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Covid-19: Indian doctors criticise directive to expedite vaccine trials

Researchers have accused the Indian Council of Medical Research of buckling under political pressure after it sent a letter to doctors instructing them to fast track clinical trials of a candidate vaccine against covid-19, proposing its launch for “public health use” by 15 August.

Doctors and researchers pointed out that it is impossible to expect a candidate vaccine for which trials have not even started to launch within six weeks and that the council, the country’s apex health research agency, should know this.

They are worried that a directive setting a target date may reflect a willingness on the part of the council to compromise safety or efficacy to please political leadership. India’s independence day is 15 August and it is widely suspected that the council set this as a target launch date to please the government. The council operates under India’s Department of Health Research, itself a government agency.

The council clarified on 4 July that a letter it sent on 2 July to the 12 clinical researchers who plan to enrol volunteers for the safety and efficacy trials of a candidate vaccine was “meant to cut unnecessary red tape without bypassing any necessary processes.”

Rajni Kant Srivastava, head of research management policy and planning at the council, told *The BMJ*, “The letter was only meant to get trial investigators to expedite work to the best of their abilities and was not intended to suggest that they should engage in short cuts.”

A spokesperson for the council said that the trials “will be done following best practice and will be reviewed by a data safety monitoring board,” although they did not respond to requests to explain the timing and the choice of launch date.

The Progressive Medicos and Scientists Forum, a network of physicians and researchers in India, has described the council’s letter as “shocking” and said that it has “taken Indian medical research to uncharted depths of ignominy.”

The forum said, “Any doctor or scientist who has been trained to practise the science and art of medicine would be outraged by the audacity of the government.”

The candidate vaccine is based on an inactivated strain of SARS-CoV-2 isolated from an asymptomatic patient by the council’s National Institute of Virology and has been developed jointly by the institute and Bharat Biotech, a private Indian vaccine manufacturer.

Bharat Biotech, announcing the planned clinical trials last week, said that it expects results by October after which it plans to conduct efficacy trials with larger numbers of volunteers. The company has made no statement since the council’s letter.

A senior Indian virologist who requested not to be named told *The BMJ*, “The council’s directive to doctors must be as embarrassing for the company as it is for the research community. India will be the laughingstock of the world.”

A senior doctor at the All India Institute of Medical Sciences, New Delhi, one of the 12 trial sites, said that the trial has not yet been approved by the institutional ethics panel that oversees biomedical research.

A member of the ethics panel at the All India Institute told *The BMJ*, “Fixing a possible launch date ahead of the start of the trial is inconsistent with the scientific rigour such a trial will demand.”

The Indian Academy of Sciences, a national body of researchers, also released a statement expressing concern that the timeline set by the council in its letter “has raised unrealistic hope and expectations in the minds of our citizens.”

The statement went on, “Any hasty solution that may compromise rigorous scientific processes and standards will likely have long term adverse impacts of unforeseen magnitude.”

Some doctors have pointed out that the council’s directive to fast track a vaccine is just the latest among controversial actions it has taken during the covid-19 pandemic. Public health experts have pointed out that the council has denied community transmission of covid-19 in India although its own researchers published evidence for it in at least 36 districts across the country in early April.¹

The council’s decision to continue recommending hydroxychloroquine as a prophylaxis against covid-19 has also been questioned by doctors.²

1 Gupta N, Praharaj I, Bhatnagar T, et al. ICMR COVID Team. Severe acute respiratory illness surveillance for coronavirus disease 2019, India, 2020. *Indian J Med Res* 2020;151:236-40.pmid: 32362647

2 Bmj India Correspondent. Covid-19: Doctors criticise Indian research agency for recommending hydroxychloroquine prophylaxis. *BMJ* 2020;369:m2170.pmid: 32471832

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