COVID-19 Vaccines and the Threat of New Variants

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The Vaccine Rollout in the United States

COVID-19 vaccines have been developed and rolled out at record speed by historical standards. As of February 27th, with the FDA's approval of Johnson & Johnson's single dose COVID vaccine, three vaccines are now approved in the United States market: the Pfizer-BioNTech vaccine; the Moderna vaccine; and now, the Janssen-Johnson & Johnson vaccine. It looks likely that the Novavax vaccine could be approved by the FDA within the first half of this year.¹ And, while approved in many countries already, there remains some question as to whether the Oxford-AstraZeneca vaccine will be approved by the FDA.² One study has shown that AstraZeneca COVID-19 vaccine has been largely ineffective against the B.1.351 variant initially identified in South Africa, and there are some concerns about whether inconsistent manufacturing of the vaccine for the clinical trials may have impacted the results.³

Despite wide ranging issues with the rollout of the vaccine across the United States, the country is significantly ahead of most countries.⁴ The Centers for Disease Control and Prevention (CDC) maintains a COVID Data Tracker that tracks the total vaccinations across the United States, by state.⁵ As of March 4, 16.3% of the US population (21.2% of the population 18 years of age or older) had received 1 or more doses, and 8.4% of the population (10.9% of the population 18 years or older) had received 2 doses of vaccine.

The approval of the Johnson & Johnson vaccine offers much hope for getting more people vaccinated due to simpler logistics of a single dose, less stringent storage temperature requirements, and the expanded supply that comes from another vaccine. Indeed, the company has indicated their aim of delivering 20 million doses to Americans by the end of March, and 100 million doses by June.⁶ Added to the expected deliveries of other vaccines, some degree of normalcy may be expected to return to life in the US by this summer.

The Risks of Complacency and New Variants

https://www.fiercepharma.com/pharma/fda-could-reject-astra-zeneca-s-covid-vaccine-efficacy-andmanufacturing-shortfalls-analyst. Accessed on March 2, 2021.

¹ Paul Taylor, Nick. Novavax targets May approval for COVID-19 vaccine in the U.S. Fierce Biotech. March 2, 2021. Available at: <u>https://www.fiercebiotech.com/biotech/novavax-targets-may-approval-for-covid-19-vaccine-u-s</u>. Accessed on March 2, 2021.

² Weintraub, Arlene. FDA could reject AstraZeneca's COVID-19 vaccine on efficacy and manufacturing shortfalls: analyst. Fierce Biotech. February 17, 2021. Available at:

³ Ibid.

⁴ Coronavirus (COVID-19) Vaccinations. Our World in Data. Updated regularly. Available at: <u>https://ourworldindata.org/covid-vaccinations</u>. Accessed on March 2, 2021.

⁵ COVID Data Tracker. CDC. Updated regularly. Available at: <u>https://covid.cdc.gov/covid-data-tracker/#vaccinations</u>. Accessed on March 4, 2021.

⁶ Steenhuysen, Julie and Erman, Michael. J&J COVID-19 vaccine shipping to U.S., but new deliveries hinge on regulators. Reuters. March 1, 2021. Available at: <u>https://www.reuters.com/article/us-health-coronavirus-usa-johnson-johnso/third-u-s-covid-19-vaccine-by-jj-available-in-1-2-days-ceo-says-idUSKCN2AT2D1</u>. Accessed on March 2, 2021.

As compared to the highest levels of COVID, there has been some attention to the fact that cases and deaths are already down significantly. This is not likely attributable to the vaccinations already administered. This is most likely because we are now past the period of holiday gatherings and social distancing best practices are being followed to a relatively higher degree.

CDC Director Rochelle Walensky noted in a March 1 White House press briefing that the recent declines in case counts are stalling. She is "really worried" about reports that states rolling back COVID-19 restrictions as cases appear to plateau.⁷ She added:

Please hear me clearly: At this level of cases, with variants spreading, we stand to completely lose the hard-earned ground we have gained. These variants are a very real threat to our people and our progress. Now is not the time to relax the critical safeguards that we know can stop the spread of COVID-19 in our communities, not when we are so close.⁸

Already, the governors of Texas and Mississippi have said that they were lifting mask mandates and allowing businesses to operate at full capacity. They are not alone, with a range of easing measures being implemented in other states, including Louisiana, Ohio, Michigan. This, as significantly more transmissible variants such as the B.1.1.7 variant initially identified in the United Kingdom has now become widespread across the United States.

Vaccine makers are now developing a third shot to fight against the more contagious COVID-19 variants. National Institute of Allergy and Infectious Diseases Director, Dr. Anthony Fauci, indicated earlier this week that clinical trials are set to start within this month.⁹ While the Moderna and Pfizer vaccines offer a "considerable cushion for protection from illness, Dr. Fauci stressed that the level of protection provided by these vaccines "diminishes by five or sixfold" when a person contracts a COVID-19 variant.¹⁰

Our Vaccination Strategy Must Be Global

To be sure, the pace of vaccination is ramping up in the United States and around the world. But, with the possibility of increased complacency in the United States, and the relatively slower pace of the vaccine rollout in many areas of the world, the concerns about new surges in cases, currently known variants, and the likelihood of additional variants are real and legitimate. Long after most Americans are vaccinated, it is apparent that new variants will likely be forming in areas around the world where vaccinations will lag.

We are turning the corner with these vaccines, but there is also a race against known and unknown variants of this disease that is likely to threaten our societies for years to come. It seems likely that third shots, and possibly a good number more will be necessary in the years ahead. We have focused here in large part on the current experiences of the United States. It is one of the key areas of focus right now

⁷ Press Briefing by White House COVID-19 Response Team and Public Health Officials. The White House. March 1, 2021. Available at: <u>https://www.whitehouse.gov/briefing-room/press-briefings/2021/03/01/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-9/</u>. Accessed on March 2, 2021.

⁹ O'Neill, Natalie. Fauci: Trials of third vaccine to fight COVID variants will start this month. New York Post. March 3, 2021. Available at: <u>https://nypost.com/2021/03/03/fauci-trials-of-third-booster-vaccine-to-fight-covid-variants-to-start/</u>. Accessed on March 3, 2021.

⁸ Ibid.

¹⁰ Ibid.

in terms of the vaccine rollout, as many other countries struggle relatively more for access to supply. But, wider access to this supply and a plan to rollout these vaccines on a global scale must be a simultaneous priority. The current vaccines and the booster vaccine shots in development may just be the start to a problem we will be facing for some time.