COVID19 Update: Sputnik V – the vaccine that came in from the cold

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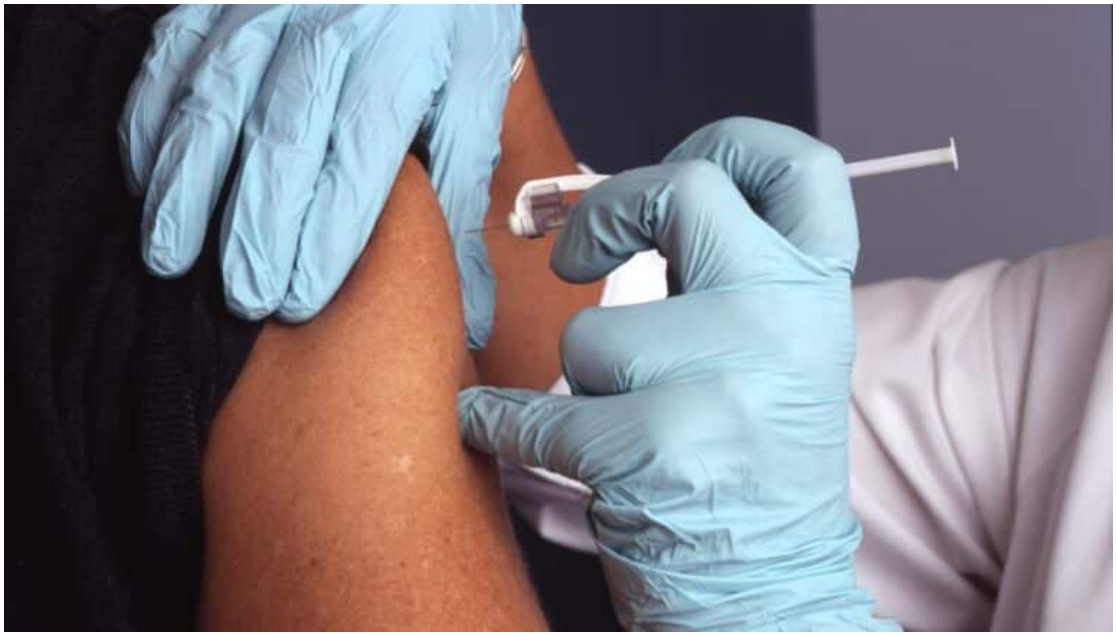

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When Russian President Vladimir Putin celebrated his “Mission Accomplished” moment on August 11 th with the announcement of Sputnik V, the world’s first SARS-CoV-2 vaccine, the global scientific community reacted with a mix of skepticism and condemnation. Is this warranted or a result of russophobia?

What is Sputnik V?

Gam-COVID-Vak, better known under its politicized name Sputnik V, is an adenovirus-vector vaccine developed by the Gamaleya Institute in the Moscow under the purview of the Russian Ministry of Health. The vaccine uses two different vectors to train the human body for the SARS-CoV-2 spike protein. Ad26 (same as the J&J vaccine) for the “primer” shot and Ad5 (same as the CanSino vaccine) as the “booster” 21 days after the first shot.

Does it work?

We do not know. Although the vaccine has two completed FDA phase I/II trials NCT04436471 and NCT04437875 with 38 participants each, no data on the results was published thus far beyond a press-release about the purported effectiveness. Equally absent are the data on trials conducted on rodents and non-human primates. This follows an established pattern of the Gamaleya Instute of not adhering to international research standards.

Although the Gamaleya Institute is the highest authority for vaccine development in Russia with a history reaching back into the 19 th century, the institute has no proven track record. It developed an Ebola vaccine that is thus far only approved in Russia, a country not very prone to Ebola outbreaks, and has not undergone the standard FDA clinical trial process.

The secrecy notwithstanding, there is no reason to believe that the developed vaccine does not elicit some immunity to SARS-CoV-2. The used vectors have shown to be effective in the CanSino (at least somewhat) and J&J vaccines. The big unknowns are the effectiveness given that the vectors are human adenoviruses for which a certain percentage of the populace has at least some immunity, rendering them ineffective, and the duration of the immunity, which in the case of the CanSino vaccine appeared to be short-lived.

Is it safe?

Probably yes. Not considering any potential contaminations during the production, the risk of serious adverse side effects from human adenovirus vector vaccines appears to be low. The vectors are unable to replicate in the human body and even if they could the elicited symptoms would be benign (common cold). Possible side effects include fever, fatigue, and muscle pain. Nevertheless, subjecting the population to vaccine with unknown rare side effects is unethical. Even if an extreme side effect appears for 1 in 2000 people, this would affect 50.000 people in Russia alone if the entire susceptible population is vaccinated.

Who will get it?

Medical personnel will be the first to receive the vaccine. According to press releases, the vaccination will be voluntary. Children will not be vaccinated, as the researchers claim that have to find a lower tolerable dose first. Russia aims to produce 5 million doses per month in December and January. At this rate, assuming that a dose refers to an entire vaccination course (primer & booster), it would take Russia 20 months to vaccinate enough of its people. The fact that the vaccine has two different components increases the monitoring requirements during distribution and will pose an administrative burden on the stretched Russian health apparatus.

Summary

Sputnik V is a publicity stunt that will at best generate some immunity for frontline health care workers with tolerable safety risks and at worst an ineffective vaccine with extreme but rare side effects. My guess is, given the low production capacity, that Russia, like most countries, will source many different vaccines to inoculate the entire susceptible population.

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