

Task force may review clinical guidelines to fight Omicron

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- **Clinicians are waiting for the drug regulator's view on trials of new treatments for covid-19.**

MUMBAI: The national task force for covid-19 could soon review its clinical guidelines in anticipation of an Omicron wave, ahead of the US regulator approving new treatments and armed with knowledge of what drugs worked and what didn't in the first and second waves of the pandemic.

Officials aware of the development said clinicians are awaiting the drug regulator's view on trials of new treatments such as Paxlovid by Pfizer Inc. and Molnupiravir by Merck & Co. that could also add armour to physicians' options. "Can't speak on task force issues; anyway, this issue is under review," said Srinath Reddy, president of Public Health Foundation of India and one of the members of the Covid-19 National Task Force.

"Basic treatments would remain the same. The question was monoclonal antibodies that none of the national and state guidelines adopted. It was an expensive therapy with limited benefits. But I think we need to start doing mock drills, check our bed availability as several hospitals have closed their covid wards. But we are better prepared," said Dr Rahul Pandit, a member of Maharashtra's covid-19 task force. Treatments to watch out for would be the new antiviral drugs.

"It is not that we are at square one with Omicron, I think we are at square five and better prepared on the clinical side," said an infectious diseases expert of a state task force who did not wish to be named.

"There also needs to be a harmony on the drugs that regulators approve and task forces recommend."

In the last two years, results from various randomized clinical trials (RCTs) have given physicians a stronger grip on treatment options. The current clinical guidelines recommend steroids, anticoagulants such as heparin, Remdesivir, and Tocilizumab for moderate to severe covid-19 patients—those who suffer from breathlessness or whose oxygen level is in less than 93% at room temperature.

The other treatment mentioned in the guidelines is inhaled budesonide. Though the evidence is low on this, it is recommended for patients whose cough and fever persist beyond five days. Drugs such as hydroxychloroquine or Ivermectin, a rage in the early days of the pandemic, are kept out of recommendations. So is the convalescent plasma therapy which multiple clinical trials including the Recovery Trial of the UK (considered to be one of the largest RCTs for covid-19) have now found to not work. Aspirin, another commonly used drug used to treat covid-19, is shown not to have any clinical benefits.

Instead, policymakers are watching drugs such as Paxlovid and Molnupiravir that the USFDA said it is expected to clear this week. Paxlovid by Pfizer has shown significant clinical improvement on patients who were hospitalized with covid-19. In the case of Molnupiravir, though the initial euphoria over its efficacy has faded, physicians see the merit of the drug if it is administered early.

"We are eagerly waiting for the regulator's view on these drugs," said Pandit, adding that the use and benefit of the drug will depend on the cost and the timing of its administration.

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India's drug regulator is expected to take a call on Molnupiravir based on the clinical trial data submitted by over eight generic companies. Meanwhile, Pfizer has shared the patent of Paxlovid with the medicine patent pool that could allow generic companies to manufacture the drug at scale.