What physicians need to know about COVID-19 clinical therapeutics

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More than a year into the pandemic, there are a handful of new and repurposed therapeutics that have been approved or authorized to treat COVID-19. This spectrum of medical therapies to treat COVID-19 continues to grow and evolve rapidly with medications approved by the Food and Drug Administration (FDA) and drugs that are made available under emergency use authorization (EUA). While clinical trials for COVID-19 therapeutics are ongoing, it is important for physicians to understand what is available.

“We’ve come a long way with regard to understanding the pathophysiology of COVID-19 and what medications may help,” said Alfredo Mena Lora, MD, an infectious disease physician and assistant professor at the University of Illinois at Chicago. He is also director of infection prevention and antimicrobial stewardship at Saint Anthony Hospital in Chicago and principal investigator for the ACTIV-1 Clinical Trial with the University of Illinois at Chicago.

In a discussion, Dr. Mena Lora shared what doctors need to know about COVID-19 therapeutics and clinical trials.

**Outpatients have different treatments**

For those in the outpatient setting, “medications like monoclonal antibodies can bind to the virus and prevent it from causing harm in the lungs,” said Dr. Mena Lora, adding that monoclonal antibodies are about 85% to 90% effective in preventing hospitalization or death.

“The big barrier to those medications is that you need to infuse them,” he said. “However, there are two new medications … undergoing the FDA review process.”
“One of them is from Merck and the other one is from Pfizer. Both drugs are given as pills, so you don’t need to go to a hospital,” said Dr. Mena Lora.

“In the future, we hope to be able to mail medications to patients or have patients drive by the pharmacy and pick them up,” he said.

There are inpatient options

The FDA has approved one drug, remdesivir (marketed as Veklury) for the treatment of COVID-19 in patients 12 or older who are hospitalized.

Remdesivir is an antiviral medication that can help “reduce hospitalization days and help a patient recover. The earlier remdesivir is given the better, and the earlier in the pulmonary phase, the better,” said Dr. Mena Lora. “Remdesivir was less and less effective for folks who are already mechanically ventilated or sick enough that they require so much oxygen.”

For patients who are sicker, dexamethasone was proven to be helpful. “The sicker you are, the more inflammation there is. The earlier you are in this illness, the more remdesivir can help,” he said.

Existing drugs need to be studied

It is important to note that existing drugs need to be studied to determine their effectiveness against COVID-19. And just because they are being studied, doesn’t mean they are ready to use.

“The National Institutes of Health is doing a study called ACTIV-6 where it is studying ivermectin in a well-designed, placebo-controlled trial,” said Dr. Mena Lora. “We really want these medications to work, but we have to prove definitively that they do.”

“For example, remdesivir was the first repurposed medication that was proven to help in a randomized control trial,” he said. “Remdesivir was actually designed against other conditions such as Ebola and hepatitis.”

Ivermectin was in clinical trials and not yet proven effective before people started taking it on their own without physician guidance. The AMA, American Pharmacists Association and American Society of Health-System Pharmacists strongly oppose the ordering, prescribing or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial.
Additionally, “there are a lot of studies trying to prevent people from getting sick and trying to find what the best combination of drugs is for this pulmonary and inflammatory phase,” said Dr. Mena Lora. “Most of the recent studies have shown that combining steroids with something else can have an improvement.”

Discover what the FDA wants doctors to tell patients asking for ivermectin.

**Clinical trial participants are still needed**

There is still an ongoing need for people to participate in COVID-19 clinical trials—inpatient and outpatient. “If we had a perfect solution for this, we wouldn't necessarily be doing all of these trials, particularly for the inpatients,” said Dr. Mena Lora. “There's still a big need for participants in trials because not everybody responds to these medications the way that we would want them to—we don't have a silver bullet with regard to making sure every hospitalized patient survives COVID-19.”

Visit the AMA COVID-19 resource center for clinical information, guides and resources, and updates on advocacy and medical ethics.

Learn more about COVID-19 therapeutics from Combat COVID, a resource created by the U.S. Department of Health and Human Services.