NEWS / HEALTH

COVID-19 patients are dying in the "no man's land" between antigen and RT-PCR tests

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A health worker takes a nasal swab for a COVID-19 test at a hospital in Delhi, on 6 July 2020.
MANISH SWARUP/AP PHOTO

COVID-19

(/covid-19)

On 9 August, Menekanta Gupta and eight members of his family went to 30 private hospitals in Andhra Pradesh's Vishakhapatnam district to find a bed for his 54-year-old father, N Venkata Rao. Rao had taken a rapid antigen test for COVID-19 that said he was negative but he was breathless, fatigued and his health rapidly deteriorated. All 30 hospitals refused to admit him citing shortages of beds and ventilators for non-COVID patients. "We were prepared to do anything—pay all the hospitals whatever they need—but they refused and told us to admit my

father elsewhere, where there were beds to treat non-COVID patients and especially where they have ventilators for non-COVID patients," Menekanta said.

Desperate, he turned to authorities at the Maharaja District Hospital in Vizianagaram, a town 15 kilometers away from his village of Padmanabhan, in Visakhapatnam district. The hospital, which is now a dedicated COVID-19 care facility, gave Rao another rapid antigen test and the result came back as negative, again. This hospital referred him to the King George Hospital in Vishakhapatnam city.

Rao died on the evening of 11 August at the King George Hospital, the night after he got a bed. His family had spent two days trying to get him into hospital. At the time of his death, his blood-sugar level had spiked to six times the normal range. His oxygen-saturation level had fallen to 40 percent, while the minimum saturation level for a healthy adult is 90 percent. The hospital listed his primary cause of death as "cardiopulmonary arrest" and secondary causes as "pneumonia, diabetic ketoacidosis and type 1 respiratory failure." Diabetic ketoacidos is a serious complication in patients who suffer from type 1 diabetes.

His family invited hundreds of relatives to his funeral rites since his death was not attributed to COVID-19. Five days after his death, local health officials told Menekanta that his father had posthumously tested positive for COVID-19 in a Reverse Transcriptase Polymerase Chain Reaction, or RT-PCR test. "He tested negative twice with the antigen test and after we lost him they told us he had COVID-19," Menekanta said, while in home quarantine with his family at their village. "He had the disease all along and yet we shuttled him from hospital to hospital where they denied him treatment."

India introduced antigen testing to complement the gold standard RT-PCR tests, to widen the net and detect more cases early. But false negatives from antigen tests have resulted in hospitals denying early life-

saving interventions. The hospitals Rao went to were overly reliant on tests before starting treatment, even when his symptoms were apparent.

The Indian Council of Medical Research issued an advisory (https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test14062 on 14 June that antigen test kits can be used as "a point of care assay" for testing in containment zones, hotspots and healthcare settings. Antigens are any foreign bodies that trigger an immune response and the kits detect proteins from antigens found in throat or nasal swabs. Currently available antigen tests have high specificity, which means that they throw up very few false positives. The problem, however, is that they have very low sensitivity, which means that they can give many false negatives. Therefore, the ICMR said, the positive antigen test could be considered a "true positive" implying that a person's treatment could be started based on that test. However, a person who tested negative for COVID-19 on the rapid antigen test should be tested again with RT-PCR to rule out infection.

Since the advisory, states have increasingly relied on rapid antigen tests not just as a quick screening tool, but as a diagnostic tool at par with the RT-PCR test. In a press conference on 4 August, the ICMR director general Dr Balram Bhargava said that between 25 and 30 percent of tests conducted in India everyday are rapid antigen tests. According to data compiled by COVID-19 India.org (https://twitter.com/covid19indiaorg/status/1295780594530390016)—a volunteer-driven website with crowdsourced data—as of 18 August, more than 50 per cent of the total tests per day in Karnataka, Andhra Pradesh and Delhi were rapid antigen tests. "The problem is not about using rapid antigen tests as a complementary tool to RT-PCR, but when state governments cut back on their RT-PCR testing and use rapid antigen tests as a substitute," Dr Rijo M John, a health economist and guest faculty at the Indian Institute of Management Kozhikode, said. Rijo, who is also a consultant for the World Health Organisation, added,

"Furthermore, states are often not re-testing patients who tested negative with antigen assay with the RT-PCR test." On 26 July, the Delhi High Court (https://www.ndtv.com/delhi-news/coronavirus-india-court-pulls-up-delhi-over-rapid-antigen-tests-as-false-negatives-rise-2269778) pulled up the Aam Aadmi Party government for using rapid antigen tests as the primary diagnostic tool and not conducting enough RT-PCR tests to rule out false negatives.

Sixty seven-year-old Maya Prashad died of COVID-19-like symptoms on the night of 13 August, in Bihar's Sitamarhi district. Prashad had developed breathlessness and nausea on 10 August. She also had hypertension and diabetes, which are known co-morbidities for COVID-19. But she tested negative in a rapid antigen she got two days later. Prashad's grand-daughter Shagun Choudhary recalled how her family desperately and unsuccessfully tried to get her into hospitals in the district before she died. "I pushed local authorities to test her through RT-PCR to confirm whether she had COVID-19, but health officials stated that no hospital in the district had an RT-PCR machine," Choudhary said.

Choudhary called the local COVID-19 helpline on 15 August, for clarifications about why an RT-PCR machine was unavailable. She shared a recording of the conversation with me. The operator of the helpline told her that "there is anyway no real cure to the virus," implying that getting admitted to a hospital would not have saved her grandmother's life. She replied: "If Amit Shah and Amitabh Bachchan could be saved through proper care and treatment even with all their co-morbidities, how can you tell me my grandmother was fated to die?"

Patients such as Rao and Prashad are stuck in what public-health specialist Sonali Vaid calls "no man's land." Vaid is a graduate from the Harvard TH Chan School of Public Health whose work focuses on improving the quality of healthcare services, and she has been closely

monitoring patient care and helping patients get access to timely treatment in Delhi. “These people are in a fix,” she said. “Non-COVID-19 hospitals don’t take them in because they have COVID-19-like symptoms and COVID-19 hospitals refuse to take them because they tested negative for the disease or they are yet to test positive for the disease.”

Even the RT-PCR test, which is accepted as the gold standard for COVID-19 testing worldwide, has a significant margin of error and can produce a number of false negative results. Studies (https://www.nejm.org/doi/full/10.1056/NEJMp2015897) determine the sensitivity of these tests between 70 to 95 per cent, leaving room for the test to miss out on a number of acute infections.

In the Maharajganj district of Uttar Pradesh, 53-year-old Murli Manohar, his wife and four children tested positive for COVID-19 on an antigen test on 12 August. Manohar was already breathless and had a racking cough. Based on the antigen test, the family decided to admit him to KMC Digital Hospital, a local private hospital. The ICMR guidelines say that antigen positive results do not have to be re-checked with RT-PCR tests because of the test’s high specificity. Yet, Manohar was given an RT-PCR test a few days later, which surprisingly indicated that he was negative. “As soon as my father’s RT-PCR test results came negative, the hospital discharged him immediately,” Manish Gupta, Manohar’s 23-year-old son, said.

Arun, the manager on duty at the hospital who goes by only one name, said that Manohar was discharged because it was the hospital’s policy not to allow an RT-PCR-negative patient to be treated in the COVID-19 facility. “The RT-PCR is the confirmatory test and the patient could not be treated as COVID-19 patient anymore,” he said.

Manohar’s family also underwent RT-PCR tests and were declared COVID-19 negative. However, they decided to quarantine themselves at home. They had known COVID-19 symptoms, including loss of smell, fever and persistent fatigue. Manish, too, had high fever. “We are all ok,

not too sick and my father does not need oxygen support anymore, but in case he was severely ill and they maintained that he was COVID-19 negative and denied him treatment, what would happen then?" he asked. Hariram Yadav, a district level health official from Maharajganj who manages the local COVID-19 helpline, said that the health administration considers the RT-PCR's result as conclusive. "They are under home quarantine now and we'll see whether they need to be tested again in case their condition deteriorates," he said.

"The antigen test or the RT-PCR test is not to blame here," Dr T Jacob John, a virologist and former professor at the Christian Medical College at Vellore, said. "What is at fault is our public health system. Regardless of a patient's test results, if he or she has symptoms suggestive of the disease, any decent physician should treat him or her immediately. If a patient is denied treatment on the basis of conflicting test results then the government is at fault for allowing for such rampant medical negligence."

Tests will always be less than 100 percent efficient. In the absence of a confirmatory COVID-19 diagnostic test result, physicians can use other clinical tools such as chest X-rays and CT scans to make an informed guess about whether a patient has COVID -19, especially at later stages of the disease. "Any qualified radiologist can look at an X-ray and CT scan and tell you whether a patient should be treated as a COVID-19 patient unless proven otherwise," Jacob said.

Dr Kunal Naidu Gudivada, a radiologist in Bengaluru, Karnataka, has seen several such cases. "As the infection sets in, radiologists can observe what looks like a ground glass density opacity," he said. Ground glass makes lungs on a chest X-ray look hazy and indicates pneumonia or inflammation.

"As we all know, the virus still has no cure," Dr Pankaj Malhotra, an internal medicine expert who helped set up a dedicated COVID-19 hospital at the Post Graduate Institute of Medical Education and Research in Chandigarh, said. "All we can do as physicians is help patients manage their symptoms and ensure that treatment and beds are not denied to those who need it." He pointed out that doctors can manage patients' symptoms by administering steroids and ventilation when needed.

All hospitals, especially government facilities, should treat patients with severe and life-threatening symptoms regardless of their COVID-19 test results. "At this point in the pandemic, I am not in favour of the segregation between dedicated COVID-19 and non-COVID-19 facilities," Vaid, the public-health specialist, said. "I believe any decent hospital facility should have the capacity to treat at least moderately ill COVID-19 patients and facilitate their referral to a larger hospital in case the patient becomes severely ill."

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