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Covid-19: What do we know about Sputnik V and other Russian vaccines?

In August 2020, Russia's President Vladimir Putin surprised the world by approving its first domestically developed covid-19 vaccine, before phase III clinical trials had even begun. **Chris Baraniuk** reviews what we know—and don't

Chris Baraniuk

What is Sputnik V?

Russia's first approved vaccine was developed and produced entirely domestically and has a name intentionally invoking the space race of the 1950s. By the time the World Health Organization declared covid-19 a pandemic, in early March 2020, the Gamaleya National Center of Epidemiology and Microbiology in Moscow was already working on a prototype of Sputnik V, funded by the Russian Direct Investment Fund (RDIF), the country's sovereign wealth fund.

Gamaleya researchers used common cold viruses in their vaccine prototype. Notably, they opted for two different adenovirus vectors (rAd26 and rAd5) delivered separately in a first and second dose, 21 days apart.¹ Using the same adenovirus for the two doses could lead to the body developing an immune response against the vector and destroying it when the second dose is administered. Two different vectors reduces the chance of this.

To make the vaccine, the adenoviruses are combined with the SARS-CoV-2 spike protein, which prompts the body to make an immune response to it.

Is Sputnik V safe and effective?

Phase I and II results, on 76 participants of an open, non-randomised trial, were published in the *Lancet* in September.² According to the paper, all participants developed SARS-CoV-2 antibodies. No serious adverse events were detected. Most adverse effects were mild, with just over half experiencing pain at the injection site, for example.

Interim phase III data were published in early February 2021.³ The randomised, double blind, placebo controlled trial included nearly 22 000 adults aged 18 years or older recruited through 25 hospitals and clinics in Moscow between 7 September and 24 November 2020. Each participant received either two doses of the vaccine, or a placebo, which were administered 21 days apart.

Interim results (based on data so far from 14 964 participants in the vaccine group and 4902 in the placebo group) indicate that the vaccine is 91.6% effective, based on its ability to prevent symptomatic infection. There were no cases of moderate or severe covid-19 in the vaccinated group at least 21 days following the first dose. Some 94% of reported side effects were very mild (grade 1). Four deaths recorded during the study were found not to be related to the vaccine.

Are scientists convinced?

Doubts were seeded when President Putin surprised the world by announcing Russian approval for emergency use of Sputnik V as early as August 2020, before phase I or II data had been published and before the phase III trial had begun.

The early approval, and Russia's bombast around the vaccine, provoked scepticism among scientists. In September, an open letter co-signed by 30 scientists worldwide criticised inconsistencies in the phase I and II study paper.⁴ The team behind Sputnik V dismissed the concerns in a letter published in the *Lancet*,⁵ pointing out that some of the alleged irregularities—such as suspiciously similar antibody counts among participants—were likely coincidences partly caused by factors such as small sample size and the rounding of numbers in data points.

Phase III data have been met more warmly. Some commentators have pointed out that, for example, the primary outcome was reported unusually early, at 21 days following the first dose, rather than following the second dose—the original protocol for the trial has not been published so it is not possible to know whether this was decided before or during the trial. But others argue the phase III data published to date have vindicated Russia's decision to go ahead with Sputnik V vaccinations.

How is Russia using the vaccine?

On 2 December, the same day the UK approved the Pfizer BioNTech vaccine for use, Putin declared that mass vaccination using Sputnik V, provided free to citizens, was to begin within days.

In fact, administration of Sputnik V began even earlier—employees of Gamaleya were among the first people to receive prototype doses in the spring of 2020 before phase I and II trials took place in the summer. Putin revealed that one of his daughters had already had two doses of the vaccine. More than 2500 Russian soldiers have also received the jab.⁶

The first members of the public to receive a dose of Sputnik V were school and healthcare workers who were offered appointments through an online booking system. However, drop-in hubs offering jabs to anyone, without an appointment, have also opened. One hub is at the GUM shopping centre in Moscow's Red Square. People can queue for a vaccine dose and those who receive one get a free ice lolly.⁷

As of 10 February, Russia had inoculated more than two million people with at least one dose of Sputnik

V, according to health minister Mikhail Murashko. That's nearly three vaccine doses per 100 people according to the latest available data⁸ (as a comparison, the UK has administered nearly 10 times as many). The rollout may be hampered by scepticism about Sputnik V among the Russian public—an online survey of 1600 Russians conducted by the *Moscow Times* found that 60% were opposed to receiving it.⁹ The swift approval has also prompted wariness among some Russian doctors.¹⁰

What other countries are using Sputnik V?

Russia has gone to great lengths to promote Sputnik V beyond its borders in a vaccine diplomacy drive, promising that it will cost less than \$10 (£7.2; €8.4) per dose for international buyers.¹¹

The RDIF says it has signed contracts with more than a dozen manufacturers in 10 countries to produce a total of 1.4 billion doses. At the time of writing, 29 countries besides Russia had approved Sputnik V for emergency use.¹² That includes Hungary, the only EU state to do so to date, although the European Medicines Agency (EMA) denied reports at the time that it was reviewing the vaccine (EU states are able to approve vaccines bilaterally for use).¹³ The EMA later announced that a review of Sputnik V had begun.¹⁴

Ursula von der Leyen, president of the European Commission, has publicly questioned why Russia is “offering theoretically millions and millions of doses while not sufficiently progressing in vaccinating their own people.”¹⁵ Indeed, hundreds of thousands of doses have been shipped to several countries. Sputnik V has already been rolled out in Argentina¹⁶ and Montenegro, according to reports.¹⁷

In addition, the University of Oxford and AstraZeneca have launched a trial to be held in Russia assessing whether mixing doses of their vaccine and Sputnik V may yield any more benefits.¹⁸

What other vaccines does Russia have?

Currently, no vaccine other than Sputnik V is publicly available in Russia.

The Russian government has, however, approved two other Russian developed vaccines for emergency use: EpiVacCorona, produced by the Vector Institute in Novosibirsk, and CoviVac, from the Chumakov Centre in St Petersburg, known for its collaboration with US scientist Albert Sabin on the polio vaccine during the cold war.¹⁹ As with the approval of Sputnik V, both these vaccines have yet to begin large scale clinical trials.

EpiVacCorona uses no live virus and instead relies on synthetic peptide antigens, based on a selection of those found within SARS-CoV-2. Like recreating the spike protein, this approach uses fragments of the virus to prompt an immune response.²⁰

CoviVac incorporates an inactivated cold virus in “whole virion” technology, similar to the vaccine candidates developed by the Chinese company Sinovac and the Indian company Bharat Biotech.²¹ This method may provoke a broader immune response that could protect against multiple variants (other vaccines have focused on just the spike protein of SARS-CoV-2, which can contain components specific to particular variants).

Scientists in Russia are also working on two versions of the initial Sputnik V vaccine²²: one that needs to be stored at -18°C, freezer temperature, and another uses dried (lyophilised) material that can be stored at 2 to 8°C in a range of standard refrigerators, which would aid transport and distribution. Yet more versions of the vaccine are also in the works, including a single dose alternative.²³

Competing interests: I have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.

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