Remdesivir for COVID-19: FDA approved but still unproven

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The United States has become the epicenter of the world in the ever increasing pandemic of COVID-19. While public health prevention strategies of social distancing, crowd avoidance, masking and frequent hand washing are of proven benefit, effective drug therapies for treatment are sparse. Not surprisingly, remdesivir has attracted

worldwide attention, first receiving an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) and especially with U.S. President Donald Trump taking the drug for COVID-19 earlier this month. Last week, the World Health Organization (WHO) published the largest randomized trial showing no benefit on reducing hospital stays or mortality. Nonetheless, remdesivir has received approval from the FDA for standard of care use for patients who are hospitalized.

In a commentary published in the journal *Contemporary Clinical Trials Communications*, researchers from Florida Atlantic University's Schmidt College of Medicine and a collaborator reviewed the totality of available evidence, in particular, the most reliable data from randomized trials to detect the plausible small-to-moderate effects of remdesivir. They concluded that the current totality of evidence that they compiled before the WHO trial results justifies compassionate use of remdesivir for severely ill patients with COVID-19.

"Remdesivir significantly decreased mean recovery time with no suggestion of a mortality benefit in a smaller trial in China. Subsequently, the larger Adaptive Covid-19 Treatment Trial or ACTT-1, found the same improvement in mean recovery time and a suggestion of a mortality benefit, which did not achieve statistical significance," said Richard D. Shih, M.D., first author, a professor of emergency medicine and division director and founding program director for the emergency medicine residency program in FAU's Schmidt College of Medicine.

According to the researchers, Dexamethasone is the only other drug having received FDA approval based on a large randomized trial showing a mortality benefit among those who were receiving either invasive mechanical ventilation or oxygen alone at randomization but not among those receiving no respiratory support. This drug also was used by President Trump.

"The U.S. accounts for less than 5 percent of the world's population but more than 20 percent of the global cases and deaths. We need far wider utilization of the preventive strategies of proven benefit of social distancing, crowd avoidance, masking, and frequent hand washing," said Charles H. Hennekens, M.D., Dr.PH, senior author, first Sir Richard Doll Professor and senior academic advisor to the dean in FAU's Schmidt College of Medicine. "While vaccine development and further research on other drug therapies to treat and prevent COVID 19 are a necessity, don't let the 'perfect be the enemy of the possible.'"

The authors also believe that in the U.S., cases and deaths in the fall and winter will far exceed those of last spring without effective implementation of nationally coordinated efforts at preventive strategies to mitigate and contain COVID-19 and which are well known to public health professionals.

Dennis G. Maki, M.D., co-author and professor in the Department of Medicine at the University of Wisconsin School of Medicine and Public Health, has been a collaborator with Hennekens since 1969, when they served as lieutenant commanders in the U.S. Public Health Service as epidemic intelligence service officers with the U.S. Centers for Disease Control and Prevention. They served under Alexander Langmuir, M.D. and Donald A. Henderson, M.D., who first promulgated these public health strategies of proven benefit.

More information: Richard D. Shih et al, Remdesivir for coronavirus 2019 (COVID-19): More promising but still unproven, *Contemporary Clinical Trials Communications* (2020). DOI: 10.1016/j.conctc.2020.100663

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