INDIA'S COVID VACCINE WOES: BY THE NUMBERS

How an explosion of coronavirus cases in India is putting global vaccine supplies at risk.

By T. V. Padma

India, one of the world's biggest suppliers of vaccines, is facing a COVID-19 vaccine crunch, partly because of an explosion of cases linked to new variants. This spells trouble for the many countries that are relying on Indian-made vaccines through the COVAX initiative for equitable access to vaccines, led by bodies including the World Health Organization.

On 19 April, India reported that it had had 273,810 new COVID-19 cases in the previous 24 hours, its highest daily total yet. It has now had more than 14 million confirmed cases in total, overtaking Brazil as the world's second-worst hit country, behind the United States (see 'Surging cases of COVID-19').

"While new variants are surfacing in India, a decline in COVID-appropriate behaviour such as wearing masks and social distancing is adding to their faster spread," says Randeep Guleria, director of the All India Institute of Medical Sciences in New Delhi.

By 14 April, more than 111 million people had been vaccinated in the country. But in March, fears of vaccine shortages led to the government temporarily halting exports of a version of the University of Oxford–AstraZeneca vaccine known as Covishield, which is produced by the Serum Institute of India (SII), in Pune.

The SII, the world's largest manufacturer of vaccine components, was expected to provide many of the doses for COVAX. But, owing in part to a fire at a facility in January, it hasn't yet been able to live up to its production target of 100 million doses per month. Currently, it produces between 60 million and 65 million per month.

Last June, AstraZeneca, which is based in Cambridge, UK, announced that it had licensed the SII to supply one billion doses of Covishield to low- and middle-income countries. But only 64 million had been sent out before the halt in exports last month, 28 million of which went to COVAX.

Approving further vaccines

Earlier this year, chief executive Adar Poonawala said on Twitter that the SII had been directed by the Indian government "to prioritise the huge needs of India and along with that balance the needs of the rest of the world".

India's battle with its surge in cases could delay planned deliveries of Covishield to 64 lower-income countries through COVAX, according to a 25 March statement by initiative member Gavi, the Vaccine Alliance, a health partnership based in Geneva, Switzerland.

Domestically, India had previously aimed to vaccinate 300 million people at high risk by the end of July, including 30 million health-care and front-line workers, and people with underlying health conditions. But state officials have complained of vaccine shortages (see 'India's vaccine crunch').

Guleria argues that there are sufficient vaccines, but that they must be redistributed to the regions with the most infections.

A second Indian company — Hyderabad-based Bharat Biotech — was given permission in January to supply its own vaccine, Covaxin, for emergency use. The firm, which developed the vaccine with the Indian Council of Medical Research, can make 12.5 million doses each month, but these represent only a small proportion of the doses administered in the country so far.

Part of the solution to the current woes will be to approve several other internationally developed vaccines that can be manufactured in India, such as Johnson & Johnson's single-shot vaccine, says Shahid Jameel, a virologist at Ashoka University in Sonipat. On Tuesday, India approved the use of Russia's Sputnik V vaccine, which the government says will be imported until domestic production can begin.
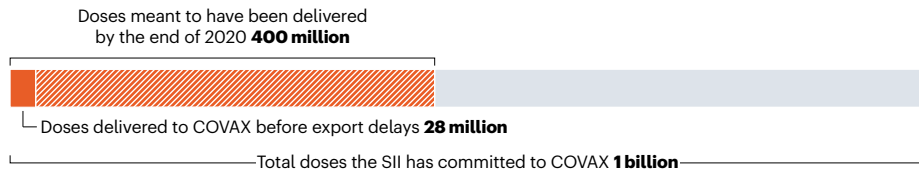
Spread of new variants

In March, India's health ministry said that gene sequencing by a consortium of ten national research laboratories has shown that several variants of the coronavirus are circulating in the country — including the B.1.1.7 variant first detected in the United Kingdom, which can spread more quickly than earlier variants.
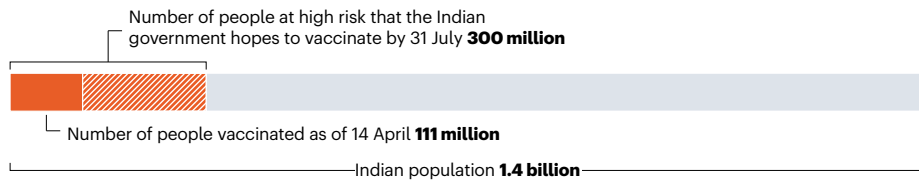
The B.1.1.7 variant has been extensively reported in Punjab state and it is "likely that

INDIA'S VACCINE CRUNCH

The Serum Institute of India (SII) has committed to providing one billion doses of the COVID-19 vaccine Covishield to the global COVAX initiative, but has delivered only a fraction of that. At the same time, surging cases and vaccine demand in India are leading to regional shortages.


Doses meant to have been delivered by the end of 2020 **400 million**

Doses delivered to COVAX before export delays **28 million**

Total doses the SII has committed to COVAX **1 billion**

Despite surging cases, as of this week, India has vaccinated only around 8% of its population of 1.4 billion.

Number of people at high risk that the Indian government hopes to vaccinate by 31 July **300 million**

Number of people vaccinated as of 14 April **111 million**

Indian population **1.4 billion**

SURGING CASES OF COVID-19

New daily cases in India have risen rapidly since March, and have now far surpassed last September's peak of around 100,000 new cases per day.

*Seven-day rolling averages, up to 12 April.
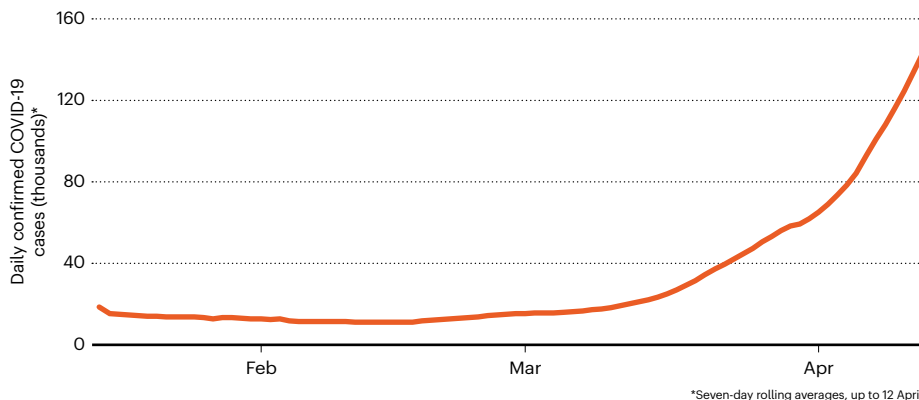
this mutant will move to neighbouring states and become the dominant mutant", says Guleria.

But Indian scientists are particularly interested in reports of a variant with two mutations that do not match previously catalogued variants of concern. The 'double mutant' has been found in 15–20% of samples from Maharashtra, India's worst-hit state, says Jameel.

Little has yet been published on this variant, but Jameel says there is cause for concern. "The two mutations are likely to improve the virus's binding capacity to the receptors and evade antibodies," he says.

India must "conduct post-vaccine surveillance", he argues, to find out whether vaccinated individuals are becoming infected, owing to mutating viruses or waning immunity.

US UNIVERSITIES CALL FOR CLEARER RULES ON SCIENCE ESPIONAGE

Trump-era research security guidelines spark concerns over transparency and racial profiling.

By Nidhi Subbaraman

The US government is converging on a long-awaited set of rules designed to protect the nation's science from theft by foreign spies. A series of announcements this year describe steps that US universities and researchers must take when reporting foreign financing and collaborations to the country's science funders.

But university groups say they need more clarity on how to implement the rules. And the guidelines do not spell out how institutions can address concerns of racial profiling sparked by the US government's crackdown on foreign interference in recent years.

The guidelines date back to the last days of former US president Donald Trump's administration; so far, President Joe Biden's administration has not indicated that it will seek to change the policies, but it is open to feedback.

Before he left office in January, Trump issued a memorandum describing the US government's responsibility to protect the country's research. Simultaneously, the White House Office of Science and Technology Policy (OSTP) published research security guidelines for universities and funding agencies. And in March, the US National Institutes of Health (NIH) announced new requirements for information that scientists applying for grants must disclose — becoming the first US agency to act on the OSTP's guidelines.

Together, the announcements represent a turning point. For years, US funding agencies have required grantees to flag funding from foreign sources. Since 2018, however, the government has imposed penalties more frequently, and sometimes pressed criminal charges, on scientists who breach that

requirement. Under this increased scrutiny, university administrators called for clearer rules on what scientists must disclose, including better definitions of conflicts of interest.

University leaders hoped that the OSTP project, launched in 2019, would address some of these concerns.

This year's announcements are positive, says Tobin Smith, vice-president for science policy and global affairs at the Association of American Universities (AAU) in Washington DC. But the AAU and other groups hope the requirements will be fine-tuned. "We would still seek additional clarity to even make it more well-defined," says Smith.

Guidelines delivered
The OSTP guidelines, drafted by the National Science and Technology Council Joint Committee on the Research Environment (JCORE),

> "We would still seek additional clarity to even make it more well-defined."

suggest that universities create teams devoted to all aspects of research security, with members who are experts on cybersecurity and export controls; set penalties for violators; and provide training for faculty members who are considering participating in foreign "talent programs" that recruit and fund researchers. One such programme is China's Thousand Talents Plan.

Trump's companion memorandum instructed funding agencies to vet foreign visitors and to limit the participation of US government employees in such talent programmes.

In the same month the OSTP guidelines and memorandum were published, US Congress voted into law some broad requirements — that federal agencies must have disclosure rules, and that the OSTP must ensure the rules are consistent across agencies — in the National Defense Authorization Act (NDAA), an annual defence policy bill.

But meeting all the requirements might be too expensive for some smaller universities, says Deborah Altenburg, associate vice-president for research policy and government affairs at the Association of Public and Land-Grant Universities (APLU) in Washington DC. She hopes that the items are viewed as recommendations and not "a checklist of things that every university should do".

One agency is pressing ahead with changes suggested by the JCORE report. In a notice released in March, the NIH for the first time asked scientists to include copies of contracts or agreements with any foreign institutions, including a translation of the original documents if they are not in English, when applying for or submitting updates to grants.

The NIH's new requirements take effect in May, a deadline that universities and researchers could struggle to meet, says Kristin West, director of research ethics and compliance at the Council on Governmental Relations, based in Washington DC. Some contracts might contain non-disclosure or confidentiality clauses, she explains, which would need to be navigated for the first time, in addition to getting translations.

The Biden administration indicated how it might deal with research security issues in March. OSTP staff member Aaron Miles, one of the authors of the JCORE report, said at a presentation to the National Science, Technology, and Security Roundtable hosted by the National Academies of Sciences, Engineering, and Medicine, that Trump's memorandum "is government policy, and we are moving forward with implementation".

It is still unclear how the Biden administration will approach concerns of scientists of Asian descent that they are being racially profiled by US research security efforts.

In January, civil-rights groups called on the Biden administration to shut down the Trump administration's China Initiative, launched in 2018 by the Department of Justice to prevent theft of US intellectual property by the Chinese government. The groups said the programme "has greatly increased the targeting and profiling of Asian Americans and immigrants, particularly those of Chinese descent who are working in science and technology".

A mass shooting in March brought fresh attention to anti-Asian racism in the United States, when a gunman killed eight people, including six Asian women, in Georgia. Civil-rights groups have seen a spike in incidents of anti-Asian violence over the past year.