

Prescribing medications responsibly in a pandemic

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As COVID-19 continues to ravage populations worldwide and the search for effective treatments for those who become ill goes on, patients and physicians have looked to novel interventions for hope. Some suggestions have been highly unscientific and dangerous, such as recommendations to ingest household cleaning products that circulated widely early in the pandemic. Others have been more plausible, such as recommendations for “off label” use of medications already approved by the U.S. Food and Drug Administration (FDA) to treat conditions other than COVID-19.

Two prominent examples of off label use have involved hydroxychloroquine and, more recently, ivermectin. Hydroxychloroquine, which was briefly available for treatment of COVID-19 under an Emergency Use Authorization between late March and mid-June 2020¹, has since been demonstrated in clinical trials not to be effective². Ivermectin, an antiparasitic drug approved in humans for treatment of certain tropical diseases, is also reportedly being prescribed off label for COVID-19, although the FDA has warned against use^{3,4,5} and the National Institutes of Health (NIH) have concluded that evidence from clinical trials is not sufficient to “recommend either for or against the use of ivermectin for the treatment of COVID-19”⁶.

Now that the first COVID-19 vaccine has received full FDA approval through a Biological License Application for use in persons over 16 years of age, the American Academy of Pediatrics has warned physicians not to prescribe the vaccine for children under 12 while clinical trials are still underway.⁷

Off-label prescribing occurs frequently⁸ and can seem especially promising in the face of a pandemic disease that carries significant risk of severe illness and death for which there are few or no effective treatments. But novel use even of approved medications raises concerns for both science and ethics. Scientifically, lack of data raises questions about appropriate dosing, safety or efficacy in the populations for whom novel use is proposed. Ethically, questions arise about how physicians should responsibly make a decision to offer a particular medication off label.