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COVID-19: Is our pre-vaccination screening good enough to catch infections and comorbidities?

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People participating in a COVID-19 vaccine delivery system trial wait for their turn at a COVID-19 vaccination center in Delhi on 2 January. ALTAQ QADRI / AP PHOTO

Mahipal Singh, a 52-year-old ward attendant at the Pandit Deen Dayal Upadhyay District Hospital in Moradabad, Uttar Pradesh, died on 17 January. He died a day after being injected with Covishield, the COVID-19 vaccine manufactured by Serum Institute of India, on the first day of India's vaccination drive. Shortly after the injection, Mahipal called his son Vishal, asking to be picked up from the hospital. "He told me he wasn't feeling good," Vishal said. "*Unhe ghabrahat si ho rahi thi, aur saas lene mein dikkat*"—He was feeling anxious and had difficulty breathing. Vishal picked Mahipal up at around 2 pm. Mahipal continued to feel worse through the day while at home. The next morning, he had a fever of 101 degrees Fahrenheit. He also had growing chest pain, difficulty breathing and palpitations. By the afternoon, Vishal took him to the emergency ward of the district hospital, where Mahipal was pronounced dead upon arrival.

Mahipal was the first person reported to have died as a result of an Adverse Event Following Immunisation with a COVID-19 vaccine in India. Moradabad health authorities ruled out a causal relationship between Mahipal's death and the vaccine. "He had existing cardiopulmonary disease and infection," Dr Milind Chandra Garg, the chief medical officer at the hospital and a member of its AEFI committee, said. "He should have informed vaccinators at the site regarding this," he said. Vishal said his father did not have a history of cardiac or pulmonary conditions. "And if he did have such a problem and was suffering from an infection, isn't it the doctors job to check the health of the individual before vaccinating them? Why did they inject him in the first place?"

Vishal raised the question: did Mahipal's comorbid conditions or his existing infection put him at greater risk of suffering an adverse reaction to the vaccine? Garg's statement that Mahipal should have reported his condition suggests so. But, if that is the case, why were health authorities so quick to rule out a link between the vaccine and Mahipal's death? A third question is whether people with different kinds of health conditions are actually ineligible to take the COVID-19 vaccines and whether the vaccination programme has been too rushed to investigate this. A fourth question is what this means for the next stage of the drive, when vaccines are to be administered to the elderly and people with comorbidities.

Since Mahipal's death, at least 40 more healthcare and frontline workers have died after vaccination. These deaths have occurred in Uttar Pradesh, Karnataka, Telangana, Haryana, Rajasthan, Odisha, Kerala, Andhra Pradesh and Gujarat. Most of these deaths have been attributed to a myocardial infarction or a heart attack by health authorities. The death of a 42-year-old ASHA worker (<https://www.thehindu.com/news/national/telangana/deaths-trigger-aeft-inquiry-job-land-promised-for-kin-of-ap-health-worker/article33649574.ece>) from Andhra Pradesh was attributed to a "thrombogenic ischemic demyelination," or a brain stroke. In all these

cases, local authorities were quick to dismiss a causal link to the vaccine, even as post-mortem reports and AEFI committee recommendations were yet to be issued. The ultimate authority that decides on AEFIs is the national AEFI committee. Rajesh Bhushan, the union health secretary, said (https://www.youtube.com/watch?v=3xabDoEChCo&ab_channel=PIBIndia) that the committee met for the first time on 5 February when it ruled that two of AEFI deaths were unrelated to the vaccine. Since then, the ministry announced any other meetings or decisions.

Like in Moradabad, health authorities looking into other AEFI cases blamed the deceased healthcare workers for not revealing existing health conditions to vaccinators. Dr HL Janardhan, a member of the AEFI committee in from Karnataka's Bellari district, where a 43-year-old hospital attendant named Nagaraju died on 18 January, two days after he was vaccinated with Covishield said that Nagaraju "was a known case of diabetes mellitus since eleven years and also a hypertensive patient. He had been taking treatment but it was under poor control." Referring to other people getting their COVID-19 shots he said, "It will be better if they report comorbidities before the vaccination."

An AEFI, the World Health Organisation says (https://www.who.int/vaccine_safety/initiative/detection/AEFI/en/), is any untoward medical occurrence that follows immunisation and which does not necessarily have a causal relationship with usage of a vaccine. For example, a person may be injured in a road accident a day after getting a vaccine shot. This is also considered and AEFI though clearly not related to the vaccine or vaccination procedures. AEFIs are categorized as mild, severe and serious. Mild events relate to vaccination are quite common for many vaccines including the COVID-19 vaccines in us and include itchiness at the site of vaccination, mild fever and fatigue. Severe events like allergic reactions and seizures can be disabling but do

not last long. Serious events are those that are life-threatening or cause long-term incapacity.

As of the third week of February, 46 healthcare workers have been hospitalised after vaccination, which is 0.004 percent of the total number of people vaccinated against COVID-19 in India. Forty one people have died after vaccination, which according to the statistics provided by the Health Ministry, is 0.0004 percent of the total number of vaccine beneficiaries. The WHO considers (<https://vaccine-safety-training.org/rates-of-adverse-vaccine-reactions.html>) a rate of serious AEFIs below 0.01 per cent very rare and not a cause to doubt the safety of a vaccine or vaccination processes. However, in its safety surveillance manual (https://www.who.int/vaccine_safety/committee/Module_AEFI.pdf?ua=1) for COVID-19 vaccines, the WHO notes that “the identification of rare (occurring in 0.01% to less than 0.1% of immunized individuals) and very rare (occurring in <0.01% of individuals) adverse events is insufficient at the time of COVID-19 vaccine licensing and more information will be needed for which AEFI surveillance has to be strengthened.” Since the vaccine is new, we do not have enough data yet to come to conclusions about vaccine safety of the basis of the rate of AEFI events.

Vineeta Bal, an immunologist and faculty member at the Indian Institute of Science Education and Research in Pune, told me that the most likely way in which vaccination can aggravate existing ailments or conditions and cause serious AEFIs in recipients is through the stress caused by the vaccination process itself. “Adults are not used to being inoculated,” she said. “We receive most of our vaccinations as infants and now, with COVID-19, the added anxiety of a completely new disease and its vaccine, and all the talk around it with regards to safety, it is bound to create stress in the body, not just mentally, but physically.” According to her, such stress to the body can possibly offset one’s heart rate or blood pressure. “And if you are already suffering from a heart ailment, this will

complicate matters further, trigger structural or functional changes that may even cause heart failure,” she said.

In Mahipal’s case, Vishal told me that his father was anxious about taking the vaccine. “We had heard rumours about it being unsafe and we told him not to take it, but he said he is worried that if he refused to take the vaccine it might anger his employers, possibly affecting his employment.”

Bal said that both vaccines currently being administered in India do not have components that are likely to put people with comorbidities at greater risk for an allergic reaction or a serious AEFI. “Though as a general rule vaccinators should take extra precaution when the comorbidity is uncontrolled,” she said. “If you check someone’s vitals for example and see that they are hypertensive at the time, then you should of course put off the vaccination.”

This is where a possible gap emerges in the screening process of vaccine beneficiaries. “The post-mortem report, especially the fact that he had pus in his lungs, suggests a case of an active infection,” Bal said. “This means he shouldn’t have been vaccinated in the first place. A simple X-ray would have shown us he was not healthy enough to be vaccinated.” A lax screening process, paired with a hurried response by authorities to dismiss a possible link between the vaccine and serious AEFIs, is worrying.

In Telangana’s Nirmal district, a 42-year-old ambulance driver died on 20 January, a day after getting vaccinated. In a press release on the same day, state health authorities said preliminary reports suggested that the death was unrelated to the vaccine. “We will need a few more days to arrive at a conclusion,” Dr TS Venugopal, the resident medical officer at Nirmal, said. “There is a team of forensic experts, pathologists and other experts looking into the incident.” On 21 February, Venugopal told me that the

investigation had now been transferred to the state AEFI committee, who is yet to share the results of their investigation.

Bal told me that it was callous to quickly dismiss the link between the AEFI death and the vaccine. “Instead we should focus on what went wrong here,” she said. “What contraindications need to be taken into account before vaccinating people? How should we screen and manage beneficiaries who are already sick or suffering from existing conditions?”

Health authorities have not disclosed how many of the healthcare workers who died got Covishield and how many got Covaxin. Both vaccines currently in use in India have been approved under slightly different conditions. Accordingly, screening for comorbidities in potential recipients is also slightly different. On 14 January, two days before the vaccination drive began, the health ministry issued instructions for screening before administering either vaccine. The additional health secretary Dr Manohar Agnani sent a fact sheet comparing Covaxin and Covishield, and listing contraindications for both the vaccines to state immunisation officers and National Health Mission directors. A contraindication is a medical condition or factor that serves as a reason to withhold particular medical interventions like a drug or a vaccine.

According to this letter, lactating or pregnant women and anyone with a history of allergy to any vaccine, injectable or food item should not be given either vaccine. An allergic reaction, such as anaphylactic shock, is a dangerous, often life-threatening condition that can develop after injecting the vaccine. However, these allergic reactions mostly occur within half an hour of vaccination and are not typically known to induce myocardial infarction or heart attacks. All vaccination sites are typically equipped with anaphylaxis-management kits and, according to the health ministry’s operating guidelines on AEFI management, each vaccinator should be trained to manage such reactions. The letter also listed symptoms of an active COVID-19 infection, a history of

administration of monoclonal antibodies or convalescent plasma therapy for treatment or acutely unwell patients of any other disease as provisional contraindications for both vaccines. Lastly, it prescribed special precautions in vaccinating individuals with a history of bleeding or coagulation disorders.

Bharat Biotech had issued guidelines for Covaxin, on 11 January, which said that, along with pregnant and breastfeeding women and people with histories of allergies, people who are immunocompromised, are on blood thinners or have “any other serious health related issues as determined by the Vaccinator/Officer supervising vaccination” are not eligible for the vaccine. The instructions issued by the ministry however, claims that “history of chronic diseases and morbidities,” as well as “immunodeficiency, HIV, patients on any immunosuppression due to any conditions,” are not contraindicated for COVID-19 vaccines.

Satyajit Rath, an immunologist and adjunct professor at IISER Pune, told me that Bharat Biotech's guidelines appeared to have been made in a hurry. “The contraindications are not so well thought out it seems,” Rath said. “For one, I don't see why those on immunosuppressants cannot be vaccinated.” He said that all COVID-19 vaccines currently approved for use across the world do not put immunocompromised individuals at increased risk of acquiring infection. “This is because none of the vaccines in use today use a live virus to inoculate. So there is no safety issue here.” Rath noted, however, “that the vaccine might not induce a great enough immune response in an immunocompromised individual. Its efficacy will be lower in such individuals.” An immunocompromised person is not at greater risk of an AEFI, but may get a lower degree of protection as compared to otherwise healthy individuals.

Bharat Biotech's guidelines have also set off a new round of questions on whether people on blood thinning medication can be safely administered the vaccine. Both vaccine-makers have approached the Drugs Controller General of India for permission to revise their public advisories on

contraindications. Even while the confusion over contraindications persists, the vaccination drive has continued with more than 6.8 million healthcare and frontline workers being vaccinated by 10 February. “It’s important the additional guidance is shared and implemented at the earliest, considering it is almost three weeks into the vaccination drive,” Malini Aisola, a co-convenor of the All India Drug Action Network, said.

Healthcare workers posted on vaccination duty said that they struggled with conflicting instructions and were confused about who was fit to be vaccinated. A resident doctor from the All India Institute of Medical Sciences was unsure whether to vaccinate a person with asthma who was taking inhaled steroids. “That person was on low levels of steroids, but I wasn't sure if it was enough to be considered as a contraindication,” the doctor said. “They need to be clearer with us or have more senior consultants there to screen.”

On 19 January, healthcare workers on vaccination duty at AIIMS were reprimanded for rejecting potential beneficiaries with a history of “minor allergic reactions.” “So then we decided that only those who have had very serious allergic reactions in the past, like an anaphylaxis, will be excluded from the vaccination drive,” the doctor said. Doctors working at Covishield vaccination sites were also unsure about screening beneficiaries. “We were just told to be careful with pregnant ladies and those with a history of allergies,” a doctor posted for vaccination duty at Delhi’s Dr NC Joshi Memorial Hospital said. “And you know how it is in India—most people don’t even know what they are allergic to!”

On 20 January, Dr Anshul Garg, an official at the United Nations Development Programme, moderated an online meeting for vaccinators. Dr Suresh Seth, Delhi’s state immunisation officer, attended the meeting, in which many healthcare workers raised their concerns about the conflicting instructions. “Many of us were concerned whether we should vaccinate people on blood thinners, or people who have cancer,” the resident doctor at AIIMS, who attended the online meeting, told me.

Only Covaxin was being administered to healthcare workers at AIIMS. The doctor told me that Seth directed everyone present at the meeting to stick to the health ministry’s instructions. “Someone in the meeting asked whether they could vaccinate an 80-year-old healthcare worker with cancer, and Dr Seth told them those are the kind of people that should be vaccinated on priority. However, we still have our reservations. At AIIMS we were handed the Bharat Biotech instructions by our seniors, so it gets really stressful to take a call when an immunocompromised individual or an older person with comorbidities comes in.”

Rath said that people with comorbidities and underlying conditions should be vaccinated on priority. “It is not that those with comorbidities are more at risk for an AEFI, but that if they do get an allergic reaction, it can be exacerbated due to existing comorbidities like a heart ailment,” Rath said. “But I don’t believe such risk of reaction should come in the way of vaccinating people.” However, a robust screening and surveillance system needs to be in place to ensure that no one suffers a life-threatening AEFI. Referring to the Mahipal Singh case, Rath said that an active infection should have been easily detected and that Mahipal’s vaccination should have been postponed. “From what I have read in news reports, the man had pneumonia,” Rath said. “Even if he was not able to inform vaccinators regarding his symptoms, the screening process in place should be thorough enough to elicit these answers from beneficiaries.”

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Mathew Thomas
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Covid is like a brand name. Many people think they are aware of it. Basic questions to ask before proceeding on the assumptions that Covid-19 is a serious disease, that vaccines will prevent it etc. 1. Has the virus been isolated? 2. Are there excess deaths attributable to Covid-19? 3. Were autopsies done before deciding cause of death as due to Covid-19? 4. Can RT-PCR test be used for detection of infected cases? Replies to me on RTI queries are negative.

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