Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

4 Bucci E, Andreev K, Björkman A, et al. Safety and efficacy of the Russian COVID-19 vaccine: more information needed. *Lancet* 2020; **396:** e53

5 Logunov DY, Dolzhikova IV, Tukhvatullin AI, Shcheblyakov DV. Safety and efficacy of the Russian COVID-19 vaccine: more information needed—Authors' reply. *Lancet* 2020; **396:** e54–55.

6 Sangnawakij P, Böhning D, Holling H. On the exact null-distribution of a test for homogeneity of the risk ratio in meta-analysis of studies with rare events. *J Stat Comput Simul* 2021; **91:** 420–34.

Authors' reply

Clear and transparent regulatory standards exist for provision of clinical trial data, including data reported in clinical study reports that are considered sufficient for regulatory review and approvals. The reporting of the interim analysis[1] in the phase 3 Sputnik V clinical trial fully complies with those standards. It is on this basis that Sputnik V has received registration in 51 countries, which confirms our full transparency and compliance with regulatory requirements.

The amendment was made to the protocol on Nov 5, 2020. The complete protocol, as amended (Section 10.4 Interim Analysis and Statistical Significance Level Applied), was submitted to *The Lancet* along with the rest of the documents for review.

Efficacy is assessed within 6 months after first dose (time of observation of study participants); however, the calculation of the primary outcome is based on the number of cases of COVID-19 in participants who received both doses (after second dose), as indicated in the protocol. This is consistent with the primary outcome of other studies.

The registration scheme for COVID-19 cases is described in the Article (p 674).[1] When COVID-19 was suspected, participants were assessed according to COVID-19 diagnostic protocols, including PCR testing at a central laboratory in Moscow, Russia. Severity of disease was established upon confirmation of the COVID-19 diagnosis by site investigators. A description of the assessment criteria for severity of COVID-19 is available in the appendix of the Article.[1] Thus, we have described the clinical parameters to determine COVID-19. PCR testing was done in hospitals using test systems registered in Russia.[1] It seems strange to ask about the number of amplification cycles when performing PCR on a registered test system.

Enrico Bucci and colleagues correctly note that 21 977 individuals were included in the study, as of Nov 24, 2020, as shown in figure 1 of the Article.[1] The ClinicalTrials.gov record states that as of Jan 20, 2021, the number of participants increased to 33 758. 13 986 individuals were indeed excluded; some of the volunteers were screened and had not yet been randomised at the time of the snapshot, and others were excluded according to the exclusion criteria or did not meet the inclusion criteria.

Numerical inconsistencies were simple typing errors that were formally corrected.

We provide data on the number of cases, sample sizes, efficiency values, confidence intervals, and significance level for each age group in the Article.[1] According to the above formula for calculating the efficiency and the method for calculating the confidence interval, readers can calculate and confirm that the efficiency values are the same as shown in table 2.[1] The homogeneity of the values only confirms the fact that, as described in the Article, the effectiveness of the vaccine does not differ between age groups. In this case, the main parameter by which one can judge the difference in effectiveness is the confidence interval, the differences in which are quite significant due to the different sample sizes and the number of COVID-19 cases at the time of analysis.

With regard to the data on the upper limit of the confidence interval in the placebo group in table S3 of the appendix, we confirm the data shown are correct.

It is important to note that the safety and immunogenicity of the Sputnik V vaccine has been confirmed by researchers in Argentina, where the vaccination with Sputnik V began. Preliminary data[2] show the vaccine has an appropriate safety profile, and the most common adverse events were pain at the injection site, fever, and muscle pain. A study of immunogenicity showed 16 titres of neutralising antibodies to SARS-CoV-2 after the first dose and 64 titres after the second dose, which correlates with the published results from vaccine clinical trial phase 1/2 and phase 3 in Russia.[1,3] Unfortunately, due to the use of different ELISA kits, it is not possible to compare the specific IgG concentrations in these studies. However, it should be noted that a specific humoral response was detected in all vaccinated participants.

An important detail in the report from Argentina[4] is the observation that vaccination of people with a history of COVID-19 leads to a quick and significant increase in antibodies after a single dose of vaccine.

Thus, to date, the safety and immunogenicity of the Sputnik V vaccine has been confirmed in multiple studies.

We declare patents for an immunobiological expression vector, pharmaceutical agent, and its method of use to prevent COVID-19.

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1 Logunov DY, Dolzhikova IV, Shcheblyakov DV, et.al. Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia. *Lancet* 2021; **397:** 671–81.

2 Pagotto V, Ferloni A, Soriano MM, et al. Active surveillance of the Sputnik V vaccine in health workers. *medRxiv* 2021; published online Feb 5. https://doi.org/10.1101/2021.02.03.21251071 (preprint).

3 Logunov DY, Dolzhikova IV, Zubkova OV et al. Safety and immunogenicity of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine in two formulations: two open, non-randomised phase 1/2 studies from Russia. *Lancet* 2020; **396:** 887–97.

See **Online** for appendix

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Refugee access to COVID-19 vaccines in Lebanon

Lebanon is currently experiencing multiple unprecedented crises—political, infrastructural, and economic. The Beirut port explosion, in August, 2020, damaged 36% of health facilities.[1] The Lebanese pound has lost 90% of its value, pushing more than half of the population into poverty.[1] Complicating its desperate plight, Lebanon hosts the largest refugee population per capita in the world.[2] The COVID-19 pandemic has exacerbated this situation, leaving an ill-equipped health-care system overwhelmed.[1] Given that the country struggles to care for its own citizens, the individuals who are most vulnerable, such as refugees, are at a heightened risk, particularly given the historical neglect of refugee populations in Lebanon's routine vaccination efforts.[3] Amid Lebanon's crises, the risk of failing to ensure equitable access to the COVID-19 vaccine for its 1·7 million refugees represents an impending public health crisis.

In Lebanon, refugees make up approximately 30% of the population.[2] Refugees live in high-density camps with scarce access to clean water, sanitation, and hygiene services, which leaves these individuals highly vulnerable during an infectious disease outbreak. According to the non-profit organisation Anera, public health interventions have been scarce across refugee camps since the beginning of the COVID-19 pandemic. Consequently, COVID-19 deaths were elevated among Syrian and Palestinian refugees in Lebanon, with a fatality rate that is four times and three times the national average, respectively.[4]

For more on the **findings from Anera** see https://www.anera.org/where-we-work/lebanon/

The Lebanese Ministry of Public Health prepared a National Deployment and Vaccination Plan (NDVP) for COVID-19 vaccines, which aims to vaccinate 80% of its total population, including non-citizens.[2] However, the acquired number of doses thus far—including those from COVID-19 Vaccines Global Access (COVAX)—is only sufficient to vaccinate 2 million people.[2] Although the NDVP commits to vaccinating refugees, routine immunisation rates among refugees in Lebanon have historically been alarmingly low compared with the native population. Only 12·5% of Syrian refugee children in Lebanon are fully immunised through routine vaccination services.[3] Given that Lebanon does not have enough doses to vaccinate its own citizens, international support is needed to ensure that refugees in Lebanon receive the COVID-19 vaccine.

Access to vaccinations by the most vulnerable is critical in curtailing the spread of COVID-19. While Lebanon struggles to address its economic and political crises, it is untenable for Lebanon to solely provide vaccinations for its refugee communities. Thus, international aid organisations must step in to ensure that those most at risk of COVID-19 are prioritised in vaccinations. Without international efforts to ensure equitable access, vaccine distribution in Lebanon risks becoming another crisis and a catastrophic moral failure.

We declare no competing interests.

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Department of Error

Tatum M. Outcry over persecution of health workers in Myanmar. Lancet *2021;* ***397:*** *1609*—In this World Report, 260 arrest warrants had been issued by April 25, rather than April 23. This correction has been made to the online version as of May 20, 2021.

Hyde R. Controversy surrounds Merkel's new lockdown powers. Lancet *2021;* ***397:*** *1610*—In this World Report, the Social Democratic Party was incorrectly referred to as the opposition party. This correction has been made to the online version as of May 20, 2021.

The Blood Pressure Lowering Treatment Trialists' Collaboration. Pharmacological blood pressure lowering for primary and secondary prevention of cardiovascular disease across different levels of blood pressure: an individual participant-level data meta-analysis. Lancet *2021;* ***397:*** 1625–36—For this Article, The Blood Pressure Lowering Treatment Trialists' Collaboration group list has been updated. This correction has been made to the online version as of May 20, 2021.

Anderson M, Pitchforth E, Asaria M, et al. LSE–Lancet Commission on the future of the NHS: re-laying the foundations for an equitable and efficient health and care service after COVID-19. Lancet *2021;* ***397:*** *1915–78*—In this Commission, the third sentence in the Financial and political context section should read "Efforts to support individuals and businesses—for example, through furloughing, grants, and loans—have substantially increased government borrowing, which reached approximately £350 billion in 2020". This correction has been made to the online version as of May 20, 2021 and the printed version is correct.