# The Case for Early Use of Hydroxychloroquine, along with Azithromycin (or Doxycycline) and Zinc, to Save the Lives of COVID-19 Patients

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### **Introductory Note**

A treatment is available that has been proven to work well against SARS CoV-2: Hydroxychloroquine (especially in combination with azithromycin/doxycycline and zinc). It is especially effective when given within the first five days of COVID-19 symptom onset.

Harvey A. Risch, MD, PhD, Professor of Epidemiology, Yale School of Public Health, states in a recent Opinion piece in *Newsweek* that because hydroxychloroquine has been pushed to the sidelines, "...tens of thousands of patients with COVID-19 are dying unnecessarily. Fortunately, the situation can be reversed easily and quickly." <sup>1</sup> He also states in a television interview that he believes 75,000 to 100,000 lives could be saved if the drug was widely used.<sup>2</sup>

This white paper will demonstrate:

- I. Hydroxychloroquine works if given within the first five days of symptom onset, especially if combined with azithromycin (or doxycycline) and zinc
- II. Hydroxychloroquine is safe, when given in safe doses (although people with specific contraindications should not take it)
- III. Countries which have implemented widespread, early usage of hydroxychloroquine have strikingly fewer deaths per million than the United States.

The complete truth about hydroxychloroquine (HCQ) must be investigated and reported. Our fellow Americans must be equipped with the facts so they can make their own healthcare decisions. Doctors need to know the facts as well, and to be unafraid to prescribe HCQ.

I. Hydroxychloroquine works if given within the first five days of symptom onset, especially if combined with azithromycin (or doxycycline) and zinc

On June 30, 2020 a study entitled, "COVID-19 Outpatients – Early Risk-Stratified Treatment with Zinc Plus Low Dose Hydroxychloroquine and Azithromycin: A Retrospective Case Series Study," strongly supports the efficacy of using HCQ, Azithromycin and Zinc in the early treatment of COVID-19 patients. Results of the study state, "...the odds of hospitalization of treated patients were 84% less than in the untreated group. One patient (0.7%) died in the treatment group versus 13 patients (3.5%) in the untreated group

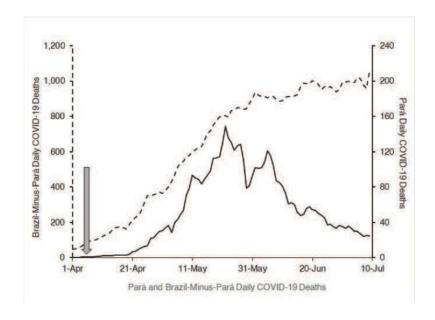
(odds ratio 0.2, 95% CI 0.03-1.5; p=0.16). There were no cardiac side effects." In other words, people treated with the protocol medication were 84% less likely to enter the hospital when compared to patients who were not treated with the protocol. One person died in the treatment group, compared to 13 in the untreated group. Also, the full study states on page 12 that the person who died in the treatment group "had a history of cancer and did only take one daily dose of the triple therapy before hospital admission." 3

A study by the New York University Grossman School of Medicine, published in May 2020, was the first in the United States to prove that adding zinc to HCQ and azithromycin improves the outcome of COVID-19 patients.<sup>4</sup> Page 12 of the full study states, "The main finding of this study is that after adjusting for the timing of zinc therapy, we found that the addition of zinc sulfate to hydroxychloroquine and azithromycin was found to associate with a decrease in mortality or transition to hospice among patients who did not require ICU level of care, but this association was not significant in patients who were treated in the ICU." Note that the benefit was seen when the patient was given the medication before being admitted to the ICU. This study reveals that giving HCQ, azithromycin and zinc to COVID-19 patients as early as possible decreases mortality.

In addition, on July 1, 2020, a study was published by the Henry Ford COVID-19 Task Force, which evaluated the outcomes of patients who received HCQ, versus those who received HCQ and azithromycin. It states in the results, "Hydroxychloroquine provided a 66% hazard ratio reduction, and hydroxychloroquine + azithromycin 71% compared to neither treatment (p < 0.001)." <sup>5</sup> This study proves that giving HCQ and azithromycin together improves patient outcomes better than giving HCQ alone.

"Doctors from Harvard and Yale Medical Schools Support Dr. Zelenko Treatment Method," provides additional information about the safety and efficacy of HCQ, azithromycin and zinc.<sup>6</sup> Of particular interest are pages 87-88, which lists the results of additional studies. Pages 90-91 document the results when Pará, Brazil began to use HCQ, ivermectin and azithromycin.<sup>6,7</sup> A chart showing the dramatic downward dive of daily deaths is included (see below).<sup>6</sup> Information about other areas in Brazil is located on pages 211-222 (these areas used HCQ and prednisone).

Pará, Brazil<sup>6</sup>



## Early Treatment in Brazil; dramatic reduction in need for hospital beds in Unimed Belém - State of Pará <sup>7</sup>



In addition, a study done at St. Luke's Hospital in Cedar Rapids found, "Survival of those treated with hydroxychloroquine-azithromycin was 92%, compared to 86% of those treated with hydroxychloroquine alone."8

Didier Raoult has published several studies on the efficacy of of HCQ and azithromycin. One, a meta analysis, was published in July 2020 and it states on page 4, "This new meta-analysis (Figure 1) included 18,211 patients (10,409 treated by a chloroquine derivative) from 12 studies and assessed mortality in 4 countries (China (27), France (22,23,28-30), Spain (31), and USA (24-26,32,33). A two-fold decrease of the risk of death was confirmed in clinical studies (number of comparisons (n) = 8, odds ratio 0.53, 95% confidence interval (95%CI) 0.40 - 0.71, p = .00003)..." A "p" value of .00003 is extremely statistically significant—it provides strong evidence that the two-fold decrease in the risk of death is directly attributable to being treated with the chloroquine derivative. What is more, the death rate in Marseille, France (where Didier Raoult cares for patients and where HCQ and azithromycin are used at IHU - Méditerranée Infection) is significantly lower than in Paris, New York, or Montreal. One of the patients and where Infection is significantly lower than in Paris, New York, or Montreal.

Last, but definitely not least, the website <a href="www.c19study.com">www.c19study.com</a> lists all of the studies currently published about HCQ. Sixty-four studies are currently catalogued, 39 of which are peer reviewed. The conclusion, as stated on the website, is that "early treatment studies show high effectiveness, while late treatment shows mixed results." In other words, HCQ works well when given early to COVID-19 patients.

## **II. Hydroxychloroquine is safe, when given in safe doses** (although people with specific contraindications should not take it)

#### Patients with contraindications, and QTc prolongation concerns

Hydroxychloroquine is safe, when given in safe doses. While this is true, there are people with specific contraindications who should not take it, especially in combination with azithromycin. (Please see page 75.)<sup>6</sup> If a patient can safely take HCQ (but not in combination with azithromycin), then doctors have been successfully prescribing doxycycline + HCQ instead of azithromycin + HCQ. <sup>11,12</sup> More information about doxycycline and why it is effective against SARS CoV-2 can be found in a paper by Alexandre E. Malek. A clinical trial is also currently underway to discover the efficacy of doxycycline + HCQ + zinc compared to azithromycin + HCQ + zinc.

Another concern about taking HCQ is the potential risk of QTc prolongation (prolongation of the heart rhythm). Several studies have assessed the likelihood of QTc prolongation while using HCQ and azithromycin. One of these studies was published by the American Heart Association. In the conclusions of the American Heart Association study the authors state, "In the largest reported cohort of coronavirus disease 2019 patients to date treated with chloroquine/hydroxychloroquine ± azithromycin, no instances of Torsade de pointes, or arrhythmogenic death were reported. Although use of these medications resulted in QT prolongation, clinicians seldomly needed to discontinue therapy." Another study seems to indicate that the longer the drugs are taken, the more likely QTc prolongation will occur in certain patients. Another study has been published, as well. In summary, the combination of HCQ and azithromycin appears to be safe for most people.

#### Is HCQ a dangerous treatment for COVID-19 patients?

However, with these important notes aside, many of us have heard alarming reports about the dangers of HCQ (prescribed alone, without azithromycin), and how clinical trials have been halted because it has been "proven" to be dangerous. However, based upon the following studies, HCQ is only proven to be dangerous when it is given in extremely high doses. Let's start with the first major study to raise red flags about the safety of HCQ.

In the beginning of April, 2020, a study in Brazil was halted early because patients were dying when given chloroquine. (Not HCQ—both drugs are aminoquinolines.) However, the chloroquine (CQ) doses given were extremely high (600 mg twice daily for 10 days (1,200 x 10 =12,000 mg total)) vs. the alternate treatment arm that used 450 mg twice daily for the first day and then 450 mg once a day for 4 days (2,700 mg total). For a comparison of normal CQ and HCQ dosing, please see "Chloroquine (Aralen) vs. Hydroxychloroquine (Plaquenil) for COVID-19?" The dosing regimens for CQ and HCQ are similar, although less is needed for HCQ.

A lethal dose of CQ is estimated to be 30-50 mg/kg (in other words, for a 150 pound person a lethal dose would be between 2,040 mg and 3,400 mg).<sup>20</sup> One case report states that a lethal dose of HCQ "is not well established, although severe symptoms occur with ingestion of 4 gm" (4,000 mg).<sup>21</sup> What is more, CQ and HCQ build up in the tissues. This means that when the patient continues to take doses of the medication, the drug continues to be stored in the tissues (rather than being flushed away), which leads to toxicity. "Both HCQ and CQ have prolonged half-lives, between 40 and 50 days."<sup>22</sup> The Brazilian doctors who administered these high doses of CQ are now facing a legal investigation.<sup>23</sup>

A second study "proving" that HCQ is dangerous was published in *The Lancet* on May 22, 2020.<sup>24</sup> It was retracted on June 4, 2020 because the data used could not be verified. The company who provided the data, Surgisphere, has had their website removed from the internet. It is widely suspected that the data was allegedly fraudulent. Several articles provide in-depth information about what happened.<sup>25,26</sup>

Finally, researchers at Oxford in charge of the RECOVERY trial reported that HCQ was not effective in treating COVID-19 patients, and in fact led to more deaths.<sup>27</sup> However, the doses given were extremely high.<sup>28</sup> 2,400 mg was given on the first day, followed by 800 mg a day for 9 more days, for a total of 9,600 mg.<sup>27</sup> (Please see lines 114-117.) Amazingly, even at those high doses line 44 states, "There was no excess of new major cardiac arrhythmia." Regarding the high dosages given, *FranceSoir* reports, "...the AMM in France considers the overdose rate at 25mg/kg of hydroxychloroquine, i.e. for a 75kg patient, 1875mg for one day, requiring immediate emergency hospital care."<sup>28</sup> In other words, the dosage given on the first day of the RECOVERY trial would be considered an emergency situation in France. The death rate in the RECOVERY trial was abnormally high for both treatments arms (with HCQ and without HCQ).<sup>29,30</sup> HCQ was also administered to patients in the later stage of the disease, rather than when it is most helpful as an anti-viral in the early stage of the disease.<sup>30</sup>

Why the high doses in the RECOVERY trial? The RECOVERY Supplementary Appendix states on page 21 the reasons behind the dosage modeling.<sup>27</sup> However, the *FranceSoir* newspaper has done an excellent series of articles on this study, exposing the fact that Martin Landray, one of the doctors in charge of the trial, thought the toxic dose of HCQ was 10 to 20x higher than what was actually administered to patients within the clinical trial, and he mentioned as an aside that it is given to patients for amoebic dysentery. Hydroxyquinoline is used for amoebic dysentery—not hydroxychloroquine.<sup>28</sup> This conversation was recorded, and is available on the *FranceSoir* website.<sup>31</sup> Other questionable activities regarding the RECOVERY trial are documented by *FranceSoir*, as well.<sup>32</sup> The *Australian Spectator* delves deeper into this story, including a disturbing angle on ties with drug companies who may be affiliated with the doctors in the RECOVERY trial.<sup>33</sup> In addition, this same article states that the WHO's Solidarity trial uses the same dosing level of HCQ as the RECOVERY trial.

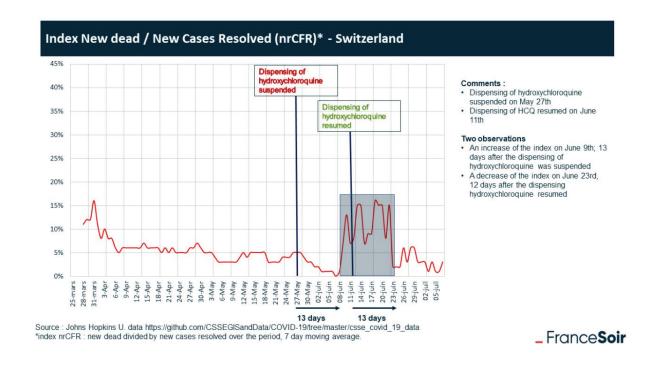
Within the previous paragraphs are examples of three high profile studies "proving" that HCQ is dangerous. However, one would question whether potentially lethal doses could ever provide any sort of a health benefit to anyone. It also makes one wonder about the abnormally high mortality in the clinical trials. On the surface, these clinical trials seem to "prove" that HCQ is dangerous and also ineffective. But when one views the underlying facts, a different story emerges. The trials were flawed, and therefore the conclusions drawn are invalid.<sup>34</sup>

Few of these facts have been reported to the American public. In fact, these studies continue to be cited in news articles as "proof" that HCQ is both dangerous and ineffective. However, HCQ was approved as a safe drug by the FDA 65 years ago.<sup>35</sup> It has a 65 year proven track record of safety. One clinical trial example was posted in *The Journal of Rheumatology* in 1997.<sup>36</sup> More examples about the safety of HCQ are detailed in a report entitled, "White Paper on Hydroxychloroquine," by Simone Gold, MD, JD, pages 2-8.<sup>37</sup> The idea that HCQ is dangerous is ludicrous (if given in safe doses, and especially for a short period of time, and to patients with no contraindications), and yet that is the story that is repeatedly told to us.

## III. Countries which have implemented widespread, early usage of hydroxychloroquine have strikingly fewer deaths per million than the United States.

First, a case study about Switzerland. This country used HCQ, and then it was banned from May 27 - June 11, 2020, due to fears raised in *The Lancet* study (now retracted).

FranceSoir reports, "Looking at the evolution curve of this index for Switzerland, we note a 'wave of excess lethality' of two weeks from June 9th to 22nd, with a lag of a dozen days compared to the period of suspension of the use of hydroxychloroquine by WHO." In other words, the negative effect of stopping HCQ was seen about 13 days after stopping HCQ. A positive effect was again seen about two weeks after resuming the use of HCQ. The following graph was compiled by FranceSoir.<sup>38</sup>



The previous graph clearly demonstrates the efficacy of using HCQ.

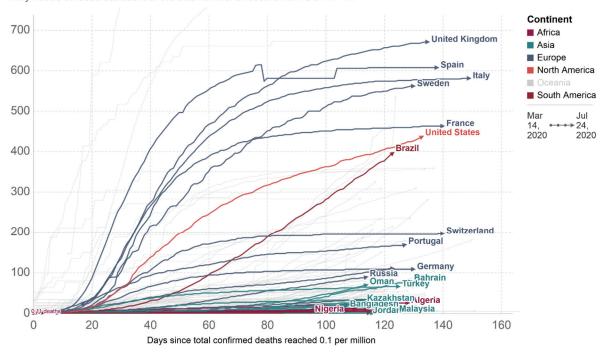
For final evidence on the efficacy of HCQ, please see the following graphs and data tables. The countries which do not use HCQ are the United Kingdom, Spain, Italy, Sweden, France, United States, and Germany. All other countries in the graphs/data sets use HCQ. The same countries are used in all examples. Note that the case fatality rates and deaths per million (and deaths per 100,000) are significantly lower in the countries which use HCQ.

### Deaths Per Million from Our World in Data<sup>39</sup>

## Cumulative confirmed COVID-19 deaths per million people



Limited testing and challenges in the attribution of the cause of death means that the number of confirmed deaths may not be an accurate count of the true number of deaths from COVID-19.



Source: European CDC - Situation Update Worldwide - Last updated 24 July, 10:38 (London time), Our World In Data

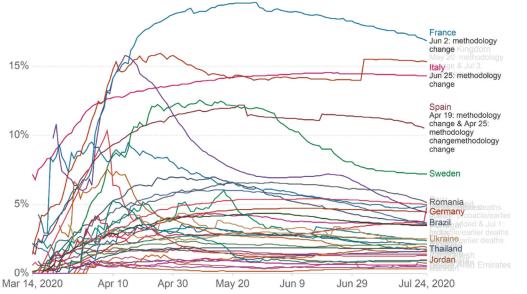
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## Case Fatality Rate from Our World in Data<sup>40</sup>

## Case fatality rate of the ongoing COVID-19 pandemic

Our World in Data

The Case Fatality Rate (CFR) is the ratio between confirmed deaths and confirmed cases. During an outbreak of a pandemic the CFR is a poor measure of the mortality risk of the disease. We explain this in detail at OurWorldInData.org/Coronavirus



Source: European CDC – Situation Update Worldwide – Last updated 24 July, 10:38 (London time)

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## Countries Sorted by Deaths Per 100,000 Population<sup>41</sup>

Country	Case Fatality Rate	Deaths per 100,000 Population	Countries which Use HCQ
Thailand	1.80%	0.08	*
Jordan	0.90%	0.11	*
Congo (Kinshasa)	2.30%	0.23	*
Malaysia	1.40%	0.39	*
Venezuela	0.90%	0.4	*
Nigeria	2.20%	0.41	*
Kenya	1.70%	0.46	*
Chad	8.40%	0.48	*
Morocco	1.60%	0.77	*
Cuba	3.60%	0.77	*
Congo (Brazzaville)	1.80%	0.95	*
Senegal	1.90%	1.07	*
Indonesia	4.80%	1.58	*
Bangladesh	1.30%	1.65	*
India	2.40%	2.08	*
Algeria	4.60%	2.57	*
Pakistan	2.10%	2.66	*
Kazakhstan	0.80%	3.2	*
Ukraine	2.50%	3.4	*
United Arab Emirates	0.60%	3.53	*
Argentina	1.80%	5.33	*
Turkey	2.50%	6.69	*
Oman	0.50%	6.75	*
Bahrain	0.30%	8.16	*
Russia	1.60%	8.59	*
Romania	5.30%	10.47	*

Germany	4.50%	10.97	
Portugal	3.50%	16.45	*
Switzerland	5.90%	23.14	* (HCQ suspended for 2 weeks)
Brazil	3.80%	38.25	* (only parts of the country)
US	3.70%	43.07	
France	14.10%	45.05	
Sweden	7.20%	55.38	
Italy	14.30%	58.01	
Spain	10.70%	60.83	
United Kingdom	15.30%	68.28	

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United Arab Emirates	0.60%	3.53	*
Kazakhstan	0.80%	3.2	*
Jordan	0.90%	0.11	*
Venezuela	0.90%	0.4	*
Bangladesh	1.30%	1.65	*
Malaysia	1.40%	0.39	*
Morocco	1.60%	0.77	*
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India	2.40%	2.08	*
Turkey	2.50%	6.69	*
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### **Conclusions**

The data revealed in this paper demonstrates the efficacy of treating COVID-19 patients early with HCQ (especially in combination with azithromycin and zinc). This treatment works if given in the earliest stage of the illness, when an antiviral will work best. In addition, it is safe, and countries who use it are seeing far fewer deaths per million than we are here in the United States.

Physicians across America are battling right now to be able to use HCQ to save their patients' lives.

Imperial Valley physicians are pleading with their state health department to employ a plan to use HCQ, because they have found it to be extremely effective for their patients. They state:

In our attempts to keep people alive, we have had an opportunity to use many different types of treatments — remdesivir, dexamethasone, convalescent plasma replacement, etc. Yet, by far the best tool beyond supportive care with oxygen has been the combination of hydroxychloroquine (HCQ), with either azithromycin or doxycycline, and zinc. ... We, the undersigned, urge your rapid employment of the plan presented in this letter.<sup>42</sup>

One of the physicians, George Fareed, MD, authored the original version of this letter, which was published a week earlier. It includes a great deal of additional information.<sup>43</sup>

The AAPS (American Association of Physicians & Surgeons) filed "its motion for a preliminary injunction to compel release to the public of hydroxychloroquine by the Food & Drug Administration (FDA) and the Department of Health & Human Services (HHS)..." on June 22, 2020.<sup>44</sup> In a recent update, the AAPS has submitted additional evidence in a federal court as a part of their lawsuit against the FDA and HHS, and their role in "interfering with the delivery of hydroxychloroquine for treatment of COVID-19." Furthermore, this article states,

"The mortality rate from COVID-19 in countries that allow access to HCQ is only one-tenth the mortality rate in countries where there is interference with this medication, such as the United States," explained Andrew Schlafly. ..."In some areas of Central America, officials are even going door to door to distribute HCQ," Andrew Schlafly adds. "These countries have been successful in limiting the mortality from COVID-19 to only a fraction of what it is in wealthier countries."

For those who believe we should wait for clinical trials to complete before moving forward with using HCQ, I have to ask, why? How long will we wait? Our fellow Americans are dying now. I also have to ask—why can clinical trials give toxic doses to COVID-19 patients, but outpatient doctors are discouraged from giving safe doses of the same medication in order to save their patients?

Americans need to know the truth about HCQ right now. They need to know the facts so they can make their own best healthcare decisions. If the truth is not published, thousands of people will continue to die. Please don't let that happen. You have the facts. You can stop this virus right now.

As Harvey A. Risch, MD, PhD, Professor of Epidemiology, Yale School of Public Health, stated in *Newsweek*, "The key to defeating COVID-19 already exists. We need to start using it." <sup>1</sup>

Please investigate the true story about HCQ. Please share your findings with our fellow Americans.

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