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Healthcare Workers, First Responders Can Volunteer for 3,000-person Study

DETROIT – Henry Ford Health System will lead the first large-scale study in the United States of the effectiveness of an anti-malarial drug in preventing COVID-19 in healthcare workers and first responders who volunteer to participate.

The study of hydroxychloroquine used prophylactically could begin as early as next week, after a plea to the federal government by Detroit Mayor Michael Duggan and Metro Detroit healthcare experts.

“This is going to be the first major, definitive study in healthcare workers and first responders of hydroxychloroquine as a preventative medication,” said the study’s organizer, Henry Ford Health System’s [Dr. William W. O’Neill](#), a world-renowned interventional cardiologist and researcher who has pioneered multiple treatments for heart disease. “There has been a lot of talk about this drug, but only a small, non-blinded study in Europe. We are going to change that in Metro Detroit and produce a scientific answer to the question: Does it work?”

Participation in the study is strictly on a volunteer basis. [Dr. Marcus Zervos](#), division head of Infectious Disease for Henry Ford Health System, will oversee this study with Dr. O’Neill.

“We are glad to see Henry Ford’s lead on this volunteer study that could help protect medical workers and first responders across southeast Michigan,” Mayor Duggan said, acknowledging U.S. Food & Drug Administration Commissioner Dr. Stephen M. Hahn. “I also deeply appreciate Dr. Hahn’s prompt support for this important effort.”

Both health care workers and first responders will be enrolled at Henry Ford Hospital Detroit. Any hospital healthcare worker within the Metro Detroit area will be able to volunteer to participate, including those from the Detroit COVID Consortium, a recently announced healthcare collaboration on COVID-19 research that includes Henry Ford Health System, Ascension, DMC, Wayne State University and Beaumont. Both health care workers and first responders will be enrolled at Henry Ford Hospital Detroit. Dr. O’Neill recently organized the group to efficiently coordinate and disseminate information about large-scale studies of COVID-19 treatments – and bring those measures to healthcare workers sooner.

Currently, there are no FDA-approved therapies to prevent or treat COVID-19. According to the U.S. Centers for Disease Control & Prevention, hydroxychloroquine (also known as hydroxychloroquine sulfate) is an FDA-approved arthritis medicine that also can be used to prevent or treat malaria. It is available in the United States by prescription only. The drug is sold under the brand name Plaquenil and it is also sold as a generic medicine. It is commonly used by patients with arthritis, lupus or other rheumatic conditions.

“Metro Detroit has a history of stepping up when things get tough,” said [Dr. Adnan Munkarah](#), Henry Ford Health System Executive Vice President and Chief Clinical Officer. “We have a commitment to do that right now – to look at all options in a scientific way – in the face of this worldwide pandemic.”

The study, titled WHIP COVID-19 Study, is a 3,000+ subject look at whether the drug prevents front-line workers from contracting the virus. Once they provide a blood sample, the study subjects will receive vials with unidentified, specific pills to take over the next eight weeks: a once-a-week dose of hydroxychloroquine, a once-a-day dose, or a placebo (a pill that



looks like the medication, but does not contain any medication or other active ingredients). The study medication was specially procured for this study and will not impact the supply of medication for people who already take the medication for other conditions.

Participants will not know what group they are in. They will then be contacted weekly and in person at week 4 and week 8 of the study to see if they are exhibiting any symptoms of COVID-19, including dry cough, fever or breathing issues, as well as any medication side effects. At eight weeks, they will be checked again for symptoms, medication side effects, and have blood drawn. Results will be compared among the three groups to see if the medication had any effect.

“Given our broad clinical trials and translational research infrastructure, we are grateful to bring this type of large-scale effort to the COVID-19 battle,” said [Dr. Steven Kalkanis](#), CEO, Henry Ford Medical Group and Senior Vice President and Chief Academic Officer of Henry Ford Health System. “We see the heroics of the frontline responders in healthcare, public safety and service. Henry Ford Health System is poised to do anything we can to help them stay safe.”

The FDA will provide the drug directly to Henry Ford Health System physicians to distribute. Recruiting has not yet begun. More information can be found at www.HenryFord.com/whipCOVID19.

The CDC describes hydroxychloroquine, which has been used for 75 years, as a relatively well-tolerated medicine. The most common adverse reactions reported are stomach pain, nausea, vomiting, and headache. These side effects can often be lessened by taking hydroxychloroquine with food. Hydroxychloroquine may also cause itching in some people. Minor side effects such as nausea, occasional vomiting, or diarrhea usually do not require stopping the antimalarial drug. Although rare, serious side effects can occur while taking this medication.

If the study finds the drug effective as a preventative medication for COVID-19, it is possible that the study could expand to include hydroxychloroquine in other COVID-19 treatment options, the doctors said. Henry Ford Health System doctors are prescribing hydroxychloroquine as an off-label treatment for only hospitalized COVID-19 positive patients who meet specific criteria as outlined by the hospital system’s Division of Infectious Diseases. As required by the state of Michigan’s Department of Licensing and Regulatory Affairs, the physicians are documenting the prescribed use in the patient’s electronic medical record.

Henry Ford, as one of the region’s major academic medical centers with more than \$100 million in annual research funding, is already involved in numerous COVID-19 trials with partners around the world. Henry Ford is also becoming involved in an Abbott-led study of a rapid, point-of-care test for COVID-19. The equipment, about the size of a toaster, delivers positive results in as little as five minutes and negative results in 13 minutes.