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COVID-19: Is the post-vaccination surveillance system working for the mega vaccine drive?

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Medical workers wait to be inoculated with a Covid-19 coronavirus vaccine at a hospital in Delhi on 16 January. JEWEL SAMAD / AFP / GETTY IMAGES

On 19 January, VK Paul, a member of the NITI Aayog, told journalists at a press conference that the COVID-19 vaccines being administered in India were completely safe. In the three days since the start of India's mass-vaccination drive on 16 January, two healthcare workers had died after suffering serious Adverse Events Following Immunisation. By the third week of February, the health ministry reported 41 AEFI deaths.

In his 19 January statement urging people to take the vaccines, Paul—who is also the chairman of the National Expert Committee on Vaccine Administration for Covid-19, or NEGVAC—offered assurances about the AEFI-surveillance system. "Look at the AEFI-surveillance system that has been perfected in our country," he said. "It hasn't come in the last six weeks. It has been built at least since the past two-and-a-half decades. This is a very functional program based on best practices of the world and operates under WHO oversight." However, the treatment of the

deaths after COVID-19 vaccinations in the first month of their rollout has indicated an unnecessary rush in AEFI investigations, coupled with a lack of transparency. Civil-society groups focussed on public health have written to the government urging it to recognise the deaths as a cluster of serious AEFIs and to make investigation reports public.

According to the National Health Mission's guidelines (https://nhm.gov.in/New_Updates_2018/NHM_Components/Immunization/Guilde AEFI surveillance and management, an AEFI "is any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine." While minor AEFIs are merely recorded in an online portal or registry—the CoWIN app for the COVID-19 vaccination drive—more serious or severe AEFIs need to be reported to the district's immunisation officer and AEFI committee. AEFI committees at the district, state and national level, evaluate AEFI reports, identify AEFI clusters and patterns, determine causes of AEFIs and make recommendations for managing post-vaccination illnesses.

The first AEFI death in the COVID-19 vaccination drive occurred in the evening of 17 January. Mahipal Singh died in Moradabad a day after he got the Covishield vaccine. *The Caravan* accessed his post-mortem report, which noted that Singh had pus pockets in his lungs and his heart had enlarged to weigh 500 grams from the normal weight of 200 grams. The report ruled the cause of death as a "heart attack/ septicemic shock." Dr Milind Chandra Garg, the chief medical officer in Moradabad, told me that the district AEFI board had met twice before arriving at the decision that Singh's death was not caused by the vaccine. "We had a meeting once on 17th night right after his death and on 18th after the post mortem report." Garg refused to share details of the discussions held in the meetings.

Vineeta Bal, an immunologist and faculty member at the Indian Institute of Science Education and Research in Pune, noted that the fact that

Singh was vaccinated despite a possible active infection in his lungs was a reason to examine the surveillance system. In her opinion, Singh should not have been vaccinated.

In the absence of a direct and obvious link, AEFI committees are likely to declare an event or death as unrelated to vaccination. This, in turn, leads to lower scrutiny of unwell people before vaccination because of the feedback that severe AEFIs or deaths are not linked to the vaccine. "The stress on establishing a causal link needs to be done away with," Bal said. "It is hard to pinpoint a cause and effect for a condition. You never know what little change in the human body can trigger a serious ailment, even death."

Establishing a causal link in a thorough AEFI investigation typically takes much more time than government officials have taken for the COVID-19 vaccines, Dr Santanu Tripathi, the former head of experimental pharmacology at the Calcutta School of Tropical Medicine observed. "The possible association, if any, needs to be investigated following standard methodology," Tripathi said. "It is unfair to instantly declare an association or the lack of it, without doing the statutory causality analysis based on thorough investigation by the responsible stakeholders. Neither a quick dismissal of a possible link between an injury and the vaccination nor an early attribution of an injury to the vaccine, is acceptable."

Tripathi said that investigators should look out for "relatedness" between the vaccine and a serious AEFI, especially for Covaxin, which has been approved before the third phase of its clinical trial was completed. India's New Drug and Clinical Trial rules (https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf) define relatedness as the link between a vaccine and a severe adverse event. These rules outline the processes of conducting clinical trials in India and define the compensation process in case a trial participant suffers a severe adverse

event during the trial. The concept of relatedness provides a broader category of adverse reactions or side effects that can be considered as linked to the vaccine, while existing AEFI guidelines on causality assessment are narrower in scope. For example, while the AEFI guidelines list simply "immunisation error related reaction" as one possible cause for an AEFI, the clinical trial rules list "violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator leading to serious adverse event" as a basis for establishing a link between the vaccine and the adverse event. "For Covaxin, the safety surveillance is characteristically different from that of Covishield, and is active and solicited," Tripathi said. "Further, there is a provision for compensation for vaccination-related injury; and hence there should be a mechanism for 'relatedness assessment' over and above the usual causality analysis by the AEFI-management team."

AEFI surveillance for the two COVID-19 vaccines being used in India are different due to the different conditions of their approval. Covishield—the vaccine developed by the Serum Institute of India in collaboration with Oxford University and Astrazeneca—which has reported phase-three trial data for efficacy and safety, is being monitored through passive surveillance. The onus is on recipients to report symptoms or adverse side effects and seek medical care. Bharat Biotech's Covaxin, which the Drugs Controller General of India approved despite the absence of phase-three data, has been rolled out in what the regulator calls "clinical trial mode." Recipients of Covaxin have to sign consent forms and are essentially part of an extended clinical trial. The consent form assures Covaxin recipients that they will be "monitored for any adverse event under this clinical trial mode and supported for medical care under the existing public health program." At the 19 January press conference (https://www.youtube.com/watch?v=e4fpPkFOEfc&t=1962s&ab_channel=JimmyKimmelLive), Rajesh Bhushan, the health secretary, claimed Covaxin beneficiaries were being actively surveyed for AEFIs. "Covaxin has an active follow up," he said. "A doctor rings you up on a daily basis to check on you."

However, doctors working as vaccinators in Delhi told me they had received no instructions to conduct active surveillance for Covaxin. "We have given them a contact number to call on if they feel any side effects but there are no instructions to reach out to them on a regular basis, or call them at all post-vaccination," a resident doctor from Safdarjung Hospital, which is one of the sites for Covaxin in Delhi, told me. The doctor, who wished to remain anonymous, said they were conducting a passive form of surveillance, where all recipients were given a diary card in which they have to record any side effects or symptoms for a period of seven days after their first dose of the vaccination. "They are expected to bring this diary card with them when they come for the second dose," the doctor said. "Apart from this we give them a number on which they can call during an emergency."

Another possible weakness of COVID-19 vaccine surveillance is that it relies on a system geared towards childhood immunisation. Even though India's Universal Immunisation Program has been highly successful, it largely bypasses adult vaccinations. The UIP's guidelines on AEFI surveillance puts the onus of reporting symptoms on the recipients, or the parents of the recipients, unless the AEFI or allergic reaction takes place immediately after vaccination in the presence of the vaccinator. The 2015 guidelines on AEFI surveillance and response ask (https://nhm.gov.in/New_Updates_2018/NHM_Components/Immunization/Guilde providers to advise parents on how to manage common or minor symptoms and side effects of vaccination at home. They also advise vaccinators to insist that immunised children be kept in observation for a 30-minute period.

According to Bal, the existing mechanism of AEFI surveillance and reporting works well for childhood immunisation programs "because healthcare workers are well versed with these vaccines, and their common side effects, and how to manage and report them etc. They have had years if not decades of experience with some of these vaccines." This surveillance system needs to be rejigged for COVID-19 mass vaccination.

“With the COVID-19 vaccine, we need more trained experts on the ground,” she said. “We need more specialists in the district and state AEFI committees who can investigate the AEFI.”

Dr Satyajit Rath, an immunologist and adjunct professor at IISER Pune, said that adapting immunisation and AEFI-surveillance programmes towards adult vaccination need an extra schedule of precautions and a detailed standard operating procedure for managing people who have existing ailments or are immunocompromised. “You need to follow up on them more regularly, keep them under observation for longer periods and have active surveillance, regardless of whether they are given Covishield or Covaxin.”

The health ministry issued (https://drive.google.com/drive/u/0/folders/0BwUXOPGNv3URaU1wUktrMWFiSnM guidelines in December that have overarching recommendations on reporting and managing AEFIs. These include instructions on categorising AEFIs into minor, serious or severe events and reporting severe or serious AEFIs to appropriate authorities. The guidelines further explain how to manage an on-site anaphylactic reaction and ask for vaccinators to look out for recipients with a history of allergic reaction to vaccination or a recent history of the disease itself. They do not mention active surveillance or extra precautions for managing recipients with comorbidities, other contraindicated conditions or vulnerable populations.

The operational guidelines asked states to expand AEFI committees to include more medical experts such as neurologists, cardiologists, pulmonologists and gynecologists. “But who checks that all of this is actually happening on the ground?” Dr Anant Phadke, a member of the All India Drug Action Network who is associated with the people’s movement Jan Swasthya, asked. “Have these recommendations actually been implemented? We don’t know how these committees operate.” In the case of Singh’s death in Moradabad, Garg, the chief medical officer,

said that the only addition made to the district AEFI committee was a gynecologist. According to Garg, the committee lacked specialists including a pulmonologist and a cardiologist, both of which would be relevant in analysing the cardio-pulmonary complications reported in the deceased healthcare worker's post mortem report. "We were only asked to get a gynecologist in the committee, so we did that," he said.

Phadke said that the lack of transparency in AEFI surveillance and reporting ensured lapses of even well-framed policies and guidelines on recognising contraindications, screening patients, or reporting AEFIs on time. "How do we know how many AEFIs are actually reported?" he asked. "How many recipients are hospitalised and treated or receive compensation for their injury?"

On 31 January, public-health activists, ethicists and other members of civil society wrote to the health minister Harsh Vardhan, the DGCI Venugopal G Somani, the NEGVAC chairperson Paul and the secretary at the department of biotechnology Renu Swarup, calling for transparency in the investigations of AEFI deaths in healthcare workers. The letter said that though district- and state-level officials claimed no link between COVID-19 vaccines and the 11 AEFI deaths that had occurred at the time the letter was written, the reports of the AEFI committees on these investigations had not been released. "No details of who investigated the deaths, and the methodology used for each investigation, have been made public," the letter said. "The National Committee has an obligation to investigate possible patterns in causative factors for these deaths."

The authors of the letter also demanded that the 11 deaths be considered as a "cluster of serious AEFIs" in accordance with the World health Organiation's definition: when two or more AEFIs related in time, place or by vaccine occur. Such cluster events, the letter said, "must be investigated urgently in order to issue warnings to people who should not take it due to contraindications, to correct errors, to reassure the public, as well as to identify potential serious problems in the vaccine."

The letter asked whether a committee of experts had discussed pausing the current vaccination program to investigate deaths, whether the program would be altered due to the deaths and whether no-fault compensation would be paid to family members of deceased healthcare workers.

One big reason for rushed and sub-standard AEFI investigations is that vaccine manufacturers and governments do not want to be blamed or sued for severe AEFIs. It may be assumed that there will be a small number of vaccine-related injuries or deaths in a large vaccination drive under emergent circumstances. One way to ensure participant safety and robust investigations is to have no-fault compensations. Researchers from the Yale School of Public Health and the Yale Institute of Global Health wrote in a December 2020 article for the *New England Journal of Medicine* that a global no-fault compensation model was essential to stop pharmaceutical companies from demanding indemnity (https://www.google.com/search?q=indemnification&oq=indemnification&aqs=chrome..69i57j0i433j0l5j0i395.2972j1j7&sourceid=chrome&ie=UTF-8) from governments. It would also save low- and middle-income companies from the dilemma of choosing whether to "refuse to offer manufacturers protection against liability and go without COVID-19 vaccines or to extend liability protections (if doing so is constitutionally possible) and risk having a large number of people injured to whom the government is unable to offer compensation."

Bal said that the Indian government should have implemented a no-fault compensation mechanism before the COVID-19 vaccination drive started. Such a compensation would have ensured that any recipient who suffered an AEFI would be compensated without holding the vaccine manufacturer or the government liable. "In this way you ensure that the interests of beneficiaries are safeguarded without them having to go to court over such issues and incriminate vaccine manufacturers," she added. "This will also give authorities less incentive to rid themselves of

accountability and hastily dismiss any causal relation between the vaccine and the AEFI."

Rath said that an audit of the AEFI-surveillance system and the vaccination drive was essential to ensure that the health of beneficiaries was not compromised. "Every vaccination drive will result in AEFIs, sometimes even death of recipients," he said. "But what matters is whether authorities are taking adequate precautions to prevent and manage such events." He added that, at the very least, families of those who die of an AEFI "have the right to demand that the investigation reports on the AEFI and the process of determining cause of death be revealed to them. They can't be left in the dark without recourse."

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