

A ground staff walks past a container kept at the Cargo Terminal 2 of the Indira Gandhi International Airport in Delhi, which according to the officials will be used as a COVID-19 vaccine handling and distribution center, during the media preview on 22 December 2020. ANUSHREE FADNAVIS/REUTERS

On the first day of India's COVID-19 vaccination drive, healthcare workers from some government hospitals in Delhi expressed apprehension about Covaxin, which was developed by the pharmaceutical company Bharat Biotech. This is due to the government clearing the vaccine for use despite the company having not published any of its phase three clinical trial data. Many health workers refused to go to their vaccination sites on the morning of 16 January.

India granted emergency approval to two vaccines in early January. One was Covishield, manufactured by the Serum Institute of India in association with Oxford University and the British-Swedish pharmaceutical Astrazeneca. The other is Covaxin, made by Bharat Biotech in collaboration with the Indian Council of Medical Research. Astrazeneca's vaccine has completed phase three trials and the company <u>claims (https://www.astrazeneca.com/content/astraz/mediacentre/press-releases/2020/azd1222hlr.html)</u> an average efficacy of 70 percent. Covaxin's phase three trials are still being conducted and there is no efficacy data on the vaccine as of yet. The Covaxin consent form, which beneficiaries have to sign before they get the vaccine, acknowledges that "clinical efficacy of Covaxin is yet to be established and is still being studied in phase three clinical trial." This lack of efficacy data and the fact that the healthcare workers did not get the chance to choose between the two vaccines led to many doctors opting out of the vaccination drive.

"This is a matter of grave concern," Dr Pawan Sinhmar, general secretary of the resident doctors association at the All India Institute of Medical Sciences in Delhi, said. "Yes, this is in essence a voluntary exercise. If we were being offered Covishield, we might still have gone for it, but I don't see the point of getting inoculated with a vaccine whose trial is still going on and whose efficacy is unknown." Sinhmar is a volunteer in the phase three of the Covaxin trial at AIIMS Delhi and still disapproved of the vaccine being launched for general use before the trial was complete. He told me that if he had not volunteered for the trial, he would not have participated in the vaccination drive held at AIIMS. "There is a difference between volunteering for a trial and getting vaccinated against a disease," he clarified. "In a trial, you know there are risks involved and you know that you cannot be sure of the efficacy of a vaccine. But when the vaccine has been approved, it should be because it has established efficacy against fighting the disease."

Delhi had <u>prepared (https://www.ndtv.com/india-news/over-10-700-</u> <u>covid-deaths-later-delhi-all-set-for-vaccination-battle-2353339)</u> to vaccinate more than eight thousand health workers on the first day. According to data that the health ministry released in the evening, only 4,319 people were vaccinated. Across India, 1,91,181 people got the vaccine. AIIMS is among six other central government-administered district hospitals designated as Covaxin vaccination sites in Delhi. Seventy five other sites, including private hospitals and public hospitals run by the Delhi government, were designated as sites for Covishield to be administered. At all the vaccination sites, a list of hundred beneficiaries was drawn up beforehand and uploaded on an application—the COVID-19 Vaccine Intelligence Network or Co-WIN. The health ministry created the app to monitor the mass vaccination drive in India.

A resident doctor from AIIMS who was posted on vaccination duty at the hospital said many healthcare workers who were on the list of the first hundred, refused to come in at the last moment. "Out of the original list of hundred beneficiaries which was uploaded in Co-WIN, only about forty agreed to come," the doctor, who asked not to be identified, said. I spoke to a nursing officer posted at the vaccination site at AIIMS, who said that staff members had to make calls to beneficiaries because Co-WIN had crashed and could not send out automated messages. "Since many of the people in the list refused to come or made excuses like they are out of town, we had to make last minute appeals to other senior doctors and faculty members," the nursing officer said. The people on the original list who got vaccinated at AIIMS on the inaugural day included Vinod K Paul, a member of the NITI Aayog and the head of the national expert group on vaccine administration, Balram Bhargava, the director general of the ICMR and Randeep Guleria who is the director of AIIMS.

By 3:30 pm in the afternoon, only about forty people had reported at AIIMS. The vaccinators had to show that they had administered all 100 vaccine doses. "We sent out frantic messages to everyone, asking whoever wished to be vaccinated to come in," the doctor at the site, told me. "Security guards were asked to go and physically recruit staff from the campus as well and by 5 pm we met the 100 people mark."

At Ram Manohar Lohia Hospital in New Delhi, another central government hospital dedicated as a Covaxin vaccination site, members of

the resident doctors' association sent a letter to Rana Anil Kumar Singh, the medical superintendent of the hospital, expressing their anxiety about Covaxin. The letter said that many doctors "might not participate in huge numbers thus defeating the purpose of vaccination." They asked to be vaccinated with Covishield, which "has completed all stages of the trial before its roll out." A senior resident doctor from RML hospital told me that only about ten out of the hundred beneficiaries who were inoculated at the site were healthcare workers from the hospital. The rest were health workers working in other places in Delhi. "And I don't expect many more to come and participate if we don't get the choice to opt in for Covishield," the senior resident said.

Nirmalya Mohapatra, the president of the resident doctors' association at RML hospital circulated a video message on 16 January among social media groups with other doctors in which he said, "At the moment we do not wish to take Covaxin, and we prefer Covishield. This is not to say that Covaxin is not a good vaccine or that Covishield is better. It is just the fact that the trial is not completed and we would like to wait for data from the phase three trial before we opt in for Covaxin."

Amidst all this, the health ministry and government officials have continued to make statements assuring citizens of the safety and efficacy of Covaxin. In his address to the nation while inaugurating the vaccination drive, Prime Minister Narendra Modi <u>asked</u> (https://www.thehindu.com/news/national/covid-19-vaccines-safe-dontbelieve-rumours-modi/article33586672.ece) people to dispel rumours and have faith in "India-made vaccines," which was a reference to Covaxin. At AIIMS, Paul, the NITI Aayog member, <u>told</u> (https://www.hindustantimes.com/videos/coronavirus-crisis/covid-drvk-paul-aiims-director-urge-people-to-trust-researchers-on-vaccine-<u>to1610802664437.html</u>) reporters, "Both vaccines have been authorised for emergency use and there should be o doubt about their safety. They

have been tested on thousands of people and side-effects are negligible.

There is no risk of any significance." In Bengaluru, K Sudhakar, the Karnataka health and medical education minister <u>claimed</u> (http://www.businessworld.in/article/Historic-day-says-Karnataka-Health-Minister-on-vaccine-drive-against-COVID-19/16-01-2021-366222/) that all precautions had been taken in case of side effects. On 5 January, *The Caravan* reported (https://caravanmagazine.in/health/inbhopal-covaxin-trial-volunteers-allege-irregularities-in-recruitmentand-treatment) on irregularities in recruitment and treatment of Covaxin trial volunteers in Bhopal.

Many doctors told me they had not been swayed by the assurances of elected leaders and bureaucrats, and are still asking for scientific data on Covaxin's efficacy. "We want a vaccine, all of us do," Sinhmar from AIIMS said. "But we should not be forced to choose a vaccine that we are not sure will protect us from the disease in the long run. We deserve better than that."

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Correction: An earlier version of this article incorrectly named VK Tiwari as the medical superintendent of Ram Manohar Lohia hospital. The current director and medical superintendent is Rana Anil Kumar Singh. The Caravan regrets the error.

