark Center - Gate C
Store Hill Road and Cherry Road
Old Westbury, NY

Suffolk CCC - Brentwood
Suffolk Federal Credit Union Arena
1001 Crooked Hill Road
Brentwood, NY

9. Study Suggests that mRNA COVID-19 Vaccine Appears to be Safe in Pregnancy

Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons

Tom T. Shimabukuro *et al. New Engl. J. Med.*, April 21, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2104983?query=featured_home

ABSTRACT

BACKGROUND

Many pregnant persons in the United States are receiving messenger RNA (mRNA) coronavirus disease 2019 (Covid-19) vaccines, but data are limited on their safety in pregnancy.

METHODS

From December 14, 2020, to February 28, 2021, we used data from the "v-safe after vaccination health checker" surveillance system, the v-safe pregnancy registry, and the Vaccine Adverse Event Reporting System (VAERS) to characterize the initial safety of mRNA Covid-19 vaccines in pregnant persons.

RESULTS

A total of 35,691 v-safe participants 16 to 54 years of age identified as pregnant. Injection-site pain was reported more frequently among pregnant persons than among nonpregnant women, whereas headache, myalgia, chills, and fever were reported less frequently. Among 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which 115 (13.9%) resulted in a pregnancy loss and 712 (86.1%) resulted in a live birth (mostly among participants with vaccination in the third trimester). Adverse neonatal outcomes included preterm birth (in 9.4%) and small size for gestational age (in 3.2%); no neonatal deaths were reported. Although not directly comparable, calculated proportions of adverse pregnancy and neonatal outcomes in persons vaccinated against Covid-19 who had a completed pregnancy were similar to incidences reported in studies involving pregnant women that were conducted before the Covid-19 pandemic. Among 221 pregnancy-related adverse events reported to the VAERS, the most frequently reported event was spontaneous abortion (46 cases).

CONCLUSIONS

Preliminary findings did not show obvious safety signals among pregnant persons who received mRNA Covid-19 vaccines. However, more longitudinal follow-up, including follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary to inform maternal, pregnancy, and infant outcomes.

10. What COVID Vaccination in Kids?

COVID Vaccines and Kids: Five Questions as Trials Begin (see https://www.nature.com/articles/d41586-021-01061-4)**;** *Nature*, April 21, 2021

Parents are clamoring to enroll their kids in the first COVID-19 vaccine trials in young children. "Somebody told me they called and called and called until they were allowed to participate," says Kawsar Talaat, an infectious-disease physician and vaccine scientist at the Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland. She is part of a trial that began testing the Pfizer–BioNTech vaccine in children under 12 in late March.

As such trials get under way — Moderna began a similar study of its vaccine last month — scientists are seeking answers to important questions about how safe and effective the vaccines are in kids.

Nature looks at how the trials will account for differences in children's immune systems and susceptibility to COVID-19, compared with those of adults, as well as the added safety precautions that surround medical research in kids. "Children are not little adults," stresses Talaat.

Do we even need to vaccinate children?

Children rarely develop severe forms of COVID-19, and deaths from the disease are rarer still. On rare occasions — one estimate puts it at around one case in 1,000, although it could be even lower— kids who've experienced even mild infections can later develop a sometimes deadly condition called multi-system inflammatory syndrome

in children (MIS-C). “I’m tired of seeing sick kids. I want to see them protected,” says James Conway, a pediatric infectious-disease specialist and vaccine researcher at the University of Wisconsin–Madison.

Evidence is building that vaccines might block transmission of SARS-CoV-2, so vaccinating children could have beneficial knock-on effects in the wider community. “If we really want to get back to normalcy, we really need to achieve herd immunity across all the groups that potentially contribute to transmission,” Conway adds.

Children, particularly younger kids, probably aren’t super-spreaders of SARS-CoV-2, as they are for viruses including influenza. But the emergence of faster-spreading variants, along with rising adult vaccination rates in some countries, means that children and adolescents might soon be contributing more to spread. “COVID transmission is now hottest in younger people. The virus will find ways to survive and spread unless we close off the pathways,” says Talaat.

How will the trials in kids work?

In some ways, vaccine trials in children under 12 years old will be a replay of early trials in adults. The first recipients — who will be on the older end of the spectrum, although trials will eventually include children as young as six months — will receive a range of doses to find one that triggers a strong immune response without too many side effects. “Some of them are too much, some of them are too little. You’re looking for that sweet spot,” says Conway. “It’s the Goldilocks effect.”

Once an ideal dose is identified, several thousand participants will be randomized to receive either two doses of vaccine or of a placebo injection. Researchers will then follow the children for months and even years, to study the safety and effectiveness of the vaccines.

In adult trials, participating individuals provide informed consent. When participants are children, however, their legal guardian must agree to their involvement. But researchers are also obliged to obtain assent from any child participants old enough to understand the trial, says Beates Kampmann, a pediatric infectious-disease specialist and director of the Vaccine Centre at the London School of Hygiene & Tropical Medicine. “Our kids are savvy, they understand. They’ve heard about this all year,” says Talaat, who generally seeks assent from kids aged five and over —and sometimes younger, depending on the child.

Will children and adults respond differently to COVID-19 vaccines?

Children’s immune systems are brimming with cells that haven’t seen pathogens, so they tend to produce a strong immune response to vaccines, says Donna Farber, an immunologist at Columbia University in New York City. “It’s those first few years of life, where you’re learning about pathogens.”

Early trial results have shown that 12–15-year-olds who received two standard doses of the Pfizer–BioNTech vaccine developed substantially higher levels of virus-blocking antibodies than did 16–25-year-olds in earlier trials. Farber wonders whether children who are even younger will get the same immune response from a lower dose.

Children’s potent immune responses mean that they are more likely than adults to develop a fever after vaccination, says Talaat, so researchers will need to strike a balance between triggering a strong immune response and minimizing the side effects that come with it. However, this might not be such a problem, because children seem to be less bothered by fevers than are adults, says Arber.

As COVID-19 vaccines are tested in ever-younger children, researchers will want to make sure they’re not interfering with immunity generated by routine childhood vaccinations, says Kampmann. The Pfizer–BioNTech trial plans eventually to enroll children under five who may still be due to receive boosters of polio vaccines and jabs against measles, mumps and rubella, as well as other immunizations, but Talaat says children will need to be up to date on their vaccination schedules to participate. Studies of how a COVID-19 vaccine should best be integrated into a child’s immunization schedule will need to come later, she adds.

How will scientists know if vaccines work in children?

We know that vaccines prevent COVID-19 in adults because the clinical trials were designed to show this. They involved tens of thousands of people randomly assigned to receive either the vaccine or placebo, and showed compelling differences in the rates of disease between the two groups.

In the pediatric trials, which will involve only a few thousand children, there might be too few symptomatic infections to measure efficacy in the same way, says Talaat. It makes more sense, she says, to look at immune markers after vaccination. "If we see the pediatric immune responses are the same or better than we saw in adults, we can make inferences that the vaccine will be effective. "Both the Moderna and the Pfizer–BioNTech trials list such markers as their primary measures of success.

Conway would like to see good evidence that the vaccines can actually prevent COVID-19 in kids. The Pfizer–BioNTech trial in adolescents recorded 18 cases in the placebo group, and none in those who got the vaccine, so it's not inconceivable that trials of younger kids will also show such efficacy, says Talaat, but it will depend on community infection rates.

However, if the primary aim of childhood vaccination is to stop transmission, trials should show this, says Christiane Eberhardt, a physician-scientist in clinical vaccinology at the Geneva University Hospitals in Switzerland. This would ideally involve frequent swabs in kids — unlikely to be popular — and in unvaccinated family members. Instead, the Moderna and Pfizer–BioNTechtrials intend to look at blood markers of asymptomatic infection, which Eberhardt sees as acceptable under the circumstances. "That's the closest you can get."

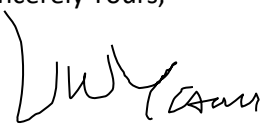
How will researchers know if the vaccines are safe in young children?
Safety is paramount in clinical trials involving children, and researchers are aware that COVID-19vaccine trials in kids will get extra scrutiny. "Anything that smears vaccines in general, and makes people question the safety of vaccines in kids, is a step backwards from a public-health standpoint," says Conway.

Early adult trials paid close attention to the possibility that people who received the vaccine could develop 'enhanced disease' if they later became infected. The trials found no evidence for this, but Conway says that pediatric trials should look for immune responses that might exacerbate disease, as well as signs that participants are developing immune reactions similar to those seen in MIS-C.

It is not yet clear how concerns over very rare blood clots potentially linked to the Oxford–AstraZeneca and Johnson & Johnson vaccines will affect pediatric trials. The University of Oxford, K, has paused a small trial in kids aged 6–17 that began in February. Johnson & Johnson announced at the start of April that it was set to begin including adolescents in an ongoing trial of its vaccine, but has since paused all its trials as the clots are investigated.

That's about it in the world of COVID-19 pandemic last week. Once again, I hope the information provided here is useful to you in keeping track of the progression of the pandemic. While the decreasing infection rates and increasing rollout of COVID vaccines are encouraging trends, we should remain vigilant. So please do keep safe and healthy.

Sincerely Yours,



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