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‘Gross Violation’: In Open Letter, Russian Scientists Criticize Lack of Vaccine Data

Russia has launched mass Sputnik V vaccinations. But concerns over weak data and cut corners continue to mount.

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Russia has launched mass coronavirus vaccinations, so far for healthy medical workers and teachers.
Sergei Kiselyov / Moskva News Agency

A group of scientists from leading Russian universities has blasted the development process of Russia’s Sputnik V coronavirus vaccine as “completely unacceptable” and “ridiculous” in an open letter raising new concerns over a lack of sufficient data on its safety and effectiveness.

The experts said Russia’s state-run Gamaleya Research Institute, which is developing the jab, has ignored requests to share data — despite public pledges to do so — and have raised fresh fears over political meddling and a string of alleged shortcomings in the vaccine research.

Related article: As Russia Begins Mass Coronavirus Vaccination, Its Medics Aren't On Board

Concerns were first raised over Russia's Phase 2 trials — a limited program which involved just 76 volunteers — in the summer, after its results were published in The Lancet. But as Russia moved to Phase 3 trials and launched mass vaccinations, worries over poor standards of scientific research have compounded.

The group heavily criticized Russia's decision to start a mass vaccination program — which is officially only open to healthcare workers and teachers under the age of 60 with no underlying health conditions — while large-scale medical trials were still at such an early stage. Russia first published data on the vaccine's efficacy after it had recorded just 20 cases of Covid-19 among volunteers — a threshold that a number of international regulators deem far too small. Pfizer, Moderna and AstraZeneca, for instance, had to hit at least 90 cases before they could publish interim results.

"This completely unacceptable — even ridiculous — political action to create a competition between vaccines is in violation of the most important testing standards," wrote the scientists — led by Vasiliy Vlassov, an esteemed epidemiologist at Moscow's Higher School of Economics, former adviser to the Russian Health Ministry and World Health Organization (WHO) and vice chairman of a Russian Academy of Science commission against the falsification of research.

The race-like atmosphere made the vaccine developers "hostage" to Russia's political goals, they said. "It threatens the benign testing of the vaccine and, therefore, poses a threat to the health of Russians."

Related article: Leading Scientists Question 'Highly Improbable' Russian Vaccine Results Published in Lancet

The letter was written by Vlassov along with Olga Rebrova, a professor at the Russian National Research Medical University, and Valery Aksyonov, scientific editor of Bionica Media. It was first published in November, and first reported Thursday by BBC Russia after having been sent to The Lancet in October.

Russia launched its mass vaccination program last weekend. In addition to volunteers in medical trials, tens of thousands of the country's political elite and healthcare workers had already been given the vaccine before it became widely available.

Doctors told The Moscow Times this week they are highly skeptical about having the jab.

Trial differences

Only limited data on the results of the mass trials have been published, with 39 confirmed cases in the volunteer group and a claimed efficacy of around 92%. That is based on eight volunteers who were administered the vaccine catching Covid-19, and 31 in the placebo group.

Russia has also not released details of the ages of participants in the trials or results broken

down by demographic group. Vlassov believes this indicates that Russia prioritized vaccinating people under 60, as the vaccine could prove to be more effective on younger people and thus lead to more impressive results for the study.

In another difference with the Western vaccine trials, Russia split its volunteers into different-sized groups: 14,095 received the vaccine and 4,699 got the placebo — a three-to-one ratio. In its guidance on vaccine trials, U.S. regulators caution against conducting large-scale trials on anything other than a one-to-one ratio, as reducing the pool of volunteers receiving the placebo can skew results and could make it harder to catch enough different demographic groups across ages, health conditions and ethnicities to make statistically meaningful comparisons.

"31 of 4,699 in the placebo group is a fairly small number in absolute terms and could easily change. The ratio of eight to 31 does not look statistically significant," said Konstantin Andreev, a medical researcher at U.S.-based Northwestern University who signed a different open letter criticizing the research.

Adding more confusion to the results of Russia's Phase 3 trials, deputy Moscow Mayor Anastasia Rakova told reporters last Friday that 273 volunteers had been infected with Covid-19, hailing the fact that meant only 1.5% had caught the disease. That number is misleading, Vlassov said, since efficacy is calculated based on a comparison of infection rates among a vaccinated group with a non-vaccinated group, not the overall infection rate. Moreover, Sputnik V developers are set to publish the next batch of interim results when there are 78 confirmed infections among the volunteers, and have not yet done so.

Retraction

The Russian scientists also called on leading medical journal The Lancet, which published Russia's only peer-reviewed study on the vaccine's early trials, to retract the article which has drawn criticism from scientists around the world.

That article summarized research on the vaccine's safety and whether it triggered an antibody response among a very small cohort of 76 volunteers. Similar early-stage studies by the other vaccine candidates used significantly larger pools — up to 600 in the case of Moderna, the BBC reported.

"We believe that poor methodology, study design flaws, errors in data analysis, and a poor description of the study call into question the main conclusions about the safety and efficacy of the vaccine," Vlassov and his colleagues, members of the Russian Society of Specialists in Evidence Based Medicine, wrote.

Russian and international scientists separately requested the Russian developers share more data on the trials — as they had pledged to do in The Lancet paper. Neither received the data, nor an acknowledgement of their request.

Related article: Russia Ignores Requests to Share Controversial Coronavirus Vaccine Data

"We consider this to be a gross violation of the norms of publication ethics and, accordingly,

urge the editor of the journal to withdraw the article," the Russian group wrote.

Concerns ranged from apparent duplication of results across different volunteer groups to unexplained reasons for why two dozen volunteers passed the medical screening but were not included in the study.

The Lancet has repeatedly said it passes on concerns directly to the Russian vaccine developers and has encouraged them to share data. It refused to publish the letter of concern or retract the article.

"The fact that they haven't shared the full data yet worries me," Vlassov told The Moscow Times. "It suggests there is something wrong with it."

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