

HYDROXYCHLOROQUINE USE FOR COVID-19 IN THE UNITED STATES

P. Navarro and S. Hatfill

ABSTRACT

Although the true statistics are obscured by inaccurate testing and data collection, the disease associated with the novel coronavirus SARS-CoV-2 known as COVID-19 has killed thousands of Americans and millions of victims worldwide.

The evidence to date is overwhelming If hydroxychloroquine (HCQ) had been aggressively used as an early treatment in an outpatient setting, it is likely that at least many as half or more of these COVID-19 cases would have survived.

These needless deaths occurred because of a “Hydroxy Hysteria” that was propagated for political reasons and corporate financial gain.

This monograph will attempt to outline the role for hydroxychloroquine and the purposeful destruction of its use for COVID-19 in the United States by media elites and a dysfunctional FDA leadership, to make way for highly experimental vaccines and highly expensive in-hospital treatments.

DISCLAIMER

This report is for discussion and educational purposes only. No individual should take chloroquine or hydroxychloroquine for any condition without first consulting his or her medical provider.

I. A Brief History of Hydroxychloroquine (HCQ)

The Hydroxychloroquine (HCQ) story begins with a medicine known as chloroquine. Chloroquine was first approved for use in the U.S. by the Food and Drug Administration (FDA) in 1947 to treat malaria.¹ In 1955, scientists developed a synthesized derivative of chloroquine with the same efficacy and fewer side effects.² Thus HCQ was born.³

A Medicine Historically Deemed Safe

For more than six decades, HCQ has been viewed as a relatively safe medicine.⁴ Like chloroquine, HCQ is listed on the World Health Organization's Model List of Essential Medicines.⁵ Within the United States, the FDA has approved HCQ to treat malaria as well as autoimmune conditions that include Rheumatoid Arthritis and Lupus.⁶

According to the Mayo Clinic, the standard HCQ dosage for Lupus is "200 to 400 milligrams (mg) taken as a single dose or in two divided doses once a day." For Rheumatoid Arthritis, the daily dose is 400 to 600 milligrams per day.

In comparison, the HCQ dosage originally recommended by the FDA for the treatment of COVID-19 is 600mg on the first day followed by 400mg per day for four to seven days of total treatment based on clinical evaluation.⁷

Thus, Lupus and Rheumatoid Arthritis patients are taking similar amounts of HCQ every day for weeks and months at a time, that COVID-19 patients are advised to take daily under physician supervision, for only a short 5 to 7-day period upon the first onset of COVID-19 symptoms.⁸

The CDC cites HCQ as a preferred anti-malarial medication due to its long history of safety. It has even deemed HCQ safe for nursing mothers and pregnant women.⁹ The American College of Rheumatology has further noted "HCQ typically is very well tolerated." "Serious side effects, including changes in the heart rhythm and vision changes, are extremely rare."¹⁰

Using FDA data, the health research website Health Grove looked at a large sample of drugs involved in the highest number of adverse reactions and ranked them by the percent of these reactions classified as serious. Neither HCQ nor chloroquine are among the top 50 most dangerous drugs. That list features drugs routinely found in American medicine cabinets such as Avastin (#3), Valium (#25), oxycodone (#31), prednisone (#42), and aspirin (#44).¹¹

Reviewing these facts, it seems both comic and tragic that a drug that has been considered safe for diseases such as Lupus and Rheumatoid Arthritis for decades would be deemed dangerous in similar dosages when used in the COVID-19 context.

A Low Cost and Easy to Administer Medicine

Hydroxychloroquine has been considered relatively safe to use for decades. It is easy to administer and one of the least expensive medicines on the market. At a cost of no more than 60 cents per 200 milligram tablet,¹² a treatment course adds up to less than \$12 per patient; and this medicine can be taken orally and at home outside of a hospital setting. It is safe for use in pregnancy and safe for nursing mothers. Only a few drugs have ever had that safety profile.

In contrast, another therapeutic that has been recommended for use in the treatment of COVID-19 – a drug known as Remdesivir – can cost over \$2,000 per patient.¹³ Rather than be taken at home

like HCQ, remdesivir must be administered intravenously in a hospital setting for at least five days.¹⁴ As will be seen, the efficacy of Remdesivir for COVID-19 is highly questionable.

A recent study published in the *Journal of Virus Eradication*, attempted to analyze the cost of manufacturing Remdesivir by examining the chemical synthesis of the drug.

It concluded that a 10-day course of injectable Remdesivir would cost just \$9 to make.¹⁵ However, on 29 June 2020, the California-based drugmaker Gilead Sciences announced its pricing plans for Remdesivir, stating the treatment would cost \$520 per dose for U.S. private insurance companies and \$390 per dose for the U.S. government. A five-day treatment using the drug would entail six vials. The total charged to hospitals for patients with private insurance in the U.S. will be \$3,120. For those under U.S. government health programs, the total will be \$2,340 per patient.¹⁶

II. Hydroxychloroquine and COVID-19

In a landmark *in vitro* 2005 study published in the *Virology Journal*, researchers found chloroquine to be a relatively cheap and safe drug that was effective in inhibiting the infection and spread of the original 2003 SARS-1 virus in monkey cells grown in tissue culture. On the basis of these findings, they concluded that because “the drug has significant inhibitory antiviral effect,” it may have “possible prophylactic and therapeutic use in SARS virus infections.”¹⁷

How Does Hydroxychloroquine Work to Fight SARS Viruses?

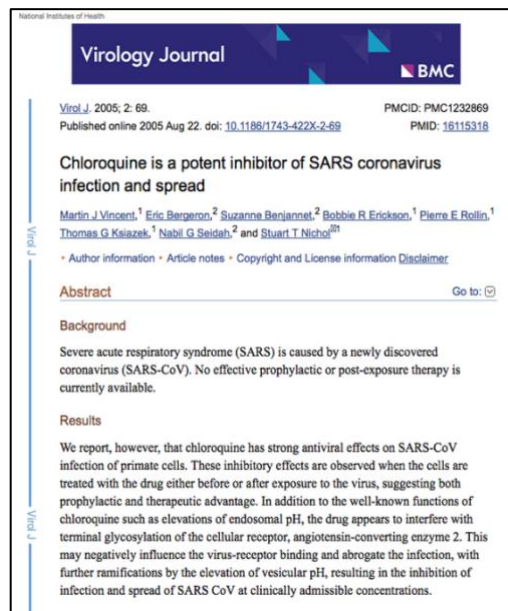
Both Chloroquine and HCQ are hypothesized to work through at least two biological pathways: Both appear to block the entry of the COVID-19 virus into human cells by altering the sugar content of the ACE-2 receptors (the “antiviral blocking effect”).

Both drugs may also help kill the virus or slow down its replication by raising the pH or alkalinity within your cells (the “alkalinity effect”).

III. Use of Prophylactic/Post-Contact Hydroxychloroquine

Prophylactic refers to taking HCQ *prior* to exposure to the COVID-19 Virus. Thus, for example, doctors and nurses might take HCQ as a preventative prophylaxis *before* they go into the field to tend to patients infected with the virus. By taking HCQ before exposure, an individual may be able to build up his or her cellular defenses through both the blocking and alkalinity effects we have described. It is useful to note here that people who take HCQ for malaria begin their treatment several weeks before entering a malaria zone.¹⁸

In contrast, *post-contact* use of HCQ as a preventative, means that an individual will take HCQ only *after* exposure to an individual or group of individuals infected with the virus. Consequently, they will receive a treatment dosage schedule of HCQ .



From these observations, it follows that if HCQ is efficacious in a prophylactic role, we should observe a statistically significant lower rate of infection in the group taking HCQ relative to the control group not taking this drug. In contrast, in a post-contact use study, we may *not* observe a difference – or at least a big difference – in the rate of infection. However, post-contact administration of HCQ should give individuals a better chance of surviving an infection relative to those in the control group in the case of infection.

A Flawed University of Minnesota Study Promotes Hydroxy Hysteria

Over the first six months of the pandemic, numerous flawed studies would emerge that would be used by the media to fan the flames of Hydroxy Hysteria. A June 3, 2020 Post-Exposure use study from the University of Minnesota published in the *New England Journal of Medicine* provides one such illustration.

*The Minnesota study highlights the importance of distinguishing between true preventative prophylactic use of HCQ versus **post-contact use** in the discussion and evaluation of research results and the apparent failure of the media (and much of the scientific community) to grasp the importance of this distinction.*

The Minnesota study was “a randomized, double-blind, placebo-controlled trial.”¹⁹ This would appear to be a good start as such randomized, blind, controlled studies are thought by many to represent the gold standard in clinical trial research. As with many things, however, the devil is in the details.

One important detail in the June 3 study is that HCQ was *not* administered to patients with COVID-19 until after as many as four-days of symptom onset, *at the very earliest*. At that time the infection process would already be established and COVID-19 virus replication already well underway. Therefore, one would expect a smaller difference in the clinical effect between the HCQ-treated group and the control group than if the medicine had been administered in a timelier manner.

A second important detail is that this June 3, 2020 study, did not have enough trial subjects to yield a statistically significant result if the difference in the infection rate was in fact small across the HCQ and control groups. Here, it is useful to note that the study focused on only 821 participants spread across the groups – 414 receiving HCQ and 407 receiving a placebo medication.

So, what were the study results? The researchers actually did find a lower rate of symptomatic infection in the HCQ group relative to the control group – 2.4%. However, because of the small sample size, this potentially important result was not found to be statistically significant at a level of 95% or higher.

So, how did the mainstream media report this finding? A CNN headline blared in typical partisan fashion: “*Trump said he took HCQ to prevent coronavirus, but new study shows that it doesn't*

work.” In the body of the article, the reporter asserts without any reference to the small sample size: “No difference between HCQ and placebo.”²⁰

The New York Times (NYT) played a similar Hydroxy Hysteria fake news game. Its headline proclaimed: “Malaria Drug Promoted by Trump Did Not Prevent COVID Infections, Study Finds.”²¹

*In a later study, the data from this paper was combined with the data from four other published papers also claiming no effect of HCQ with early use. This combined data was subjected to a meta-analysis which found a 24% reduction across the board in COVID-19 infection, hospitalization or death. No serious adverse cardiac events were reported.*²²

Other Prophylaxis Studies of Note

Before leaving the subject of the use of HCQ as a prophylaxis, it is worth noting several additional studies that suggest possible efficacy in preventing COVID-19 infection.

A June 1, 2020 research paper published in the *Indian Journal of Medical Research* examined the use of HCQ as a prophylaxis for a sample of 751 health care workers – 378 cases and 373 in a control group. The study found that while “simply initiating HCQ prophylaxis did not reduce the odds of acquiring” the COVID virus infection..... “With the intake of four or more maintenance doses of HCQ, the protective effect started emerging” and the odds of infection became reduced by more than 80%.²³

A 9 June 2020 research finding, also published in India, likewise looked at prophylaxis among health care workers. The study found that those taking HCQ had a statistically significant lower likelihood of contracting COVID-19.²⁴ Only 9.38% of the HCQ prophylaxis group developed COVID-19 from a contact exposure, compared to 54.55% of the non-HCQ group who later developed a COVID-19 infection.²⁵

On 7 June 2021, Indian scientists published the largest multicenter study on HCQ prophylaxis on healthcare workers (HCW).²⁶ This study was a prospective, observational, multicenter cohort study involving 44 hospitals in 17 Indian states during May-Sept 2020. Taking HCQ for 2-3 weeks, 4-5 weeks or more than 6 weeks significantly reduced COVID positivity by 34%, 48% and 72% respectively. Later modeling has shown that the level of protection with HCQ varies with dosing, duration of use, and co-morbidities including geographical location.

The study shows that HCQ is effective in reducing risk of COVID-19, at 800 mg loading and 400 mg weekly dose with more than 2 weeks dosing. Protection improves as duration of intake increases to 6 weeks or more. Logistic regression modeling has indicated the extent of protection in different scenarios of risk factors. Overall, HCQ was well tolerated.

Despite the limitation of an observational study relying on online data capture, the strengths of large sample size, wide geographical coverage and real-life effectiveness, an assessment through multivariate analysis lends credence to the study findings. It may also help explain the inconclusive results and lack of HCQ benefit observed in some other studies.

In their conclusion, the researchers note: “HCQ is effective in reducing risk of Covid-19, at 800 mg loading and 400 mg weekly dose with more than 2 weeks dosing, and that HCQ was “well tolerated” among the participants.²⁷

IV. Early vs. Late Treatment Use of Hydroxychloroquine as a Therapeutic

Just as one must distinguish between prophylaxis versus a post-contact use of HCQ, it is critical to distinguish between an “early treatment” versus a “late treatment” with HCQ. There are two relevant points:

1. HCQ is likely to *succeed* as a therapeutic *only if* it is administered as an “early treatment” within a seven-day window from the first onset of symptoms of COVID-19. This is when symptoms such as fever, cough, sore throat and fatigue become noticeable and the patient remains ambulatory without shortness of breath and the need for supplemental oxygen.
2. HCQ is more likely to *fail* as a “late treatment” therapeutic if it is given after a patient requires supplemental oxygen, or more than three of the five lung lobes in the pulmonary system show infection, and/or if the body develops an over-reaction of the immune system known as a “cytokine storm.”

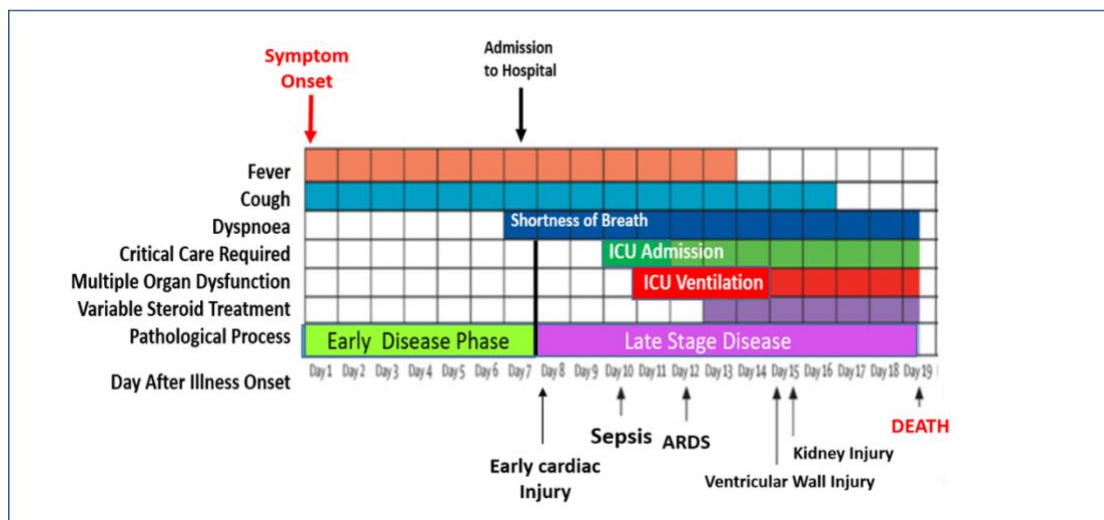


Figure 2. COVID-19 Disease Course

The Biology of Early Treatment vs. Late Treatment

As noted in the Figure above, “early treatment” means that a COVID patient must be treated within an approximate seven-day window of first exhibiting symptoms. During this early disease phase, patients experience a fever that may become severe. Patients can also develop an initial dry

persistent cough as the virus spreads through their upper airway. Also common is an abnormally profound fatigue. In a patient with advancing age, these are particularly serious symptoms.

There are roughly six different **early** clinical presentations with signs and symptoms ranging from a headache with a loss of taste and smell, to muscle aches and gastrointestinal problems, or the development of a “hives-like” rash, or the onset of inflammation in the walls of medium-sized arteries throughout the body with swollen lymph nodes, a high fever, chilblain damage to the capillary beds in the skin (most often in the hands or feet) and abnormal blood clotting phenomena.

What has been ignored by the CDC, is that the eyes may also be a portal of entry after an exposure to a COVID-19 virus aerosol. After contacting the thin film of fluid covering of the eyeball, the viral particles drain through the tear ducts into the nose where there are lots of ACE-2 positive cells. This exposure route is typified by the victim developing an unusual itching of the eyes.²⁸

During the end of this early treatment phase, the microscopic blood vessels inside the lungs may become “leaky,” and fluid may start to collect between the air sacks of the lungs. Consequently, the infected individual loses exercise tolerance and becomes short of breath very quickly. At this stage, the individual is still ambulatory and does not yet require supplemental oxygen. While a CAT scan may detect early lesions, a plain normal X-ray often does not until a day or several days later.

If HCQ is administered within this first critical seven-day window – the earlier the better – it can mitigate, slow, or reduce the onset of the more severe signs and symptoms associated with late phase COVID-19 infection.. In such situations, a favorable outcome is measured by factors such as a reduced viral load (measured by cell culture), reduced need for hospitalization and supplemental oxygen, reduced risk for intensive care and mechanical ventilation, and a reduced mortality rate.

Dangers Past the Critical Treatment Window

While the vast majority of symptomatic COVID-19 cases will recover, there is a darker side to the disease. After Day Seven from the start of symptoms, some 15% of cases may go on to develop a shortness of breath that will require hospitalization. This is most common in older patients above 40 years of age with pre-existing chronic medical conditions and in the elderly.

The patient is now moving past the maximum treatment window, into the late-phase of COVID-19 with multiple developing new pathologies that are well outside mitigation by the positive effects exerted by HCQ.

In this late phase of the disease, the patient is developing areas of more severe local inflammation inside the lungs with damage to the microscopic air sacs . The dry persistent cough becomes more of a “wet” or “productive” cough that begins to bring up phlegm from the lower airways.

As the lungs become more severely inflamed, the patient will experience an increasing shortness of breath, requiring the use of supplemental oxygen. This declining state may also be accompanied by the risk for developing a generalized inflammation in the small blood vessels of the body.

By this point, the optimum window for early treatment with HCQ has closed and the physical air sacs of the lungs have now become involved. Microscopic blood clots can start to form in the tiny capillaries in the lungs, kidneys, and other organs unless preventative medications are given.

The Late Cytokine Storm

During the late phase of COVID-19, the patient may develop a type of severe unregulated immune reaction in what is called a “cytokine storm.” In effect, a cytokine storm is a condition in which a patient’s immune reaction to the COVID-19 Virus is so strong that it not only attacks the virus but also the normal tissues of body. As noted by *newscientist.com*:

[W]hen SARS -CoV-2 – the virus behind the covid-19 pandemic – enters the lungs, it triggers an immune response, attracting immune cells to the region to attack the virus, resulting in localized inflammation. However, in some patients, excessive or uncontrolled levels of cytokines are released which then activate more immune cells, resulting in hyper inflammation. This can seriously harm or even kill the patient.²⁹

During a cytokine storm, widespread blood clots can form in both the large and small caliber blood vessels throughout the body. The lungs lose their compliance and become more rigid and harder to mechanically ventilate and oxygenate. The kidneys, heart, brain, intestines, and major blood vessels may be damaged, and the organs become dysfunctional and may start to fail.

In addition to the COVID-19 virus causing heart damage, the late-stage cytokine storm may also damage the heart, which can affect its normal rhythm. Studies on the late treatment use of HCQ are prone to confounding this viral and cytokine cardiac effect with any supposed alleged negative cardiac effects derived from the use of HCQ.³⁰

*Once a severe cytokine storm develops, roughly half of these patients will die over the next few days. The current data shows that this may be significantly prevented by taking eleven to fifteen 200 milligram tablets of hydroxychloroquine over a 5 to 7-day period **during the early treatment phase of COVID-19.**³¹*

V. What Do Research Studies Say about HCQ as a Therapeutic?

Based on the news, you may have read or heard about both chloroquine and HCQ as a therapeutic and the various actions taken by the FDA in limiting its use. You may think that these medicines have been universally discredited by the research studies. **In fact, numerous studies published from January 2020 to October 2021, continue to show the overwhelming positive effects of this drug in COVID-19, without any serious adverse cardiac events.**³² Here’s a key topline point:

During the first critical six months of the pandemic, there were far more positive studies of HCQ confirming its safety and efficacy as both a prophylactic and therapeutic than negative studies. Yet news from very deeply flawed negative studies completely overwhelmed this positive news in the mass media, thereby contributing to a climate of Hydroxy Hysteria. The root of this

problem appears to have been the politicization of HCQ in an election year by an anti-Trump media and a small scientific elite.

A Brief Sampling of the Positive Studies

For example, in France, a March 20, 2020 study in the *Journal of Anti-microbial Agents* offers a non-randomized controlled trial of 42 cases. This small sample study showed that HCQ treatment was significantly associated with a viral load reduction and disappearance in COVID-19 patients who demonstrated a shorter period of illness.³³

A second April 11, 2020 observational French study published in *Travel Medicine & Infectious Disease* examined 80 patients receiving HCQ and azithromycin. It reported that 81.3% of patients had a positive response to this COVID-19 drug treatment.³⁴

Still a third May 5, 2020 French retrospective study, published in *Travel Medicine & Infectious Disease*, reviewed 1,061 patients and it showed a virological cure in 91.7% of the patients by Day 10 of the treatment.³⁵

In China, an April 10, 2020 study of 62 patients was conducted with the participants randomized in a parallel-group trial with no difference in age or sex between the two groups. The 31 patients who received a 5-day HCQ (400 mg/d) treatment were observed to have a shorter time to clinical recovery, a shorter cough remission time, and a larger proportion of patients with improved pneumonia (80.6%, 25 of 31) compared with the control group (54.8%, 17 of 31).³⁶

In a May 1, 2020 retrospective Chinese study of 568 critically ill patients, researchers discovered that the levels of the inflammatory cytokine IL-6, was significantly lower in the HCQ group with no change in the control group. The authors concluded: “Hydroxychloroquine treatment is significantly associated with a reduction in mortality in critically ill patients with COVID-19 through attenuation of the inflammatory cytokine storm.”³⁷ This has been reported by another investigative group as well.

In Brazil, an April 15, 2020 study examined 636 symptomatic patients. These patients were grouped into 412 patients treated with a combination of HCQ and azithromycin versus 224 patients who refused medication. The authors found that the need for hospitalization in the control group (5.4%) was 2.8 times higher than in the group treated with HCQ and azithromycin (1.9%).³⁸

The Composite Meta-Analysis of HCQ Use. (Updated 22 October, 2021)

A database of 294 clinical trials comparing HCQ treatment with non-treated control groups involving 4,723 scientists and **412,766 patients** shows unequivocally the positive effects of HCQ administration for COVID-19 infection.

- These studies demonstrated that HCQ is *not effective* when used very late in the COVID-19 disease process using unwarranted high dosages over a long period of time such as in the faulty UK RECOVERY Clinical Trial.
- The effectiveness of HCQ improves with earlier usage and improved dosing. *Early treatment consistently shows positive effects.*³⁹

- The Center for Drug Evaluation and Research under the former leadership of Janet Woodcock MD (now the Temporary FDA Commissioner under the Biden Administration) incorrectly determined that that therapeutic levels of HCQ could not be obtained in actual patients. This was based on faulty FDA computer models involving tissue culture studies which inexcusably ignored the early existing published observational trials of HCQ in France, South Korea, and China.

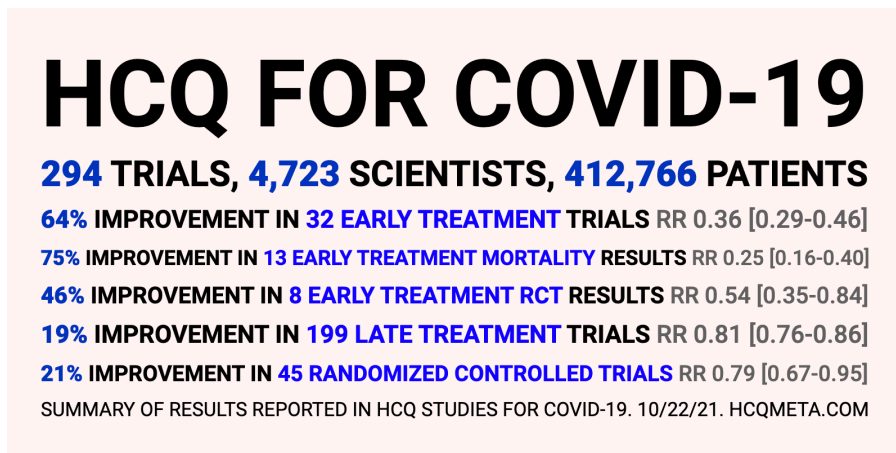


Figure 3. Summary of Results in HCQ Studies for COVID-19 10/22/2021 ⁴⁰

- 83% of [Randomized Controlled Trials \(RCTs\)](#) for early Pre-exposure, or Post-exposure Prophylactic HCQ treatment, report positive effects. The probability of this happening for an ineffective treatment is 0.0038.⁴⁰
- 97% of the 32 [early treatment](#) studies report a positive effect (13 statistically significant in isolation).
- Meta analysis using the most serious outcome reported shows 64% [54-71%] improvement for the 32 [early treatment](#) studies. Results are similar after exclusion-based sensitivity analysis and after restriction to peer-reviewed studies.
- Restricting to the 8 [RCTs](#) shows 46% [16-65%] improvement, and restricting to the 13 [mortality results](#) shows 75% [60-84%] lower mortality.
- Late treatment is less successful, with only 68% of the 199 studies reporting a positive effect. Very late-stage treatment is not effective and may be harmful, especially when using excessive dosages.
- There is evidence of [bias towards publishing negative results](#). 76% of prospective studies report positive effects, compared to 71% of retrospective studies.
- [Studies from North America](#) are 2.7 times more likely to report negative results than studies from the rest of the world combined, $p = 0.0000000477$.

- The probability that an ineffective treatment generated results as positive as the 294 studies is estimated to be 1 in 263 trillion.
- [Negative Meta-analyses](#) of HCQ generally choose a subset of trials, focusing on late treatment, especially trials with very late treatment and excessive HCQ dosages.

-
- *97% of early treatment studies report a positive effect, with an estimated reduction of 64% in the effect measured (death, hospitalization, etc.) from the random effects meta-analysis, RR 0.36 [0.29-0.46].⁴⁰*
 - *Late treatment studies are mixed, with 68% showing positive effects, and an estimated reduction of 19% in the random effects meta-analysis. Negative studies mostly show evidence of significant unadjusted confounding, including confounding by indication; usage is extremely late; or they use an excessively high HCQ dosage.*
 - *75% of Pre-Exposure Prophylaxis studies show positive effects, with an estimated reduction of 30% in the random effects meta-analysis. Negative studies are all studies of systemic autoimmune disease patients which either do not adjust for the different baseline risk of these patients at all, or do not adjust for the highly variable risk within these patients.*
 - *88% of Post-Exposure Prophylaxis studies report positive effects, with an estimated reduction of 33% in the random effects meta-analysis.*
-

In Summary, COVID-19 is a treatable condition if managed very early

[A Sampling of the Negative Studies and Their Role in Hydroxy Hysteria](#)

In contrast to the positive findings, a number of studies published between April 14 and May 22, 2020 purported to find no therapeutic value and/or increased mortality rates associated with HCQ.

As shown above, these studies generally failed to properly distinguish between early and late treatment use, and all had other serious flaws.

These flaws ranged from dangerous overdosing and skewed or biased sampling to the possible confounding of effects that may occur because of the testing of HCQ in combination with other drugs that have potential cardiac side effects in critically ill patients.

Despite these flaws, these studies would be used heavily to promote Hydroxy Hysteria by an anti-Trump media seemingly more concerned with an election outcome than saving American lives.

Confounding the Efficacy of Early Treatment and Late Treatment in France

A study of 181 patients in four French hospitals published on April 14, 2020 on a non-peer reviewed server called *MedRxiv*, aptly illustrates how the failure to properly distinguish between early treatment and late treatment use of HCQ can contribute to Hydroxy Hysteria. All 84 patients in the HCQ group of this study received the medicine within 48 hours of admission, which would suggest early treatment use.

However, buried in the text is an admission by the authors that most of the patients “had an inflammatory syndrome defined by C-reactive protein higher than 40 mg/l, which suggests that a “cytokine storm” was already starting. In other words, the patients were likely already well into the late treatment phase of the disease when HCQ was first administered – and, as noted earlier, at this stage, the medicine is far less likely to provide any benefits.

Not surprisingly, the authors conclude that their results “do not support the use of HCQ for a documented SARS-CoV-2-pneumonia.” The title of the article itself is equally misleading. It declares there is “*no evidence of clinical efficacy of HCQ.*”

In reporting this study’s findings, a CNN headline read: “*French study finds HCQ doesn’t help patients with coronavirus.*” In the lead paragraph, and as testimony to the partisan nature of Hydroxy Hysteria, the journalist then stated: “*A drug that’s been touted by President Trump as a ‘game changer’ didn’t help hospitalized patients....*”

In the body of the CNN article, a clueless infectious disease specialist at Children’s Hospital of Philadelphia declared: “*This provides evidence that HCQ does not apparently treat patients with COVID-19.*”⁴⁰

These sweeping statements reflect partisan journalism, bad science, a failure of doctors to read the medical literature, and just more grist for the Hydroxy Hysteria mill.

A Brazil Study Designed to Kill Actually Does Kill

As an example of dangerous overdosing leading to death, there is the Brazilian study of 81 patients posted on *MedRxiv* on April 16, 2020.⁴¹ The study was not peer-reviewed at the time and it was ostensibly a double-blind, randomized study which is good. However, the study design was negligent enough to literally kill.

This Brazilian study separated its 81 patients into “a low and high dosage group.” The high dosage group was then given doses of chloroquine well in excess of any reasonable science. Adding to this extreme risk, only older patients (over the age of 75) were enrolled in the high dosage group. Not surprisingly, this high dosage group “saw multiple deaths and worsening conditions;” and the trial was suspended.⁴²

The use of lethal doses in the study notwithstanding, this didn’t stop the mainstream media from writing fear-mongering headlines that included phrases like “*fatal heart complications*” (New York Times),⁴³ “*lethal for some patients*” (Guardian),⁴⁴ and “*study ends early due to deaths*” (CNN).⁴⁵

The Washington Post coverage was perhaps the most indicative of the partisan-motivated harm that Hydroxy Hysteria was doing. Its headline read: “Drug promoted by Trump as coronavirus ‘game changer’ increasingly linked to deaths.”⁴⁶

The reporters go on to falsely claim: “Clinical trials, academic research and scientific analysis indicate that the danger of the Trump-backed drug is a significantly increased risk of death for certain patients. Evidence showing the effectiveness of HCQ in treating covid-19 has been scant.” [Emphasis added]

The one unquestioned truth in the article, and a tragic one at that, spoke to the depressive effect of Hydroxy Hysteria on HCQ use:

Many hospitals then stopped using the drug outside of clinical trials. “We no longer are keeping large quantities and have returned most of it,” said Nishaminy Kasbekar, director of pharmacy for the Penn Presbyterian Medical Center in Philadelphia. “I think they should revoke the EUA because clearly based on the data it is no longer considered a treatment for COVID.”

This media hysteria was the precise recipe for the destruction of the National Pandemic Plan for Respiratory RNA viruses and a national disaster leading to thousands of deaths accompanied by a threat to the national economy and national security.

A Veterans Study Not Sponsored by Veterans Affairs

As yet another example of a fatally flawed study used to promote Hydroxy Hysteria, consider another non-peer-reviewed article posted on April 23, 2020 on *MedRxiv* based on a data set from the records of hundreds of American veterans. This study would indeed have an outsized effect on Hydroxy Hysteria, in part, because it was falsely linked to the U.S. Department of Veterans Affairs.⁴⁷

This small sample study sorted 368 patients into three treatment groups – a HCQ only group, a HCQ with azithromycin group, and a control group. It not only found “no benefit” from the use of HCQ. It also found a statistically significant higher mortality rate. From these results, the authors argued for a suspension of the emergency use of HCQ when they wrote:

An association of increased overall mortality was identified in patients treated with HCQ alone. These findings highlight the importance of awaiting the results of ongoing prospective, randomized, controlled studies before widespread adoption of these drugs.” [emphasis added]⁴⁸

Beneath the surface of this seemingly damning evidence and implicit call for a HCQ moratorium were a long list of significant study flaws:

- All patients were very ill; the Hydroxychloroquine-only group had the highest risk of dying prior to treatment.
- All of the patients were 59 years or older;

- Virtually all had significant co-morbidities, including myocardial infarction, congestive heart failure, peripheral vascular disease, renal disease, AIDS and diabetes – in other words, the medicine was given to the sickest of patients with the lowest chance of survival.
- Reflecting the extreme sloppiness of the researchers, the HCQ group also had a statistically higher number of smokers that was not adequately noted in the text.

Upon the study's release, the CNN headline blared: "*Study finds no benefit, higher death rate in patients taking HCQ for Covid-19.*"⁴⁹ Nowhere in the article was any acknowledgement of the study's numerous flaws – despite the fact that one of the CNN article's authors was a medical doctor who should know better. Instead, the CNN authors used the results to advance the Hydroxy Hysteria narrative, writing that "*Physicians have warned that while Trump is enthusiastic about the drug, it still needs to be studied to see if it works and if it's safe.*"

The *Lancet* Poisons Science with Politics and Sullies Its Reputation

Perhaps no research study has done more to fuel Hydroxy Hysteria – and has done more to suppress the use of HCQ – than an article published on May 22, 2020 in the *Lancet*. To the acute embarrassment of this once prestigious journal and its partisan editor Richard Horton, this article was swiftly retracted on June 5 – but not before doing irreparable damage.⁵⁰

The *Lancet's* sham article featured what would turn out to be a **fake data base** of 96,032 hospitalized patients, with a study group of 14,488 drawn from this universe. Those in the study group were described as receiving some form of medicated treatment, HCQ alone, or in combination with azithromycin or clarithromycin, which is 15 times more cardiotoxic than azithromycin. The paper grouped these two different antibiotics together as “macrolides” and combined the results from these two different groups.⁵¹ The authors concluded that patients taking HCQ had a significantly higher mortality.

The mainstream media had a field day reporting this fake news. The CNN headline read "*Large study finds drug Trump touted for Covid-19 is linked to greater risk of death and heart arrhythmia.*"⁵² The article goes on to describe the president as a “cheerleader” for HCQ and quotes the study's author as saying in what can only be described as the dangerous hyperbole of a charlatan: “

*Our data has very convincingly shown that across the world in a real-world population that this drug combination, whichever way you slice it or dice it, does not show any evidence of benefit, and in fact, is immutably showing a signal of grave harm.*⁵³ [emphasis added]

This study would indeed do tremendous damage. Its data would later turn out to be fabricated and the paper would quietly have to be withdrawn from publication.

Yet, three days after its publication, the World Health Organization announced a temporary halt to its global clinical trial.⁵⁴ Shortly thereafter, the French government banned the prescription of HCQ to treat COVID-19,⁵⁵ and one maker of the drug, the French company Sanofi, suspended the recruitment of new patients for its clinical trials.

Predictably, the mainstream media failed to cover the eventual retraction of this fraudulent paper with anywhere near the same amount of attention as it did the original phony study. In its coverage, CNN did not even bother to solicit comment from any of the medical professionals who had called into question the original article.⁵⁶

The Lancet is Forever Compromised and Horton Should Step Down

The publication of the fake *Lancet* article and its subsequent retraction raises an even bigger issue. Medical journals are not supposed to be political. Yet on May 15, 2020, the Lancet's Editor-In-Chief Richard Horton apparently editorialized for the defeat of President Trump in the 2020 election.⁵⁷

Horton, has also praised the authoritarian Chinese government for its lockdown of Wuhan, and said that it is “*very disappointing*” to see politicians “*damaging the prospects of international collaboration*” when they criticize the Chinese Communist Party (CCP) for its covering up of the virus.”⁵⁸

Under pressure from the Chinese Communist Party, the Lancet also retracted a February 24 letter by two Chinese nurses who described “*a severe shortage of protective equipment, hands being covered in painful rashes because of the frequent hand washing, nurses having pressure ulcers on their ears and foreheads, and daunting numbers of Chinese healthcare staff contracting the virus, and even passing away as a result.*”⁵⁹

It must also be noted that the Lancet editorial board and senior staff, feature numerous Chinese nationals that have worked directly or indirectly for the Chinese government and the Chinese Communist Party.⁶⁰

Amidst this raft of unethical, partisan, and immoral behavior, Lancet's Board of Directors needs to remove Horton from his post forthwith. There is no excuse for this pattern of behavior.

The Tragedy of Hydroxy Hysteria

Because of these very real negative effects on the use and study of HCQ, Hydroxy Hysteria has cost far more lives than the journalists and pundits responsible for this hysteria are purporting to save. This may be so for two obvious reasons:

1. To the extent doctors and nurses at the front lines, and others exposed to the COVID-19 virus, became reluctant to use HCQ as a prophylactic, leading to higher infection rates.
2. To the extent that patients who present with early symptoms of infection are not being prescribed HCQ as an early treatment, leading to higher mortality rates.

By failing to accurately report the scientific evidence, the mainstream media has created an enduring climate of fear and hysteria over HCQ. This Hydroxy Hysteria has not only significantly reduced the use of HCQ in hospitals

in both America and around the world. It also significantly impaired the ability of the scientific community to conduct the kind of blind, randomized, clinical trials that were insisted on by the Conflict-Of-Interest riddled COVID-19 Treatment Group at the NIH, led by Dr. Anthony Fauci which might have settled once and for all the questions of HCQ's safety and efficacy as a prophylactic and early treatment therapeutic.

These negative effects from Hydroxy Hysteria have resulted in one of the great tragedies of the COVID-19 pandemic as the preponderance of studies have now found HCQ to be both safe and efficacious as a prophylactic and/or early treatment therapeutic.

How Many Lives Have Been Lost?

The July 1, 2020 pioneering study of early treatment use of HCQ in the *Journal of Infectious Diseases*⁶¹ from the Henry Ford Hospital system in Detroit provides a rough estimate of the lives that have been lost – and continue to be lost – because of the lack of widespread use of HCQ as a therapeutic.

The Henry Ford Hospital system examined 2,662 patient entering its five-hospital system in southeast Michigan from March 10, 2020 to May 2, 2020. This patient universe was sub-divided into four groups: a control group, a HCQ group, a HCQ with azithromycin group and an azithromycin-only group. As the study notes:

The postulated pathophysiology of Covid-19 of the initial viral infection phase followed by the hyperimmune response suggests potential benefit of early administration of HCQ for its antiviral and antithrombotic properties.”
[emphasis added]

This Ford Hospital Study found at a statistically significant level that the HCQ alone group was associated with a significantly lower mortality rate compared to patients not receiving HCQ.⁶²

This finding translates into a 51% reduction in the mortality rate for patients receiving **early hospital** treatment of HCQ. These results, in turn, suggest that tens of thousands of Americans would have survived with an early treatment regimen of HCQ.

The Ford study findings were quickly reaffirmed by the findings by the findings of a Mount Sinai study⁶³ and a large Spanish study which showed a 66% reduction in mortality with the early hospital use of HCQ.⁶⁴

Yet the Food and Drug Administration Drug and safety Division under the leadership of Janet Woodcock and the NIH Treatment Panel led by Dr. Anthony Fauci, continued to ignore these findings and the much broader positive HCQ literature as it engaged in numerous actions to suppress the proper use of HCQ.

VI. The FDA's Unconscionable War On Hydroxychloroquine

Regrettably, the American Food and Drug Administration (FDA) has contributed in its own ways to Hydroxy Hysteria and the needless loss of American lives. The FDA has done so by first failing

to understand the science of HCQ and then taking numerous actions either to suppress HCQ's use in early out-patient treatment or kill the use of HCQ completely.

The FDA Failed to Realize the Adverse Cardiac Effects Caused by the COVID-19 Virus

In the very early months of the COVID-19 pandemic, doctors began to notice that patients would be hospitalized with viral pneumonia and yet they would die from heart failure. Cardiologists also began to notice that elevations of the Troponin I protein were being released from damaged heart muscle cells to circulate in the blood of these patients. Troponin was being found in 10-30 % of hospitalized COVID-19 patients; and it was a risk factor for their later dying.⁶⁵

In the laboratory, scientists were finding that the COVID-19 virus could infect heart muscle cells in tissue culture; and pathologists were finding traces of the virus's genetic material and actual SARS CoV-2 viral particles inside the heart muscle on autopsy. However, these were late cases that had died. Even more concerning was that even some early COVID cases were showing signs of myocarditis. While not that unusual (at least 20 other types of viruses can cause this), on autopsy this myocarditis was usually not accompanied by the presence of detectable virus.

Instead, an indirect effect seemed to be happening. The COVID-19 virus appeared to be triggering widespread inflammation throughout the body including the blood vessels, heart, lungs, kidneys and even the pancreas and bowel.⁶⁶

In July, a team led by Valentina Puntmann at University Hospital Frankfurt showed that 78 percent of people who had recovered from COVID-19 (including many who had never been hospitalized) still had some kind of heart abnormality that was detectable with MRI scans two months later. About 60 percent still had signs of myocarditis.⁶⁷

This study was explosive. It spawned a wave of articles and papers about the possibility that COVID-19 could inflict both stealthy and prolonged harm upon the hearts of people who were not outwardly sick, and this reportedly influenced decisions about whether college athletes should be allowed to play. These intense discussions also sparked intense criticism.

At present, here's what can be said: There are subsets of COVID-19 cases where patients are relatively healthy with mild COVID-19 yet these mild cases still developed cardiac abnormalities. The clinical implications for those COVID-19 patients whose symptoms have abated but whose MRI scans are still abnormal are still being defined.⁶⁸ However, a new study in 2021 now provides evidence consistent with the fact that the patients' heart damage in COVID-19 results from the virus invading and replicating inside heart muscle cells. This leads to cell death and interferes with heart muscle contraction.⁶⁹

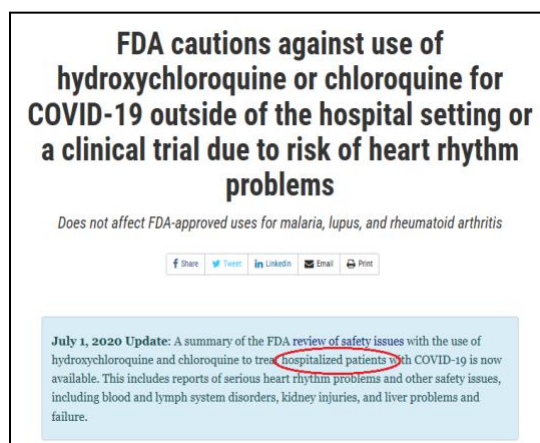
Here's the key HCQ point:

COVID-19 cases can appear with heart conduction abnormalities that have been blamed on HCQ. Yet these same abnormalities can be present in COVID-19 patients who have never taken a single tablet of this drug. These

abnormalities include the full lethal spectrum of QT prolongation, Ventricular Tachycardia and Ventricular Fibrillation and death.

Clearly, the FDA failed to grasp this key point. On April 24, 2020, it issued a “Drug Safety Communication” that highlighted “known side effects” of HCQ and chloroquine. This notice warned of “abnormal heart rhythms such as QT interval prolongation, dangerously rapid heart rate called ventricular tachycardia and ventricular fibrillation, and in some cases, death.”⁷⁰

This decision was imprudent in the extreme in light of the long safety record of HCQ in Lupus and Rheumatoid Arthritis patients when given under higher doses and much longer durations than used in COVID under a physician’s guidance. The FDA warning had, however, a noticeably chilling effect both on the distribution of HCQ to our nation’s hospital systems as well as the ability to recruit subjects for clinical trials.⁷¹



The FDA Revokes an Emergency Use Authorization for Hydroxychloroquine

On June 15, 2020, the FDA took one step further in casting a pall over the use and study of HCQ: It revoked the Emergency Use Authorization (EUA) for emergency use of oral formulations of HCQ as well as chloroquine.⁷² According to at least one media account, this decision by the FDA “appears to formally close the door on U.S. officials’ willingness to use the drug to prevent or treat Covid-19.”⁷³ Because the FDA’s decision has in all likelihood led to the loss of tens of thousands of American lives, it is therefore worth reviewing the basis of the FDA’s decision.

The **FDA’s Chief Scientist Denise Hinton** cited three reasons in her letter of revocation of the EUA.⁷⁴ The first reason was that both HCQ and chloroquine “are unlikely to produce an antiviral effect.”

This statement is contradicted by the numerous studies reviewed in this report. Both the preponderance of evidence and the underlying science remain firmly pointed in the direction of definite HCQ therapeutic efficacy.

A second reason cited by Hinton is that the National Institute of Health (NIH) guidelines “now recommend against” the use of HCQ or chloroquine “outside of a clinical trial.” However, a review of these NIH guidelines indicate they were based on what can only be described as a cursory review of the existing research, one that leaves out any significant discussion of the many positive studies of HCQ and makes no mention of the numerous early use studies.⁷⁵

On September 8, FDA Commissioner Stephen Hahn openly admitted during a radio interview that some studies do indeed “suggest a benefit” for using HCQ for COVID-19 infections.⁷⁶

The third reason cited by Hinton, which is the most curious and questionable, actually spans two of the four bulleted reasons in her letter. She cites “recent data from a large randomized controlled

trial” as showing “no evidence of benefit for mortality or other outcomes such as hospital length of stay or need for mechanical ventilation.”⁷⁷

As we have discussed, this statement is completely false.

A Problematic British Study Leads the FDA Further Astray

The controlled trial in question was conducted by Drs. Peter Horby and Martin Landray under the sponsorship of Oxford University and under the auspices of the British government. It compared 1,542 patients randomized to HCQ and 3,132 to the usual care comparator.

What is curious about this trial is that Horby and Landray had not yet released the full study and underlying data. Instead, they simply issued a summary press statement claiming that the *“data convincingly rule out any meaningful mortality benefit of HCQ in patients hospitalized with COVID-19.”⁷⁸*

It is *highly unusual* for scientists to cite summary results *before* releasing the full study and data. Indeed, such behavior should not only raise eyebrows but also ethical questions. Such behavior also calls into question the use of these summary results by the FDA to make such a critical decision as revoking the HCQ EUA.

This observation leads to the questionable part of the British study. From what little was known about the trial at the time, there were at least two fatal flaws that completely undermined the FDA’s reliance on British statement of no effects on mortality or other outcomes.

The first problem was that HCQ was given in non-therapeutic / toxic doses and it was largely given *outside* the window of maximum potential effectiveness. The HCQ dosing regimen used in the trial was 12 tablets during the first 24 hours (800mg initial dose, 800 mg six hours later, 400 mg 6 hours later, 400 mg 6 hours later), then 400 mg every 12 hours for 9 more days. This represented 2.4 grams of the drug given during the first 24 hours and a cumulative dose of 9.2 grams given over 10 days.

A published clinical series indicated that an accumulated dose of 4g of HCQ can cause severe adverse symptoms in patients. The best one can say here about the trial is that excessive dosing makes it difficult to properly assess therapeutic efficacy.

The second flaw is arguably the fatal one – and one which the FDA appears to have ignored. To wit, the study was yet another late-treatment study doomed to failure. This we can glean from the study’s focus solely on hospitalized patients with very high mortality rates (>20%) in both the HCQ and control groups. These high mortality rates are clear, albeit indirect, indicators that the patients under study likely did not receive the medicine until the infection was significantly advanced and well into the late treatment phase.

The limited collection of any safety data in this trial obscured any adverse *or* positive drug effects and what was eventually released, lacked even basic clinical information. The simple press release stated the UK would be halting its ongoing HCQ studies because it had no effect on COVID mortality. It supplied no data and no proof, just a brief press statement accompanied by some negative drug comments made by one of the study directors.

On October 8, 2020, some actual data was finally published by the RECOVERY Collaborative Group. It was titled, *“Effect of Hydroxychloroquine in Hospitalized Patients with COVID-19.”⁷⁹*

The study considered only inpatient HCQ treatment and it had no relevance whatsoever to early outpatient treatment with HCQ. Furthermore, there were other serious defects in this clinical trial;

- The study was not a randomized trial; instead, the allocation of the drug was randomized, and the timing of drug administration varied widely.
- Median number of days from symptom onset [to treatment] was 9 days – far too late for any early treatment effect.
- The study suffered from “confounding by indication”: patients who received HCQ were already sicker than those who did not.
- As mentioned, the drug dosage far exceeded the recommended 2,800 mg over six days; nevertheless, **a later independent re-analysis showed HCQ had a significant beneficial effect in patients on a ventilator.**

The study director could not explain the unwarranted high doses of HCQ that he was giving to his study trial participants, **nor did he mention his links to the manufacturer’s expensive competing drug called Remdesivir.**

Without releasing his HCQ data for others to study, the study director was claiming negative results for what was just another useless late patient study using unjustified toxic doses of the drug.

In addition, while the data eventually presented in the RECOVERY trial was correct, the way it was presented obscured the finding of HCQ effectiveness. This difference between the number of ventilated patients on HCQ who died of 32.2% and those not on HCQ who died of 42.3% is large enough that it should have been reported. Yet the RECOVERY trial described HCQ as *offering “no benefit”*. **The data had been presented so as to minimize this result.**⁸⁰

Again, in summary, there are commonalities among all the negative studies used to discredit HCQ which include one or more of the following;

1. The HCQ Protocol tested was not for the early ambulatory phase of the disease. It involves a study that confines the patients to hospitalized cases.
2. The HCQ Protocol tested involved extremely high dosages of HCQ (higher than recommended under the guidelines for ANY application).
3. The HCQ Protocol tested failed to include Zinc administration. (HCQ acts as the ionophore for Zinc to enter the cell membrane and block the COVID virus replication).⁸¹
4. The HCQ protocol was used on patients that were not risk stratified, causing a dilution of any efficacy (most of the subjects would not have suffered a measured “outcome” anyway).

If we have learned anything by this point, it is that any COVID drug studies going forward must focus on early treatment use.

The British RECOVERY study and the rest of the late-phase studies have had little to nothing to say about this.

It was a major signal failure that the FDA's assessment process did not make this distinction and that it based its revocation on this study's as yet unpublished full results. There is blood on the FDA's hands for this failure.

As a comment on what is arguably an FDA overreach with potentially tragic consequences, Ms. Hinton claims that the potential benefits of HCQ “do not outweigh its known and potential risks.”⁸² Since the known and potential risks of a medicine that has been used for decades are virtually non-existent when the medicine is prescribed to persons without contravening indications, this statement is simply absurd.

Following the UK press release, on June 15, 2020, the FDA revoked its EUA for HCQ, permanently damaging the reputation of this life-saving drug and frightening doctors in prescribing it because of non-existent cardiac effects. It determined that HCQ was unlikely to be effective in treating COVID-19 and that it was causing “ongoing serious cardiac adverse events and other potential serious side effects...The known and potential benefits of chloroquine and HCQ no longer outweigh the known and potential risks for the authorized use”.

The reasons stated in the actual EUA withdraw letter were complete nonsense. It was “junk science” and both the withdraw letter and its supporting annex contained gross errors, over-reaching, unsupported statements, and incorrect interpretations of data. The cardiac side-effects that the FDA claimed for HCQ, could never be considered a factor if the drug was used early in the disease course as it was originally supposed to have been.

Multiple real-world studies now confirm there are no adverse cardiac effects in thousands of patients when treatment is given early in the COVID disease time frame, in doses recommended by the FDA itself.⁸³

This was proven in August 2020, when early COVID-infected patients were given multiple electrocardiograms during their 5-day course of HCQ therapy. There was NO change in the patient's ECG baseline during or after the HCQ treatment.⁸⁴

In weighing the evidence of a minority of negative HCQ studies (late disease stage and/or with serious study design flaws) in COVID patients, the EUA withdraw letter makes no mention nor does it try to explain, the over 40 (at the time) positive observational and controlled (but non-randomized) trials.

These 40 studies clearly demonstrated that HCQ is a safe medication that can significantly halt the progression of early COVID-19 patients into the more severe, lethal second-stage of the disease with no untoward cardiac effects.

These studies also reaffirmed that HCQ could lower the mortality of COVID patients that had already progressed into the late stage if given immediately upon hospital admission.

Furthermore, the pioneering Ford study showed this treatment could be based on clinical suspicion without waiting for COVID testing results.

What We Have Learned Since the FDA's EUA for HCQ Withdrawal.

Following the EUA withdraw for HCQ, five large peer-reviewed studies, including controlled clinical trials, all demonstrated a significant major efficacy of HCQ as a cheap, antiviral medication when used in the early stage of COVID-19 infection.

The first week of July alone was characterized by the release of two major studies: the aforementioned Detroit Ford group which showed a 51% reduction in COVID mortality with early HCQ use (drug was given upon hospital admission) and the large New York Mount Sinai Hospital experience with a 47% mortality reduction.

A later Spanish study showed a 66% reduction in COVID mortality⁸⁵ and a later Belgian study published on 25 August also showed a high-level benefit.⁸⁶

Curiously, none of the FDA warning and actions taken against HCQ applied to the FDA's-approved use for the drug in lupus and rheumatoid arthritis where periodic doses of HCQ were often given to patients with these disorders in much larger and longer doses than that recommended for COVID treatment applications.

Currently, there are well over 200 medical research papers in the literature describing the overwhelming positive effects of HCQ when given to COVID patients.

The FDA's response and the biased media overreaction to flawed studies have combined to prevent early COVID outpatients in the U.S. from having access to HCQ. These are the patients who needed it the most.

As previously mentioned, on 8 September 2020, the FDA Commissioner Stephen Hahn openly admitted during a radio interview that some studies do indeed “*suggest a benefit*” for using HCQ for COVID-19 infections. Dr. Hahn follows a very large internet chat group of national experts and he must have known the true story about HCQ for months after the FDA's decision, yet he did NOTHING.⁸⁷

The most obvious question to now ask is, if the FDA Commissioner thinks the HCQ does indeed yield a benefit in COVID-19, then please explain why the FDA rejected a proposal for a new early-use Randomized Controlled Trial (the so-called “gold standard”) submitted by the Detroit Ford group to garner just the data that the COVID-19 Treatment Panel would accept as not being “anecdotal”.

The application for the new EUA for this study was denied by the FDA in a rejection letter received on August 10.

During the radio interview, Dr. Hahn was quick to point out that doctors are free to prescribe the drug [HCQ] for “off label” use and that the FDA “*does not regulate the practice of medicine.*” Yet, one might have asked Dr. Hahn at the time to try writing a prescription for himself in Arkansas, Washington DC, New York, or any of 42 other states that have banned HCQ because of the FDA's actions. **Hospital administrations themselves have banned the use of this drug for early hospital treatment in spite of the peer-reviewed published research.**

In reality, the situation concerning private physicians prescribing the drug is out of control and both patients as well as doctors are now terrified of the drug. Doctors stopped writing outpatient scripts and the governors of Arizona and Michigan would actually ban the drug's use for COVID in their states. Other states soon followed.

In addition, a number of respected medical professors speaking out in favor of HCQ were silenced by their medical school deans in Connecticut, Detroit, and elsewhere.⁸⁸

Doctors who publicly advocated for the drug were threatened by their HMOs and occasionally fired. Doctors in private practice were being put under investigation by state Medical Boards. Some were personally ridiculed in the press and slandered on social media.⁸⁹

This was disgraceful behavior directed against highly-trained medical professionals who were simply trying their best to save human lives and control the increasing number of cases.

It was not just the doctors that were being attacked. Some state pharmacy boards began threatening pharmacists and forcing patients to disclose their medical condition and why they had a

prescription for the drug.⁹⁰ Some 42 states placed restrictions dictating either what doctors could prescribe to their patients or what pharmacies could use to fill prescriptions.

All of this disgusting behavior was based on a handful of flawed clinical trials that were never designed to research the recommended early-use phase of the COVID disease process. It seemed that for every batch of positive research papers published on HCQ, there was a faulty late-phase study published showing either no effect or a harmful effect of the drug in COVID patients.

All of these negative papers had flaws and should never have made it through the peer review process. Behind the scenes, the editors of some of the more prestigious journals had privately complained they were being forced to publish the flawed studies.⁹¹

This begs the question of who was influencing these editors....and why? Who would have the most to gain by discrediting a drug that could bring the COVID pandemic in the U.S. under control? Who could exert this type of influence over the medical journals?

At least one answer may be found in the far easier approval paths given by the FDA to treatments far more expensive than HCQ – to the benefit of a Big Pharma lobby that had a vested interest in these more expensive treatments.

The FDA Pushes Expensive and Ineffective Alternative Treatments to HCQ

On August 23, 2020, the FDA announced an EUA for the use of pooled convalescent plasma for the early treatment of COVID infections. The cost was about \$1,000 a treatment and it had to be given intravenously which precludes any early outpatient use. This did not go unnoticed by the Ford Group in Detroit, who wrote a prompt letter to the FDA correctly claiming that there was more research justification for reauthorizing the EUA for early-use studies for HCQ, than what was presented to the FDA for its EUA with respect to Convalescent Plasma.

Recent alarming data now indicates that some convalescent plasma may actually be harmful because it can contain antibodies that block Interferon, a natural chemical produced by the body to help fight off a serious viral infection.⁹²

As for Remdesivir, this is the drug that was favored by Dr. Anthony Fauci for COVID-19, a drug that likewise must be administered in a hospital setting and runs several thousand dollars for a treatment course. On August 28, 2020, the FDA announced that Remdesivir had been issued an EUA to be used on all patients hospitalized with COVID-19.⁹³ This was in spite of the fact that no published research supported the widespread use of the drug at the time.

With HCQ now lacking an EUA, and state medical and pharmacy boards prohibiting use of the drug, all COVID patients were now relegated to have Remdesivir as a therapy, at a cost of thousands of dollars per patient versus about \$12 per patient for HCQ. Further, their access to Remdesivir would come only after their disease had progressed to the point where they required hospitalization.

The net effect was that with only an intermittent supply of Remdesivir during the summer, many patients would receive no antiviral drug at all, and thousands of Americans would die, even though more than 62 million HCQ tablets – enough to treat about 5 million Americans in early use -- were sitting in the Strategic National Stockpile.

On October 19, the results of the World Health Organization's SOLIDARITY Trial were published. This study followed 11,266 *hospitalized* adults at 405 facilities in 30 countries and found Remdesivir has little or no impact on mortality, no reduction in the need for mechanical ventilation, no reduction in the time to clinical improvement, and no effect on any other patient-important outcomes. The WHO now states that there is no use for Remdesivir for any hospitalized patient.⁹⁴

Yet, on October 22, despite the failure of Remdesivir to have any impact on hospitalized patients, the drug was formally approved by the FDA to treat hospitalized adult and pediatric patients 12 years of age and older.⁹⁵

In the U.S., the COVID-19 Task Force continued to maintain the Fauci-Hahn Doctrine of insisting on testing results and quarantining cases at home until they were sick enough to come to hospital and be placed on oxygen. Through December 2020, the NIH COVID-19 treatment panel and Dr. Anthony Fauci recommend no treatment whatsoever for COVID cases until they are admitted to hospital and require supplemental oxygen.

This is sheer insanity.

Blood on Fauci's and the NIH's Hands

Viewing the FDA's conduct along with that of Dr. Anthony Fauci and the NIH through the arc of time, it was very clear by mid-March of 2020 that HCQ was having a major positive effect on COVID patients. If Dr. Fauci and NIH's COVID-19 Treatment Panel⁹⁶ actually considered early studies to be substandard, why did Fauci and this panel not immediately direct efforts to initiate what Dr. Fauci publicly considered to be suitable Randomized Controlled Trials of this drug in outpatients?

Here's the tragedy: As we have repeatedly stated, the use of an antiviral drug was clearly outlined in the National Pandemic Plan for Respiratory RNA Viruses (National Pandemic Influenza Plan-updated 2017).⁹⁷ It is unclear why the COVID-19 Task Force did not promote the early outpatient treatment of high-risk viral patients with HCQ before they required hospitalization. This was a catastrophic failure.

HCQ was working. As a cheap, easy to administer therapeutic, it fit in perfectly with the National Pandemic Plan, and Fauci and the NIH clearly had the funding. Instead, the COVID-19 Treatment Panel completely ignored the huge potential operational value of the early use of HCQ for reducing hospital medical surge requirements and minimizing deaths.

This was a lethal mistake that should not have been made by someone with the primary task of informing the national leaders of possible solutions to the COVID pandemic problem.

With glaringly absent national guidance on the need for ambulatory outpatient trials for HCQ, the drug would instead continue to be tried on hospitalized patients where, like the clinical trials for Fauci's favorite drug Remdesivir would soon show, any antiviral drug was not going to be effective.

Far too many clinicals trials for HCQ were being conducted on late-phase patients. Only a few of these were measuring acute phase blood markers and other clinical details, so there was actually little to learn from these trials - except for the Hydroxy Hysteria fact that HCQ was unable to exert its maximum effect in late patients when grouped together as a cohort with a differing severity of late-phase pathologies.

Blood is on the FDA's Hands

It is as clear now as it was then, that the FDA was incorrect in its issuance of an EUA for hospitalized patients instead of an IND Authorization for the use of HCQ in outpatients and it was incorrect in its withdraw of the EUA that it did issue.

- No other drug for Covid-19 has repeatedly and consistently demonstrated the benefits, safety profile for early use, low-cost, ease of manufacture, rapid dispensing, and ease of outpatient use, then HCQ when used under a doctor's supervision. It is even sold without prescription in some countries.
- No other drug, when properly utilized by private physicians and public health authorities, has such a dramatic ability to minimize COVID patient admissions to hospital and reduce the number of COVID deaths in high-risk populations.

The sad truth is, not only did the FDA fail to keep a proper check and balance on the pharmaceutical industry and select the best drug for the operational management of the COVID-19 pandemic, but it assisted pharmaceutical company interests by snuffing out the use of the closest competitor to Remdesivir (which at the time was HCQ).

VII. Real World Operational Data and HCQ's Ability to Control Community Outbreaks

HCQ's widespread use around the world tells us much about the practical use of the medicine to control community outbreaks and reduce mortality rates. To lay the predicate for an analysis of HCQ's use around the world, let us propose the following *Hatfill/Navarro Iron Law of Pandemics*:

Expensive investigational drugs like Remdesivir that are confined to their use in hospitalized patients will exert no impact on the community control of a pandemic when dealing with a highly-mutable RNA virus.

While inpatient drug treatment is important to reduce mortality, it does nothing to interrupt the cycle of infection outside the hospital, decrease the demand for additional surge healthcare personnel, reduce the demand for hospital beds and reduce the requirements for Intensive Care Unit (ICU) ventilators and specialized ICU personnel.

HCQ Use Around the World

Figure 5 illustrates that roughly one-quarter the world's population is now using HCQ for COVID-19 infections. Countries ranging from Spain, Italy, France, and Saudi Arabia to India, Switzerland, Turkey, and elsewhere have all reduced their infection rates when HCQ was employed in an early treatment outpatient strategy.

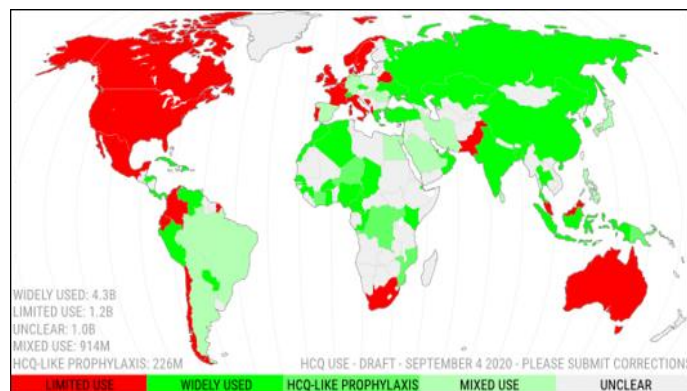


Figure 5. World-wide early-use HCQ as part of a National Pandemic Response (green) Source: c19study.com

All the countries that have published their observational results with HCQ show that the early use of this drug can dramatically reduce mortality from COVID-19. Again, early use treatment is not associated with serious adverse heart conduction deficits.

HCQ and Mortality Rates Around the World

Figure 6 illustrates the dramatic difference in mortality rates as measured by deaths per millions for countries like the U.S. and the United Kingdom which discouraged HCQ use, versus countries like Algeria, India, Indonesia, Malaysia, Morocco, and Turkey that initially used aggressive early treatment HCQ use strategies.

This figure is derived from the early phase of the pandemic in 2020, and it indicates significantly higher mortalities for the U.K. and the U.S. Canada likewise has failed to use HCQ in early outpatient use. It had a first wave death rate per million that was nearly identical with 47 U.S. States (if the greater New York City /New Jersey megaregion was excluded).

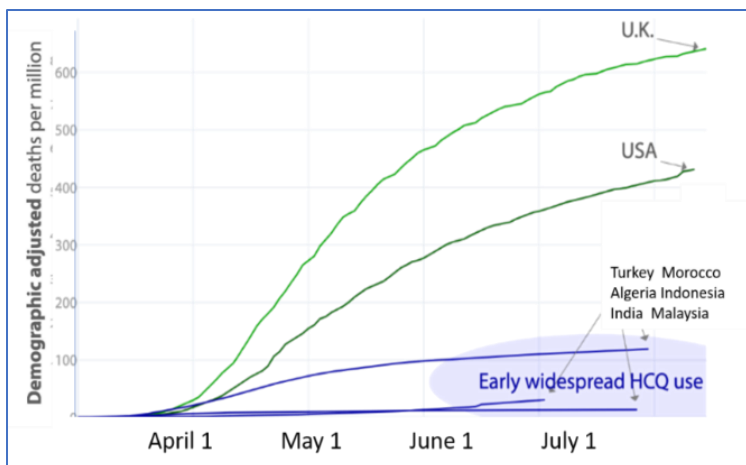


Figure 6. The U.S. and U.K. Versus Countries Aggressively Using HCQ. c19study.com

In Switzerland and Panama, when HCQ was banned, daily COVID deaths increased, and when the alarmed authorities brought the drug back, daily deaths were reduced back to the baseline.⁹⁸

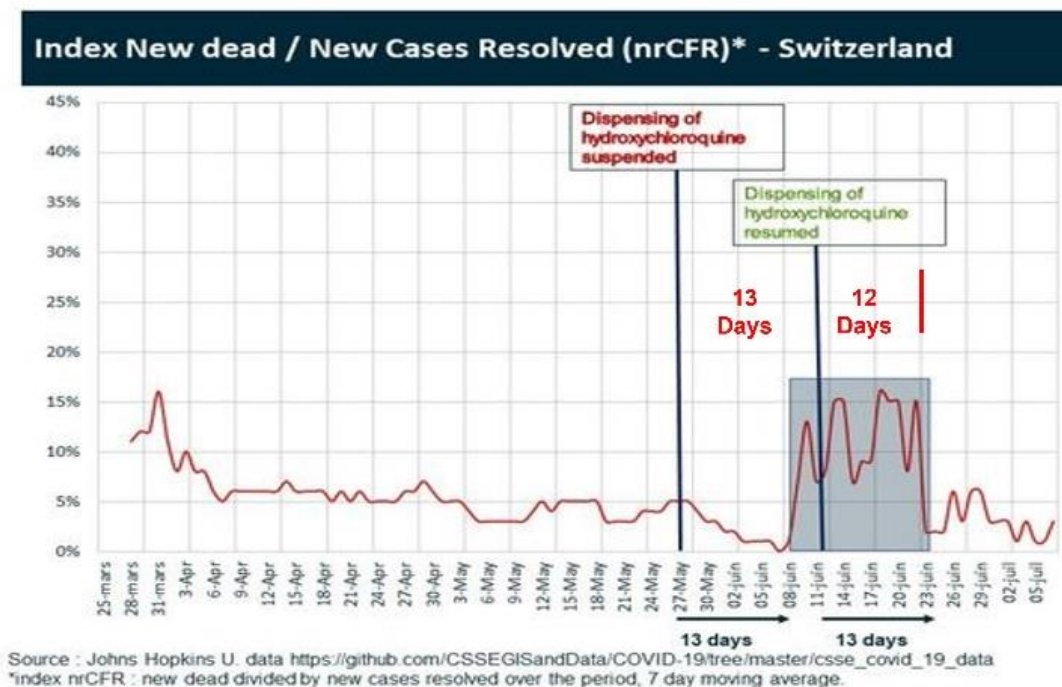


Figure 7. Switzerland HCQ use. Graph by *France Soir*

This is not simply anecdotal data, and it demonstrates that spending billions of dollars to find an expensive new drug to treat critically ill COVID hospitalized patients, does absolutely nothing to stop a pandemic and hence its final death toll. When we move from the aggregate to individual case studies of specific regions, the case for HCQ becomes even more compelling.

The Case of India – The Big Picture

Because of its high-density population, it was a foregone conclusion that India would have a massive COVID problem. However, India had not forgotten its history. The sudden loss of 18 to 20 million of its citizens during the great Influenza Pandemic of 1918⁹⁹ as well as the large outbreak of Bubonic Plague in the country in 1994, reinforced the nation's need to move rapidly with a serious infectious public health issue.

India took pandemics seriously and it wasted no time in halting its exports of active pharmaceutical ingredients and manufactured HCQ to the rest of the world (the U.S. included). It was fortunate that the U.S. Administration had already moved early to stockpile HCQ (although it would soon be to no avail).

In India (like in the U.S.), rapid COVID testing was not widely available and if it was, the results were coming back too late to make much of a difference. India's medical authorities addressed this problem by publishing a *Standard Case Definition* for COVID that doctors could use to make a provisional diagnosis. This was based on a doctor's clinical suspicion followed by a standard, short, early treatment course of HCQ.

Such widespread, safe, physician-directed outpatient treatment, largely independent of confirmed laboratory testing, was not a new practice. Doctors had been doing this for centuries and unlike in the U.S., India's own independent national media were fully supportive of this effort.

On July 17, India's Health Ministry reported an additional 34,956 confirmed COVID cases in one day. With 1.2 billion people, India's actual unconfirmed infection figures had to be enormous. Yet India only had 25,602 COVID deaths at that time. This was six times less than the United States on that same date.

The esteemed Dr. Venkata Ram from the multispecialty Apollo Hospitals and Health System in India represents a credible voice, and he has repeatedly stated that the total death counts in India are indeed accurate. With accurate death figures, this all begs for an explanation.

Why did India have such a low total number of COVID deaths?

The reason for the low number of total deaths in India, is that the nation had worked extremely hard to try to build a general pandemic response with a capability to catch COVID cases early and treat both them and their contacts with HCQ. These early-treated symptomatic outpatient cases were largely avoiding the need for hospitalization.

By the end of August 2020, thousands of U.S. health care workers had been infected with COVID. Inexcusably, comprehensive U.S. records do not exist, but it is estimated that anywhere from 600 to 1,000 healthcare workers died from their COVID infections by that time in 2020. The real-world evidence from India suggests that a majority of these U.S. deaths would have been preventable by

either pre-exposure prophylaxis or by early treatment with HCQ. These early treatment cases may still have become sick....but with a largely self-limiting illness and they would not have died.

The Case of India – The Dharavi Experiment

In 2020, the ultimate test for India – and for HCQ – was to come in the form of a COVID outbreak in Dharavi. This suburb of Mumbai is one of the densest slum areas in the world with as many as 650,000 people crammed into 2.5 square kilometers. This is where the movie *Slumdog Millionaire* was partially filmed. In comparison, New York City only has around 95,605 people for 2.5 square kilometers. It was impossible to social distance in Dharavi and the slum represented an apocalyptic infectious disease disaster waiting to happen.

The Indian government’s equivalent of the U.S. COVID-19 Task Force is called the Indian Council of Medical Research (ICMR). It had made firm plans to use widespread symptom interviews for COVID symptoms, temperature taking, and pulse oximetry for screening individuals for infection.. Not exactly high technology, but speed was of the essence. There was no time to wait on laboratory results.

This interview screening would be followed by close-contact tracing. Both the suspected case and the individuals who they were in close contact with would all be quarantined, and then treated by starting immediately on HCQ. Active cases would be transported to one of many quarantine / treatment centers set up in the area. ¹⁰¹

The first case in Dharavi was detected April 1, in a 56-year-old garment shop owner who died the same day. The area was already on a lockdown and a small army of 2,450 health workers quickly descended on the slum. There, they teamed up with the local Physicians’ Association and the private doctors that were the area’s main healthcare providers. These local physicians had a long relationship with their patients, including the migrant workers and the shopkeepers.

At the same time, other officials began converting local schools, marriage halls and community centers into free quarantine facilities with food, regular checkups, free healthcare, HCQ, and whatever laboratory testing was available. ¹⁰²

This was also part of the U.S. pandemic plan that was never initiated.

The Indian COVID teams zeroed in on five zones that they deemed to be high risk due to initial infections and they went into these areas proactively looking for patients. Wearing full-body protective ensembles, these small teams of health officials and local doctors divided up and began walking the narrow, crowded alleys, and pathways of Dharavi, knocking on doors and testing people in their houses starting at 9 a.m. every day. These workers provided not only HCQ but also health education, handed out masks, explained their use and why they were important, and tried to calm the fears surrounding the disease.

Dharavi was a community effort not a police action.

If the doctors determined someone to be possibly infected, officials sealed off the patient’s house as well as the entire block. Volunteer “*COVID warriors*” ensured these containment areas received

free supplies of essential groceries and medicine. Infected patients that needed more advanced treatment were moved to the free quarantine/treatment centers.

Unlike the situation in the majority of U.S. hospitals, COVID patients in India were being hospitalized at separate special treatment centers. The use of “Alternate Care Sites” was outlined in the U.S. National Pandemic Plan. However, it was largely ignored by the local authorities in the United States. The net result was the overload of many of the nation’s hospitals with highly infectious patients and in some areas, a halt to the normal medical services for non-COVID cases.

By the second week of April, Indian officials and private doctors had screened 47,500 people in the high-risk zones of Dharavi. Of those who reported symptoms, 20% were found to have contracted COVID-19 on later testing. In all, some 9,500 people in the slum would be placed under quarantine.

By 20 April 2020, the case-loads had dropped, the door-to-door screenings could be stopped, and the 350 private doctors were given support to reopen their community clinics. The panic over the disease had been calmed and the people were now individually fighting back. They felt they were part of the solution and were more comfortable about visiting doctors to be examined if they developed symptoms.

Of the 2,450 health workers on HCQ prophylaxis that were operating daily within this highly contaminated environment, only 30 would eventually test positive for COVID-19 and most with only minor infections.

Dharavi’s COVID-19 infection rate dropped drastically from April through June. By July 9, new infections were almost reaching zero. The operational tenet was examine, treat with HCQ and zinc, quarantine, contact trace, quarantine, treat, educate, and repeat. These were the keys to preventing a humanitarian disaster.

By mid-July, India had reported 27,497 COVID-19 deaths nationally. With a population of 1.3 billion, that is an extremely low total death figure of **19 per million** (0.002 percent). This was dramatically lower than that of some European countries like Spain, with **607 deaths per million**, and **France, with 461**. However, this was nothing compared to the death rate in the United States where the 139,659 deaths reported at the same time by the CDC on 19 July 2020, represented a total of **2,291 per million**. That was a U.S. rate roughly 20 times that of India. Why?

A major reason for the high US death rate was because of the unexplainable policy being promoted by Dr. Anthony Fauci at the NIH together with Dr. Janet Woodcock and Dr. Stephen Hahn at the FDA. This ‘strategy’ was to keep early infected patients quarantined at home and without treatment until they became so ill that they had to be admitted to a hospital. Once in hospital, they would be given HCQ which would not work well, because the patients were now too ill.

The success of HCQ in Dharavi were largely ignored by both the mainstream international media and the medical journals. However, India would soon join the United States in banning the use of HCQ. With the first wave of the pandemic dying down, on 6 June 2020, the Union Health Ministry dropped HCQ from its Covid-19 treatment protocol.¹⁰⁰

From that time on, history would be changed. The recent medical articles and papers now all state that societal “lockdowns” were responsible for the success in Dharavi, with no mention of HCQ outpatient treatment whatsoever. **In its new nine-page COVID guideline, the Indian Directorate of Health Services made no mention of HCQ which had by then, shown to have a demonstratable effect in COVID-19 infected populations.**

This poor decision was a result of criticism by some of India’s national “experts” who ignored Dharavi’s practical experience and instead followed the US and WHO guidance, and like Dr. Fauci, they incorrectly pointed out the lack of study-based evidence for using HCQ for COVID-19.¹⁰¹

The new Indian government guidelines contradicted the earlier recommendations made by the Indian Council of Medical Research (ICMR). Despite physician protestations to the government, the ICMR guidelines promoting the use of early HCQ for Covid-19, were ignored. HCQ use was now out of favor and India would soon pay the price for this incorrect decision.

Without HCQ, the screening program and quarantine centers would continue, but with a focus on “lockdowns” and identifying infections and isolating them early. It was a flawed concept and like in the US, India’s infection rates would soon skyrocket.

By August 2020, India as a nation, again began to again experience a sudden surge in daily cases as the government began to ease its restrictions to help the economy. On 30 August, India recorded 75,928 new infections in a single day (a new world record). The total national Indian deaths at that time were 64,547 **with 960 new deaths recorded that day** out of a population of 1.2 billion. On the same date **in the U.S., the COVID new deaths that day were 1,184** out of a population of only 320 million.

By September 8, 2020, the total daily COVID deaths in India had jumped to more than 1,201 a day with 97,570 new daily infections and 77,472 total accumulated deaths. With HCQ use now blocked by the government, India’s COVID cases would rapidly build to a peak in mid-September, with 97,894 new cases that day, after which the infection rates would drop on their own to 8,653 by 1 February 2021.

Unfortunately, without an early outpatient treatment, by the end of February 2021, India had already started on another wave of national infections.

Without the use of HCQ, India would be relegated to using its system for rapid case detection and quarantine to stop any exponential increase in cases. It would be unsuccessful in this effort and by 28 April 2021, India’s daily infections had exponentially increased to 379,308 new infections a day. The

second wave would peak on 6 May 2021 with an almost unimaginable 414,188 new daily cases nationwide.

The process of lockdown, rapid case identification, and quarantine without HCQ treatment, had failed to control the catastrophic national second wave of infections in India. However, when the earlier success of COVID control in Dharavi could no longer be ignored, several peer-reviewed papers appeared in 2021 touting the effectiveness of lockdowns, early case detection, quarantine, and case contact tracing.

In the peer-reviewed papers on India's outbreak placed on the NIH general access PubMed search engine, hydroxychloroquine use is never mentioned.¹⁰²

Following its ban on HCQ, any suggestion of the effectiveness of HCQ use in Dharavi was minimized by the mainstream media and medical journals, and instead attributed solely to the ineffective measures which had failed to sufficiently contain the massive second wave of COVID-19 infections in both India and the United States.¹⁰³

We find it incredible that there has been such a systematic campaign by the media and certain scientific elites against the use of early outpatient HCQ, in spite of the preponderance of scientific evidence indicating its safety and efficacy in both therapeutic and prophylactic applications. There is blood on many hands for suppressing a cheap and effective medicine that is overwhelmingly beneficial and safe to use.

This was best demonstrated with the introduction of Ivermectin in India after HCQ had been effectively banned.

The Uttar Pradesh is an area in India that contains 241 million people. The United States population is 320 million people. Therefore, Uttar Pradesh can be roughly compared to the United States, with respect to its population size. As the second wave of the Indian pandemic continued, and the ban on HCQ remained in effect, Uttar Pradesh added the drug Ivermectin to its COVID-19 outpatient management.

In a response that was maintained, the population went from roughly 35,000 cases and 350 deaths per day to nearly ZERO within weeks of adding Ivermectin to their pandemic response. Thus, emphasizing the need for early outpatient treatment. By 5 August 2021, Uttar Pradesh, using Ivermectin, had a total of only 26 new cases and exactly THREE deaths.

Uttar Pradesh on Ivermectin: Population 240 Million [4.9% vaccinated] August 5, 2021

- COVID Daily Cases: 26
- COVID Daily Deaths: 3

The United States with no Outpatient Treatment: Population 320 Million (50.5% vaccinated) August 5, 2021

- COVID Daily Cases: 127,108
- COVID Daily Deaths: 574

In contrast to Uttar Pradesh, the Tamil Nadu is an area of India that rejected the use of Ivermectin and instead followed the **Fauci-Hahn US doctrine** of no outpatient treatment for COVID-19, and then using Remdesivir once a patient needed hospitalization.¹⁰⁵ As expected, Tamil Nadu would soon lead India in the number of daily COVID-19 cases.¹⁰⁶

Tamil Nadu continues to suffer for its choice to reject Ivermectin. As a result, the Delta variant of the COVID-19 virus continued to ravage its citizens while it was virtually wiped out inside the Ivermectin-using states.¹⁰⁶ Likewise, in the United States, without acknowledgement of the role of HCQ and Ivermectin, both the vaccinated and unvaccinated continue to spread the Delta variant of the COVID-19 virus like wildfire.

The American FDA continues to effectively try to ban any use of outpatient HCQ or Ivermectin for COVID-19 outside of a clinical trial.¹⁰⁷ In spite of numerous doctor's coalitions to promote outpatient treatment and seminars to educate hospital doctors, and court rulings to force hospitals to allow Ivermectin for select patients, the biased mainstream media continues to minimize *any* inexpensive outpatient treatment. Wikipedia continues to censor or defame outpatient treatments for COVID-19 as well as physicians such as Dr. Peter McCullough and others, who have been instrumental in attempting to return both HCQ and Ivermectin to the outpatient clinical management of COVID-19.

A reader of any Wikipedia article should always read the "talk" section to go behind the scenes and understand what the editors DO NOT want you to read.

The Case of Brazil – An HCQ Civil War

Brazil represents a good analogy of the situation in the United States. It was the second country in the world after the U.S. to register more than 50,000 deaths from Covid-19. Like the U.S., the nation was politically fractionated with most of the 26 states in the country opposing the use of HCQ simply because the President of Brazil and his advisors favored its use.

On 15 May 2020, the government decreed the authorized use of HCQ for all patients (including outpatient cases) and 10 days later, the states that did permit the use of the drug began to see a plateau in their daily COVID deaths despite an ever-increasing number of national cases. This area-specific drop in fatalities appeared to be real and not an artifact. In contrast, the Brazilian states that opposed the use of HCQ showed drastically increasing case numbers, hospitalizations, and increasing deaths. The states where political strife made it difficult to gain acceptance of HCQ for pandemic control were serving as an inadvertent Control Group.

The northern state of Pará, Brazil, accepted HCQ as an early outpatient treatment for COVID-19 and it was the first state to reverse direction. The numbers of newly identified COVID-19 cases in Pará had been *increasing daily* from April 1 through to May 28. Doctors had petitioned heavily

for HCQ to be used in all Brazilian States and over 100 physicians met with the Brazilian President to plead for an early use outpatient option for HCQ plus azithromycin and zinc supplements.

On April 6, the public hospital network of Pará purchased 75,000 doses of Azithromycin and 90,000 doses of HCQ and it began distributing this to the region over the next few weeks.

Within a few weeks after the medications began their distribution, the increase in mortality numbers in Pará began to stutter. (Figure 8). Brazil, outside of Pará, was not systematically using HCQ and azithromycin over this time period and these daily COVID-19 deaths continued to increase.

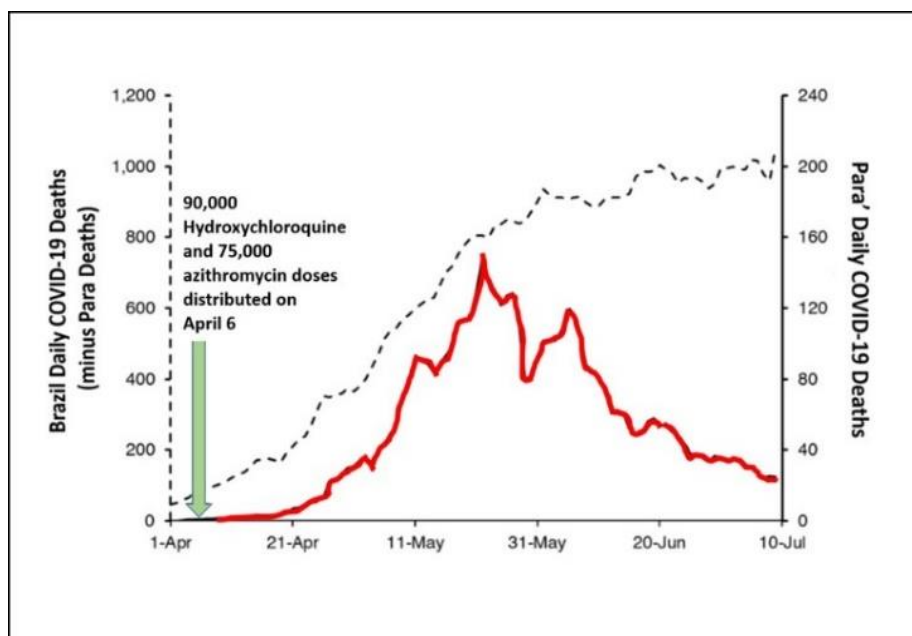


Figure 8. Pará and *Brazil-minus-Pará* Daily COVID-19 Deaths, April 1 - July 9, 2020. (Solid line, daily COVID-19 deaths in Pará). (Dashed line, daily COVID-19 deaths in rest of Brazil).

Source: Ministério da Saúde Brasil. July 2020.¹⁰⁴

Aggressive drug treatment began and within two weeks, the number of hospitalized cases had started to stutter. This time interval for effect had also been observed in France and Switzerland during their own HCQ start-stop experiences.

The reduction in hospital admissions demonstrated that in regions such as Pará where there was a dearth of testing, the use of HCQ based upon a physician's own clinical judgement for a provisional COVID diagnosis, was safe and effective.

The effect was most evident in general hospital admissions and Intensive Care Unit bed requirements (Figure 9). The Hapvida HMO hospitals in the state had also acquired the medications and started using them during the same period. Local doctors would write

prescriptions and Unimed Belem used a drive-through kiosk strategy to distribute green colored, sealed, *protocol pill packs for use in the early phase of COVID*. The instructions for use were printed on the outside. They also distributed about 10,000 packets for the prophylaxis of high-risk health care workers in Belem.



Figure 9. Unimed Belem Hospital. Total Hospital Admissions, ICU Admissions and General Bed Admissions during aggressive HCQ use in ambulatory outpatients in the regional community.¹⁰⁵

The case of Pará offers a compelling, large-scale demonstration of the community efficacy of HCQ to control a pandemic COVID-19 outbreak. This was the same doctrine used in parts of the urban slums of India and it was the emergency doctrine that had been planned and started in the United States until it was inhibited by the FDA.

Soon after the Pará results, over 10,000 Brazilian doctors began using an HCQ “treatment cocktail” without state restrictions. This early treatment program was showing effects in Manaus, and other areas with respect to reductions in pandemic mortality and hospitalizations, although there was still some reluctance by some doctors to use HCQ.

However, like in the US and India, the incorrect decisions of the US FDA and the WHO led to the abandonment of HCQ for both prophylaxis and early treatment in Brazil with the resulting eventual overwhelming of hospitals and the collapse of area health care systems.

*Apparently what happens with the FDA and Hydroxychloroquine Hysteria in the media in the United States, does not stay in the United States.
The FDA’s response and the biased U.S. media overreaction to flawed studies have combined to kill hundreds of thousands of COVID patients on a global*

basis while preventing COVID outpatients in the U.S. from having access to HCQ. These are the patients who needed it the most.

Curiously, again it must be remembered that the FDA's warning did not affect the FDA-approved uses for malaria, lupus, and rheumatoid arthritis where periodic doses of HCQ were often given to patients with these disorders in much larger and longer doses than that recommended for COVID treatment applications.

VII. Concluding Thoughts

To date, official US figures indicate that over 720,000 Americans have died of COVID-19, although these figures were probably exaggerated by the CDC during the early pandemic and now intentionally undercounted by the FDA once its ineffective vaccine program was underway.

In addition, over 30 million Americans have been driven to the unemployment lines, and the American economy has endured trillions of dollars of crippling damages.

The question examined in this report is whether HCQ may be one of the most important and low-cost life-saving prophylactic and therapeutic medicines in our arsenal to save American lives and help control the spread of both current and new evolving strains of the COVID-19 virus. The evidence, which only continues to grow, points clearly in the direction of "yes."

Based on the extant research, it is a near certainty that if hydroxychloroquine had been aggressively used as a prophylactic and in early treatment use in an outpatient setting, as many as half or more of these victims of the novel SARS-CoV-2 coronavirus from Wuhan, China would be alive today.

Despite the hard data, hard science and the facts available, too many scientific elites, too much of the mainstream media, and certain segments of the medical profession continue to ignore the overwhelming positive data of the effectiveness of early HCQ use in COVID-19. As a result, Hydroxy Hysteria continues to suppress the life-saving use of HCQ.

A particularly imprudent and immoral action by the American Medical Association underscores this problem. In March of 2020, the AMA issued a statement opposing the "off label" use of HCQ as an early treatment for COVID-19. On December 15, 2020, under the crushing weight of new evidence, the AMA published a memo to its delegates seeking support for a reversal of this position based on the overwhelming amount of evidence in support of HCQ's use.

Despite this request to the delegates, the AMA delegates still refused to reverse the position.¹¹⁰

To this day, and to its great shame, the AMA remains opposed to early treatment use of HCQ in outpatient settings despite ample empirical evidence on the other side of that opinion.

Both authors of this report served on the front lines of the Trump Administration's efforts to combat the pandemic. We see in the conduct of the AMA yet another instance of bad politics and partisanship interfering with good science. Clearly, the AMA delegates do not want to acknowledge they were wrong in their initial assessment of HCQ.

This immoral and unethical stance leaves the AMA and much of the American medical establishment with the same kind of blood on their hands that we have found with Tony Fauci at the NIH, Stephen Hahn MD and Janet Woodcock MD at the FDA, and far too many biased journalists at CNN and in the corporate media.

Given the weight of evidence in support of HCQ and given the likelihood of a persistent battle with mutations of the COVID-19 virus, vaccines notwithstanding, it is critical that HCQ be made readily available to hospitals for early use and private physicians for outpatient use.

Perhaps this report will be useful in bringing attention to the lives that may now be at risk because the debate over HCQ has become a partisan, rather than a purely medical, issue. To this point, this report offers this concluding thought from Dr. Harvey Risch of Yale University. He reflects on the need to balance risks during a pandemic emergency.

We have a [HCQ] solution, imperfect, to attempt to deal with the disease. We have to let physicians employing good clinical judgment use it and informed patients choose it. There is a small chance that it may not work. But the urgency demands that we at least start to take that risk and evaluate what happens, and if our situation does not improve we can stop it, but we will know that we did everything that we could instead of sitting by and letting hundreds of thousands die because we did not have the courage to act according to our rational calculations.¹¹¹

References

¹ U.S Department of Health and Human Services, Center for Disease Control and Prevention, "The History of Malaria, an Ancient Disease," 14 November 2018. <https://www.cdc.gov/malaria/about/history/#chloroquine>

² As noted in *Nature*, "Hydroxychloroquine sulfate, a derivative of CQ, was first synthesized in 1946 by introducing a hydroxyl group into chloroquine and was demonstrated to be much less (~40%) toxic than CQ in animals." For full article, see, Liu, Jia et al., "Hydroxychloroquine, a less toxic derivative of chloroquine, is effective in inhibiting SARS-CoV-2 infection in vitro," *Nature*, 18 March 2020. <https://www.nature.com/articles/s41421-020-0156-0>

³ Eugen Alexander Shippey, MD, Vanya D. Wagler, DO, FACP, FACR and Angelique N. Collamer, MD, FACP, FACR, "Hydroxychloroquine: An old drug with new relevance," *Cleveland Clinic Journal of Medicine*, June 2018, 85 (6) 459-467. DOI: <https://doi.org/10.3949/ccjm.85a.17034>.

A full review of the medicine's side effects may be accessed at <http://products.sanofi.ca/en/plaquenil.pdf>

⁴ According to the FDA, it is contraindicated in the presence of retinal or visual field changes attributable to any 4-aminoquinoline compound, in patients with known hypersensitivity to 4- aminoquinoline compounds, and for long-term therapy in children. As an adverse reaction, the FDA also notes that "cardiomyopathy has been rarely reported with high daily dosages of HCQ." "Dermatologic reactions ... may occur and, therefore, proper care should be exercised when it is administered to any patient receiving a drug with a significant tendency to produce dermatitis. For more information, see, U.S. Department of Health and Human Services, Food and Drug Administration, "Plaquenil ® Hydroxychloroquine Sulfate, U.S.P.," 2007. https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/009768s0411bl.pdf.

⁵ World Health Organization Model List of Essential Medicines, 21st List, 2019. Geneva: World Health Organization; 2019. <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1>

⁶ U.S. Department of Health and Human Services, Food and Drug Administration, “Plaquenil ® Hydroxychloroquine Sulfate, U.S.P.,” 2007. https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/009768s0411bl.pdf.

⁷ U.S. Department of Health and Human Services, Food and Drug Administration, “Fact Sheet for Health care Provides Emergency Use Authorization (EUA) of Hydroxychloroquine Sulfate Supplied from the Strategic National Stockpile for Treatment of COVID-19 in Certain Hospitalized Patients,” 27 April 2020. <https://www.fda.gov/media/136537/download>

⁸ The Mayo Clinic, “Hydroxychloroquine (Oral Route), 1 May 2020. <https://www.mayoclinic.org/drugs-supplements/HCO-oral-route/proper-use/drg-20064216>

⁹ U.S. Department of Health and Human Services, Center for Disease Control and Prevention, “Medicines for the Prevention of Malaria while Traveling: Hydroxychloroquine (Plaquenil),” <https://www.cdc.gov/malaria/resources/pdf/fsp/drugs/Hydroxychloroquine.pdf>.

¹⁰ “Patient Fact Sheet: Hydroxychloroquine (Plaquenil),” *Rheumatology.Org*, <https://www.rheumatology.org/Portals/0/Files/Hydroxychloroquine-Plaquenil-Fact-Sheet.pdf>

¹¹ Arapovic, Benis, “The 50 most dangerous medicinal drugs,” *NWI Times*, 29 September 2017. https://www.nwitimes.com/niche/get-healthy/the-50-most-dangerous-medicinal-drugs/collection_a5904d4d-6158-5ac8-82a2-c1020f217ed5.html

¹² Listed prices for Hydroxychloroquine range from \$0.50 to \$0.60 per tablet. *See*, “Hydroxychloroquine (Plaquenil)-Overview,” *PushHealth*, <https://www.pushhealth.com/drugs/HCO>. Additionally, Rowland, Darrel, “Fact check: Price didn’t drive promotion of remdesivir over Hydroxychloroquine,” *U.S.A Today*, 9 May 2020. <https://www.usatoday.com/story/news/factcheck/2020/05/09/fact-check-price-didnt-push-remdesivir-over-HCO/3094440001/>

¹³ Gilead is yet to put a definitive price on Remdesivir. Estimates range in the low ball park of \$10 all the way up to \$4,450 per patient. It is generally agreed upon that prices can be predicted in the middle range of \$1,000 to \$2,000 per patient. For more information, *see*, Bulik, Beth Snyder, “Can the price be right? With the world watching, Gilead faces a no-win decision on remdesivir,” *FiercePharma*, 7 May 2020. <https://www.fiercepharma.com/marketing/waiting-for-gilead-how-much-will-drugmaker-charge-for-covid-19-treatment>. Also, Lupkin, Sydney, “Putting a Price on COVID-19 Treatment Remdesivir,” *NPR*, 8 May 2020. <https://www.npr.org/sections/health-shots/2020/05/08/851632704/putting-a-price-on-covid-19-treatment-remdesivir>

¹⁴ Lupkin, Sydney, “Putting a Price on COVID-19 Treatment Remdesivir,” *NPR*, 8 May 2020. <https://www.npr.org/sections/health-shots/2020/05/08/851632704/putting-a-price-on-covid-19-treatment-remdesivir>

¹⁵ A. Hill J. Wang; J. Levi *Journal of Virus Eradication* Volume 6, Issue 2, April 2020, Pages 61-69 [Minimum costs to manufacture new treatments for COVID-19 - ScienceDirect](https://www.sciencedirect.com/journal/journal-of-virus-eradication)

¹⁶ [Coronavirus drug remdesivir to cost \\$3,120 per patient with private insurance, irking critics - ABC News \(go.com\)](https://www.abcnews.com/news/50120200/coronavirus-drug-remdesivir-cost-3120-per-patient-private-insurance-irking-critics)

¹⁷ Vincent, Martin J et al. “Chloroquine is a potent inhibitor of SARS coronavirus infection and spread.” *Virology journal* vol. 2 69. 22 Aug. 2005, doi:10.1186/1743-422X-2-69

¹⁸ According to the Mayo clinic, the standard dosage for HCQ as a preventative prophylaxis is “400 mg once a week ... starting 2 weeks before traveling to an area where malaria occurs.” *See*, The Mayo Clinic, “Hydroxychloroquine (Oral Route), 1 May 2020. <https://www.mayoclinic.org/drugs-supplements/HCO-oral-route/proper-use/drg-20064216>. Presumably, with such preventative use, a person will have his or her best chance of defending against the virus because both the blocking and alkalinity effects are in full force.

¹⁹ Boulware, David R., et al., “A Randomized Trial of Hydroxychloroquine as Postexposure Prophylaxis for Covid-19,” *New England Journal of Medicine*, 3 June 2020. DOI: 10.1056/NEJMoa2016638

²⁰ “Trump said he took Hydroxychloroquine to prevent coronavirus, but new study shows that doesn’t work,” *CNN*, 3 June 2020. https://lite.cnn.com/en/article/h_c0ce4ada9c687dc86d55121f30d7bb4a

²¹ “Malaria Drug Promoted by Trump Did Not Prevent Covid Infections, Study Finds,” *New York Times*, 3 June 2020. <https://www.nytimes.com/2020/06/03/health/HCO-coronavirus-trump.html>

²² Joseph A. Ladapo, MD, PhD¹ ; John E. McKinnon, MD, MSc² ; Peter A. McCullough, MD, MPH³ ; Harvey A. Risch, MD, PhD Randomized Controlled Trials of Early Ambulatory Hydroxychloroquine in the Prevention of COVID-19 Infection, Hospitalization, and Death: Meta-Analysis September 30, 2020 medRxiv doi: <https://doi.org/10.1101/2020.09.30.20204693>

²³ A. Pareek, et.al., Hydroxychloroquine for prophylaxis in COVID-19: Need to revisit dosing regimen. *Indian Journal of Medical Research*, 2020; Volume 152. Issue1, Page 130-132. <https://www.ijmr.org.in/article.asp?issn=0971-5916;year=2020;volume=152;issue=1;spage=130;epage=132;aulast=Pareek>

²⁴ A. Pareek, et.al., Hydroxychloroquine for prophylaxis in COVID-19: Need to revisit dosing regimen. *Indian Journal of Medical Research*, 2020; Volume 152. Issue1, Page 130-132. <https://www.ijmr.org.in/article.asp?issn=0971-5916;year=2020;volume=152;issue=1;spage=130;epage=132;aulast=Pareek>

²⁵ A. Pareek, et.al., Hydroxychloroquine for prophylaxis in COVID-19: Need to revisit dosing regimen. *Indian Journal of Medical Research*, 2020; Volume 152. Issue1, Page 130-132. <https://www.ijmr.org.in/article.asp?issn=0971-5916;year=2020;volume=152;issue=1;spage=130;epage=132;aulast=Pareek>

²⁶ Badyal Dinesh, et.al., Hydroxychloroquine for SARS CoV2 Prophylaxis in Healthcare Workers A Multicentric Cohort Study Assessing Effectiveness and Safety. *Journal of the Association of Physicians in India*, volume 69. June 2021. [Hydroxychloroquine for SARS CoV2 Prophylaxis in Healthcare Workers – A Multicentric Cohort Study Assessing Effectiveness and Safety \(japi.org\)](https://www.japi.org)

²⁷ [Hydroxychloroquine for SARS CoV2 Prophylaxis in Healthcare Workers – A Multicentric Cohort Study Assessing Effectiveness and Safety \(japi.org\)](https://www.japi.org)

²⁸ <https://www.reviewofophthalmology.com/article/how-susceptible-is-the-conjunctiva-to-covid19>

²⁹ George, Allison, “Cytokine storm: An overreaction of the body’s immune system,” *New Scientist*, <https://www.newscientist.com/term/cytokine-storm/#ixzz6NTtPEMjf>. For additional information see, Goodman, Brenda, “Cytokine Storms May Be Fueling Some COVID Deaths,” *WebMD*, 17 April 2020.

<https://www.webmd.com/lung/news/20200417/cytokine-storms-may-be-fueling-some-covid-deaths/>. See also, Shaw, Gina, “COVID-19 Brings Cytokine Storm,” *Infectious Disease Special Edition*, 21 April 2020. <https://www.idse.net/Covid-19/Article/03-20/COVID-19-Brings-Cytokine-Storm/58061>.

³⁰ COVID-19 is well-documented to cause cardiac complications. Myocarditis, or inflammation of the heart, is known to cause EKG abnormalities. This includes fatal cardiac arrhythmia, known as torsades de pointes. The risk for this effect is magnified in patients who are critically ill in the intensive care unit (ICU).

These facts make it difficult to sort out any negative cardiac effects that might be associated with HCQ given to late phase COVID patients without a cardiac biopsy.

³¹ McCullough PA., et.al. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. *Am J Med*. 2021 Jan;134(1):16-22. [Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 \(COVID-19\) Infection - PubMed \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov/)

³² M. Wang, et al. LETTER TO THE EDITOR: Cell Research, “Remdesivir and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro,” *Cell Research* (2020) 0:1–3; <https://doi.org/10.1038/s41422-020-0282-0>

³³ Gautret P, et al. “Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial,” *Int J Antimicrob Agents*. 2020 Mar 20:105949. doi: [10.1016/j.ijantimicag.2020.105949](https://doi.org/10.1016/j.ijantimicag.2020.105949)

³⁴ In this study, a rapid fall of nasopharyngeal viral load tested by qPCR was noted, with virus cultures from patient respiratory samples turning negative in 97.5% patients at Day 5. This allowed patients to rapidly be discharged from highly contagious wards with a mean length of stay of five days. The viral load was measured by cell culture, not RT-PCR. See, Gautret P., et al., “Clinical and microbiological effect of a combination of Hydroxychloroquine and

azithromycin in 80 COVID-19 patients with at least a six-day follow up: A pilot observational study,” *Travel Medicine and Infectious Disease*, 11 April 2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7151271/pdf/main.pdf>

³⁵ Million, Matthieu et al. “Early treatment of COVID-19 patients with HCQ and azithromycin: A retrospective analysis of 1061 cases in Marseille, France.” *Travel medicine and infectious disease*, 101738. 5 May. 2020, doi:10.1016/j.tmaid.2020.101738

³⁶ Zhang Z, Hu J, Chen Z, Efficacy of hydroxychloroquine in patients with COVID-19: results of a randomized clinical trial. Europe PMC. <https://europepmc.org/article/PPR/PPR130594>

³⁷ Yu B, Li C, Chen P, et al. Low dose of hydroxychloroquine reduces fatality of critically ill patients with COVID-19 [published correction appears in *Sci China Life Sci.* 2020 Jun 18;:]. *Sci China Life Sci.* 2020;63(10):1515-1521. doi:10.1007/s11427-020-1732-2 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7228868/>

³⁸ Esper, Rodrigo Barbosa, da Silva, Rafael Souza, et al. “Empirical treatment with Hydroxychloroquine and azithromycin for suspected cases of COVID-19 followed-up by telemedicine,” *Pgibertie*, 15 April 2020. <https://pgibertie.files.wordpress.com/2020/04/2020.04.15-journal-manuscript-final.pdf>

³⁹ Covid Analysis, Oct 22, 2021 <https://hcqmeta.com/>

⁴⁰ Covid Analysis, Oct 22, 2021 <https://hcqmeta.com/>

⁴¹ Mayla Gabriela Silva Borba et al. “Chloroquine diphosphate in two different dosages as adjunctive therapy of hospitalized patients with severe respiratory syndrome in the context of nCoronavirus (SARS-CoV-2) infection: Preliminary safety results of a randomized, double-blinded, phase IIb clinical trial,” *medRxiv*, 16 April 2020. <https://www.medrxiv.org/content/10.1101/2020.04.07.20056424v2> FATAL BRAZIL STUDY never peer-reviewed

⁴² Mayla Gabriela Silva Borba et al. “Chloroquine diphosphate in two different dosages as adjunctive therapy of hospitalized patients with severe respiratory syndrome in the context of nCoronavirus (SARS-CoV-2) infection: Preliminary safety results of a randomized, double-blinded, phase IIb clinical trial,” *medRxiv*, 16 April 2020. <https://www.medrxiv.org/content/10.1101/2020.04.07.20056424v2> FATAL BRAZIL STUDY never peer-reviewed

⁴³ Thomas, Katie and Knvul Sheikh, “Small Chloroquine Study Halted Over Risk of Fatal Heart Complications,” *New York Times*, 12 April 2020. <https://www.nytimes.com/2020/04/12/health/chloroquine-coronavirus-trump.html>

⁴⁴ Glenza, Jessica, “Brazilian chloroquine study halted after high dose proved lethal for some patients,” *The Guardian*, 24 April 2020. <https://www.theguardian.com/world/2020/apr/24/chloroquine-study-coronavirus-brazil>

⁴⁵ Howard, Jacqueline and Elizabeth Cohen, “Heart risk concerns mount around use of chloroquine and Hydroxychloroquine for Covid-19 treatment,” *CNN*, 14 April 2020. <https://www.cnn.com/2020/04/13/health/chloroquine-risks-coronavirus-treatment-trials-study/index.html>

⁴⁶ Olorunnipa, Toluse, Ariana Eunjung Cha and Lauria McGinley, “Drug promoted by Trump as coronavirus ‘game changer’ increasingly linked to deaths,” *The Washington Post*, 15 May 2020. https://www.washingtonpost.com/politics/drug-promoted-by-trump-as-coronavirus-game-changer-increasingly-linked-to-deaths/2020/05/15/85d024fe-96bd-11ea-9f5e-56d8239bf9ad_story.html

⁴⁷ Magagnoli, Joseph, et al., “Outcomes of Hydroxychloroquine usage in United States veterans hospitalized with Covid-19,” *MedRxiv*, 23 April 2020. <https://www.medrxiv.org/content/10.1101/2020.04.16.20065920v2> FATAL VA STUDY NEVER PUBLISHED

⁴⁸ Joseph Magagnoli et al., “Outcomes of Hydroxychloroquine Usage in United States Veterans Hospitalized with Covid-19,” 2020, <https://doi.org/10.1101/2020.04.16.20065920>.

⁴⁹ Cohen, Elizabeth and Dr. Minali Nigman, “Study finds no benefit, higher death rates in patients taking Hydroxychloroquine for Covid-19,” *CNN*, 21 April 2020. <https://www.cnn.com/2020/04/21/health/HCQ-veterans-study/index.html>

⁵⁰ Mehra, Mandeep, Frank Ruschitzka, Amit Patel, “Retraction—Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis,” *The Lancet*, 5 June 2020. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31324-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31324-6/fulltext)

-
- ⁵¹ Mandeep R Mehra et al., “Hydroxychloroquine or Chloroquine with or without a Macrolide for Treatment of COVID-19: a Multinational Registry Analysis,” *The Lancet* (Elsevier, May 22, 2020), <https://www.sciencedirect.com/science/article/pii/S0140673620311806?via=ihub>
- ⁵² Gumbrecht, Jamie and Elizabeth Cohen, “Large Study Finds Drug Trump Touted for Covid-19 Is Linked to Greater Risk of Death and Heart Arrhythmia,” *CNN*, May 22, 2020. <https://www.cnn.com/2020/05/22/health/HCO-coronavirus-lancet-study/index.html>
- ⁵³ Gumbrecht, Jamie and Elizabeth Cohen, “Large Study Finds Drug Trump Touted for Covid-19 Is Linked to Greater Risk of Death and Heart Arrhythmia,” *CNN*, May 22, 2020. <https://www.cnn.com/2020/05/22/health/HCO-coronavirus-lancet-study/index.html>
- ⁵⁴ Dzhanova, Yelena, “WHO Pauses Trial of Hydroxychloroquine as Coronavirus Treatment amid Safety Concerns,” *CNBC*, May 25, 2020. <https://www.cnbc.com/2020/05/25/coronavirus-whos-solidarity-trial-is-pausing-tests-for-HCO-amid-safety-concerns.html>
- ⁵⁵ Ledsom, Alex, “France Bans Hydroxychloroquine To Treat Covid-19,” *Forbes*, May 27, 2020, <https://www.forbes.com/sites/alexledsom/2020/05/27/france-bans-HCO-to-treat-covid-19/#6353500721ab>
- ⁵⁶ Gumbrecht, Jamie and Maggie Fox, “Two coronavirus studies retracted after questions emerge about data,” *CNN*, 4 June 2020. <https://www.cnn.com/2020/06/04/health/retraction-coronavirus-studies-lancet-nejm/index.html>
- ⁵⁷ Wagner, John and Derek Hawkins, “Lancet Editorial Blasts Trump's 'Inconsistent and Incoherent' Coronavirus Response,” *The Washington Post*, May 15, 2020. <https://www.washingtonpost.com/health/2020/05/15/lancet-editorial-trump-administration-coronavirus-response/>
- ⁵⁸ Steerpike, “Lancet Editor's Chinese Propaganda,” *The Spectator*, May 2, 2020. <https://www.spectator.co.uk/article/lancet-editor-s-chinese-propaganda>
- ⁵⁹ Zeng, Yingchun, and Yan Zhen. “RETRACTED: Chinese Medical Staff Request International ...” *The Lancet*, 24 February 2020. [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(20\)30065-6/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30065-6/fulltext)
- ⁶⁰ LinkedIn Profile of Yanyan Lu as of 4 June 2020. <https://cn.linkedin.com/in/yanyanlu>
- ⁶¹ EBioMedicine, *the Editor team*, 4 June 2020. <https://www.thelancet.com/ebiom/editorial-team>
- ⁶² Henry Ford Study <https://pubmed.ncbi.nlm.nih.gov/32623082/>
- ⁶³ [NY study finds hydroxychloroquine may have saved COVID-19 patients' lives - ThinkPol](#)
- ⁶⁴ This Spanish study was a retrospective analysis involving 4035 hospitalized patients. It showed reduced mortality with HCQ (data is in the supplementary appendix). (Risk of death, 61.9% lower, RR 0.38, $p < 0.001$, treatment 681 of 2618 (26.0%). Berenguer et al., Characteristics and predictors of death among 4035 consecutively hospitalized patients with COVID-19 in Spain. *Clinical Microbiology and Infection*, 2020 Nov;26(11):1525-1536. doi: 10.1016/j.cmi.2020.07.024. Epub 2020 Aug 4 doi:10.1016/j.cmi.2020.07.024 <https://pubmed.ncbi.nlm.nih.gov/32758659/>
- ⁶⁵ Tersalvi, Gregorio et al. “Elevated Troponin in Patients With Coronavirus Disease 2019: Possible Mechanisms.” *Journal of cardiac failure* vol. 26,6 (2020): 470-475. doi:10.1016/j.cardfail.2020.04.009
- ⁶⁶ Lindner D, Fitzek A, Bräuninger H, et al. (2020) Association of cardiac infection with SARS-CoV-2 in confirmed COVID-19 autopsy cases. *JAMA Cardiol*. Published online July 27, 2020. doi:10.1001/jamacardio.2020.3551
- ⁶⁷ Puntmann VO, Carerj ML, Wieters I, et al. Outcomes of Cardiovascular Magnetic Resonance Imaging in Patients Recently Recovered From Coronavirus Disease 2019 (COVID-19). *JAMA Cardiol*. 2020;5(11):1265–1273. doi:10.1001/jamacardio.2020.3557
- ⁶⁸ Thum, Thomas. “SARS-CoV-2 receptor ACE2 expression in the human heart: cause of a post-pandemic wave of heart failure?.” *Eur Heart J*. 2020 May 14; **41(19)**: 1807–1809. Published online 2020 May 8. vol. 41,19 (2020): 1807-1809. <https://academic.oup.com/eurheartj/article/41/19/1807/5834515>

-
- ⁶⁹ A. Bailey, L.Greenberg, SARS-CoV-2 Infects Human Engineered Heart Tissues and Models COVID-19 Myocarditis. *JACC: Basic to Translational Science*. 26 February 2021. <https://www.sciencedirect.com/science/article/pii/S2452302X21000127?via%3Dihub>
- ⁷⁰ U.S. Department of Health and Human Services, Food and Drug Administration, “Coronavirus (COVID-10) Update: FDA Reiterates Importance of Close Patient Supervision for ‘Off-Label’ Use of Antimalarial Drugs to Mitigate Known Risks, Including Heart Rhythm Problems,” 24 April 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-reiterates-importance-close-patient-supervision-label-use>
- ⁷¹ The White House Office of Trade and Manufacturing had assisted in the distribution of hydroxychloroquine to key distributors. In the wake of the FDA decision, demand for HCQ from the hospitals slowed from a flood to a trickle. According to Dr. William O’Neil, it became very difficult after the FDA decision to recruit patients for his trials.
- ⁷² U.S. Department of Health and Human Services, Food and Drug Administration, “FDA cautions against use of HCQ or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems,” 15 June 2020. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-HCQ-or-chloroquine-covid-19-outside-hospital-setting-or>
- ⁷³ Facher, Lev, “FDA revokes emergency use ruling for Hydroxychloroquine, the drug touted by Trump as a Covid-19 therapy,” *STAT News*, 16 June 2020. <https://www.statnews.com/2020/06/15/fda-revokes-HCQ/>
- ⁷⁴ Hinton, R. M., Chief Scientist. (2020, June 15). Letter Revoking EUA for Chloroquine Phosphate and Hydroxychloroquine Sulfate. Retrieved June 19, 2020, from <https://www.fda.gov/media/138945/download>
- ⁷⁵ COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at <https://www.covid19treatmentguidelines.nih.gov/>. Accessed 19 June 2020.
- ⁷⁶ <https://www1.cbn.com/cbnnews/health/2020/july/covid-doc-says-HCQ-highly-effective-and-fears-are-overblown-now-fda-chief-admits-it-might-help-nbsp>
- ⁷⁷ Hinton, R. M., Chief Scientist. (2020, June 15). Letter Revoking EUA for Chloroquine Phosphate and Hydroxychloroquine Sulfate. Retrieved June 19, 2020, from <https://www.fda.gov/media/138945/download>
- ⁷⁸ Horby, Peter and Martin Landray, “No clinical benefit from use of Hydroxychloroquine in hospitalized patients with COVID-19,” *University of Oxford*, 5 June 2020. <https://www.recoverytrial.net/news/statement-from-the-chief-investigators-of-the-randomised-evaluation-of-covid-19-therapy-recovery-trial-on-HCQ-5-june-2020-no-clinical-benefit-from-use-of-HCQ-in-hospitalised-patients-with-covid-19>
- ⁷⁹ *New England Journal of Medicine*. Published online October 8, 2020. doi:10.1056/NEJMoa2022926
- ⁸⁰ <https://www.medrxiv.org/content/10.1101/2020.07.15.20151852v1.full.pdf>
- ⁸¹ <https://www.dailymotion.com/video/x7vuqmp?playlist=x6v00u>
- ⁸² Hinton, R. M., Chief Scientist. (2020, June 15). Letter Revoking EUA for Chloroquine Phosphate and Hydroxychloroquine Sulfate. Retrieved June 19, 2020, from <https://www.fda.gov/media/138945/download>
- ⁸³ Pareek A, Sharma TS, Mehta RT. Hydroxychloroquine and QT prolongation: reassuring data in approved indications. *Rheumatology Advances in Practice*. 2020 ;4(2):rkaa044. DOI: 10.1093/rap/rkaa044.
- ⁸⁴ <https://doi.org/10.1016/j.jelectrocard.2020.08.008>
- ⁸⁵ Berenguer et al., Characteristics and predictors of death among 4035 consecutively hospitalized patients with COVID-19 in Spain. *Clinical Microbiology and Infection*, 2020 Nov;26(11):1525-1536. doi: 10.1016/j.cmi.2020.07.024. Epub 2020 Aug 4 doi:10.1016/j.cmi.2020.07.024 <https://pubmed.ncbi.nlm.nih.gov/32758659/>
- ⁸⁶ L.Catteau Low-dose hydroxychloroquine therapy and mortality in hospitalized patients with COVID-19: a nationwide observational study of 8075 participants. *Int J Antimicrob Agents*. 2020 Oct; 56(4): 106144. Published

online 2020 Aug 24. doi: 10.1016/j.ijantimicag.2020.106144

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7444610/>

⁸⁷ <https://www1.cbn.com/cbnnews/health/2020/july/covid-doc-says-HCO-highly-effective-and-fears-are-overblown-now-fda-chief-admits-it-might-help-nbsp>

⁸⁸ Doctor Who Was Canceled For Promoting Effective COVID Treatments Sans Vaccines Speaks Out : US : Christianity Daily.

⁸⁹ Doctors face sanctions for prescribing unproven COVID-19 drugs to friends and family, regulators warn. Doctors face sanctions for prescribing unproven COVID-19 drugs to friends and family, regulators warn | CBC News; Pro-Hydroxychloroquine Doctor Stella Immanuel Says 'Lying' Fauci Is Playing With People's Lives (newsweek.com)

⁹⁰ JOINT STATEMENT FROM THE: IOWA BOARD OF PHARMACY IOWA BOARD OF NURSING IOWA DENTAL BOARD IOWA BOARD OF PHYSICIAN ASSISTANTS IOWA BOARD OF MEDICINE new_guidelines_-_hydroxychloroquine_chloroquine_and_azithromycin.pdf (iowa.gov)

⁹¹ Big Pharma "Criminal" Influence On Research Exposed In Secret Recording Of Lancet & NEJM Editors In-Chief [VIDEO] | Europe ([Eng Subs](#)) [Hydroxychloroquine Lancet Study: Former France Health Minister blows the whistle - YouTube](#)

⁹² Autoantibodies against type I IFNs in patients with life-threatening COVID-19.

<https://science.sciencemag.org/content/370/6515/eabd4585>

⁹³ COVID-19 Update: FDA Broadens Emergency Use Authorization for Veklury (remdesivir) to Include All Hospitalized Patients for Treatment of COVID-19 | FDA

⁹⁴ Dyer O. Covid-19: Remdesivir has little or no impact on survival, WHO trial shows. BMJ. 2020;371:m4057. doi:10.1136/bmj.m4057 <https://www.bmj.com/content/371/bmj.m4057>

⁹⁵ FDA Approves First Treatment for COVID-19. October 2020. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19>. Accessed October 25, 2020.

⁹⁶ [Panel Roster | COVID-19 Treatment Guidelines \(nih.gov\)](#)

⁹⁷ [Pandemic Influenza Plan - Update IV \(December 2017\) \(cdc.gov\)](#)

⁹⁸ <https://fcpp.org/2020/11/08/hydroxychloroquine-is-widely-used-around-the-globe/>

⁹⁹ [The 1918 'flu: India's worst pandemic - Gateway House](#)

¹⁰⁰ [Lucianne.com News Forum - What Made Asia's Largest Slum a Success Model for Treating COVID-19?](#)

¹⁰¹ [This Indian slum contained a possible COVID-19 disaster by using hydroxychloroquine - The Palmer Foundation](#)

¹⁰² [Change away from successful treatments due to Big Pharma pressure likely cause of COVID death catastrophe in India - LifeSite \(lifesitenews.com\)](#)

¹⁰³ M. Golechha. COVID-19 Containment in Asia's Largest Urban Slum Dharavi-Mumbai, India: Lessons for Policymakers Globally. J Urban Health. 2020 Dec; 97(6): 796–801

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7437383/>

¹⁰⁴ See [J. Kaushal](#) Asia's largest urban slum-Dharavi: A global model for management of COVID-19 Jan 12, 2021 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7832248/>.

¹⁰⁵ <https://www.thehindu.com/news/national/tamil-nadu/tn-drops-ivermectin-as-covid-19-drug/article34561235.ece>

¹⁰⁶ https://www.thedesertreview.com/opinion/letters_to_editor/tamil-nadu-leads-india-in-new-infections-denies-citizens-ivermectin/article_32634012-ba66-11eb-9211-ab378d521f9a.html

[India's Ivermectin Blackout | Columnists | thedesertreview.com](#)

¹⁰⁷ <https://www.cnn.com/2021/08/05/health/us-coronavirus-thursday/index.html>

¹⁰⁸ https://en.wikipedia.org/wiki/Template:COVID19_pandemic_data/Brazil_medical_cases

¹⁰⁹ https://en.wikipedia.org/wiki/Template:COVID19_pandemic_data/Brazil_medical_cases

¹¹⁰ Resolution: 509 (November 2020) Page 3 of 6 Nov 2020 Special Meeting of the AMA House of Delegates - Handbook Addendum (ama-assn.org) 137 COVID-19: AMA did not change hydroxychloroquine stance | cbs19.tv

¹¹¹ Harvey A Risch, "Early Outpatient Treatment of Symptomatic, High-Risk Covid-19 Patients that Should be Ramped-Up Immediately as Key to the Pandemic Crisis," American Journal of Epidemiology, <https://academic.oup.com/aje/article/189/11/1218/5847586>