

First do no harm—researchers urge halt in prescribing hydroxychloroquine for COVID-19

June 3 2020



Charles H. Hennekens, M.D., Dr.PH, senior author, the first Sir Richard Doll professor and senior academic advisor in FAU's Schmidt College of Medicine. Credit: Florida Atlantic University

The sacred oath taken by physicians during graduation from medical school to "First do no harm," the first words of the Hippocratic Oath, provides a strong impetus for a commentary just published in *The American Journal of Medicine*. Researchers from Florida Atlantic University's Schmidt College of Medicine and collaborators from the University of Wisconsin School of Medicine and Public Health are urging all health care providers to always prioritize compassion with reliable evidence on efficacy and safety. They recommend a moratorium on the prescription of chloroquine or hydroxychloroquine, with or without azithromycin, to treat or prevent COVID-19, with the exceptions of obtaining the necessary evidence in randomized trials as well as compassionate use.

Despite the fact, or perhaps due in part to the fact that there are no therapeutic or [preventive measures](#) for the COVID-19 pandemic in the United States, which accounts for less than 5 percent of the world's population and about 30 percent of the cases and deaths, the widespread prescriptions of these drugs are nine times greater than in the last several years. This widespread use is leading to nationwide shortages in patients with lupus and [rheumatoid arthritis](#), for whom hydroxychloroquine has been an approved indication for decades. These patients are unable to refill their prescriptions.

On March 28, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization for chloroquine and hydroxychloroquine for the treatment of COVID-19. By April 24, however, the FDA issued a drug safety communication warning regarding hydroxychloroquine and heart rhythm disturbances that can lead to sudden cardiac death.

"If these drugs need to be prescribed for patients with COVID-19, baseline evaluations and serial monitoring are an absolute necessity," 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.

Further, the authors point out that the reassuring safety profile of hydroxychloroquine may be more apparent than real. The data on safety derive from decades of prescriptions by [health care providers](#), primarily for their patients with lupus and rheumatoid arthritis, both of which are of greater prevalence in younger and middle age women, whose risks of fatal heart outcomes due to hydroxychloroquine are reassuringly very low. In contrast, the risks of hydroxychloroquine for patients with COVID-19 are significantly higher because fatal cardiovascular complications due to these drugs are so much higher in older patients and those with existing heart disease or its risk factors, both of whom are predominantly men.

In basic research, hydroxychloroquine and chloroquine are structurally related and have similar mechanisms to inhibit the virus that causes COVID-19. Despite their structural similarities, in vitro, hydroxychloroquine appears to be more effective. In addition, when used for lupus and rheumatoid arthritis, hydroxychloroquine has fewer side effects, less drug interactions and is less toxic in overdose. The authors note that the currently available evidence is restricted to eight published studies, five on hydroxychloroquine alone; two on hydroxychloroquine plus azithromycin; and one on both in combination or alone. Of these only three are randomized trials that enrolled 225, 62, and 30 patients—all too small to provide reliable evidence. All three tested [hydroxychloroquine](#) alone versus standard of care in China. One showed no [significant difference](#) in viral clearance at 28 days, the second, no difference in viral clearance at seven days, and the third, some improvements in fever, cough and chest computed tomography findings.

"With respect to hypothesis testing, only large-scale randomized trials of

sufficient size, dose and duration can reliably detect the most plausible small-to-moderate effects, which can have enormous clinical and [public health](#) impacts," said Charles H. Hennekens, M.D., Dr.PH, senior author, the first Sir Richard Doll professor and senior academic advisor in FAU's Schmidt College of Medicine.

Co-authors include Heather M. Johnson, M.D., FACC, a preventive cardiologist/cardiologist at the Lynn Women's Health and Wellness Institute at Boca Raton Regional Hospital/Baptist Health South Florida, and Dennis G. Maki, M.D., professor emeritus in the Department of Medicine at the University of Wisconsin School of Medicine and Public Health, where Johnson also is an adjunct associate professor.

Hennekens and Maki have been collaborators 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. Hennekens, Maki and Johnson also collaborated on a recently published commentary in *The American Journal of Medicine* concerning the already alarming racial inequalities in mortality from COVID-19, which are only likely to increase further unless effective drug therapies or vaccines are distributed equitably.

More information: Richard D. Shih et al, Hydroxychloroquine for Coronavirus: The Urgent Need for a Moratorium on Prescriptions, *The American Journal of Medicine* (2020). [DOI: 10.1016/j.amjmed.2020.05.005](https://doi.org/10.1016/j.amjmed.2020.05.005)

Provided by Florida Atlantic University

Citation: First do no harm—researchers urge halt in prescribing hydroxychloroquine for COVID-19 (2020, June 3) retrieved 11 May 2024 from

<https://medicalxpress.com/news/2020-06-harmresearchers-urge-halt-hydroxychloroquine-covid-.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.