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COVID-19 Spike is Caused by Hindering Patients' Access to Hydroxychloroquine-Based Treatment

We have a spike of new COVID-19 cases all over the US. In Texas, the daily number of new cases surged nearly five times. The spike is real; it is accompanied by a larger share of positive tests (fewer tests per case). The spike started on June 16, after FDA revoked its EUA for Hydroxychloroquine (HCQ) and issued a nasty and scientifically illiterate memo on June 15, and NIH added recommendations against HCQ use to its COVID-19 Guidelines.

These papers have no legal effect. The EUA applied only to the supplies from the National Strategic Stockpile. There is plenty of Hydroxychloroquine in the retail and wholesale channels. Both Hydroxychloroquine and Azithromycin are approved drugs, dispensed by prescription, with long records of safety. Neither is addictive nor controlled substance. Doctors can prescribe them off-label. The NIH Guidelines are just recommendations.

Nevertheless, on the background of the politization of the COVID-19 treatment based on this drug, that led many doctors to fear or to delay prescribing HCQ-based treatment. The most accepted treatment is **HCQ + AZ (Azithromycin), with or without Zinc, prescribed early**, without a lab test, based on a clinical suspicion of COVID-19. This treatment saves lives of elderly and at-risk patients. Also, it used to keep CoVID-19 at bay by reducing the viral load in the population and keeping the coronavirus reproduction ratio R slightly below 1. After the FDA action, R > 1 again. Soon, we will see increase in the daily deaths' number. Larger viral load also means larger probability of adverse mutations of the coronavirus.

Even non-at-risk adults with COVID-19 symptoms should be encouraged to get such treatment (at home, by telemedicine session and drugs delivery) to reduce the coronavirus transmission and to end the epidemic quickly.

States' Governors can help by issuing orders requiring every physician seeing an adult patient with COVID-19 symptoms to inform him/her about Hydroxychloroquine-based outpatient treatment. If the physician does not offer it, s/he should provide contact information of physicians who do and are available for a tele-meeting within 24 hours.

The Problem

Thousands of physicians successfully cured tens or hundreds of thousands of COVID-19 patients. Hospitals and some private physicians are intimidated by the politization of the treatment and outlandish recommendations by the FDA, blindly followed by the NIH COVID-19 Panel and many State Medical Boards

From the declaration by Jeremy Snavely, 6/22:

> *Multiple members of AAPS have communicated to AAPS their inability to prescribe hydroxychloroquine (HCQ) for a full regimen to treat or prevent COVID-19, including but not limited to physicians in Western Michigan, Georgia, New Jersey, Arizona, and Texas.*
>
> *…*
>
> *Numerous physician members of AAPS, including this "Dr. John Doe," reasonably fear retaliation against them by state medical boards based on Defendants' irrational restrictions on HCQ along with the incorporation of the directive made to state medical boards by the Federation of State Medical Boards.*

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS v FDA et al, 1:20-cv-00493, FEDERAL COURT FOR THE WESTERN DISTRICT OF MICHIGAN.

Background

HCQ or COVID-19 – choose one

All the world uses Hydroxychloroquine (HCQ) or Chloroquine for COVID-19 treatment. Poor countries of Asia and Africa have many times lower mortality from COVID-19 than the US. In the early April, Italy and Spain broke the near exponential growth of cases and deaths and reversed the course of the COVID-19 pandemic by using HCQ. The opposition to HCQ is purely political. President Trump endorsed the drug, based on the substantial information that already existed at that time.

COVID-19 is the disease of countries that do not use Hydroxychloroquine and Chloroquine. Hydroxychloroquine and Chloroquine (CQ) are old anti-malarial drugs. COVID-19 hardly exists in malaria affected countries. The local population does not normally take CQ or HCQ for malaria prophylaxis (unlike Western tourists), but these drugs are common and readily available. Cities in India and Philippines with ten times higher population density than New York, and low medical standards have a small fraction of the COVID-19 deaths that New York experienced. This is because they use CQ or HCQ.

The only countries with large rates of cases and deaths from COVID-19 are the few Western and Latin American countries that did not use CQ / HCQ / HCQ+AZ treatment, or limited such use following anti-HCQ media campaign of May-June.

The Gamechanger

Italy and Spain were the first European countries hit by COVID-19, and initially suffered the worst. They had near exponential growth of cases and deaths. Their health care system was on the brink of collapse. But on March 16, Dr. Didier Raoult published his HCQ+AZ treatment. On March 19, President Donald Trump "touted" it. Italy and Spain adopted it, and within a couple of weeks, the trends were reversed.

On the other hand, Belgium and UK refused to adopt it[i]. When Italy and Spain were near the breaking point, they were doing well. But after a couple of months of hydroxychloroquine rejection, they accumulated more cases and deaths, ended at the top of the Table 1.

France, the Dr. Raoult's country, had complicated relations with HCQ. 20,000 deaths later, the common sense won, and it adopted HCQ. Brazil has its own version of TDS - Bolsonaro derangement syndrome. Some provinces reportedly banned or discouraged the use of HCQ.

USA made this list because of strict restrictions on HCQ fulfilment in New York, Michigan, and New Jersey. They have huge death rates, and spread them to their neighbors (https://www.worldometers.info/coronavirus/country/us/).

Table 1. The worst countries by COVID-19 deaths per million of the population

#	Country, Other	Total Deaths	Tot Cases/ 1M pop	Deaths/ 1M pop	Tests/ 1M pop
2	Belgium	9,778	5,367	844	115,239
4	UK	44,602	4,236	657	166,244
5	Spain	28,396	6,408	607	122,652
6	Italy	34,914	4,005	577	95,173
7	Sweden	5,482	7,312	543	59,404
8	France	29,965	2,596	459	21,212
9	USA	134,940	9,549	408	119,326
15	Brazil	68,089	8,089	320	21,021

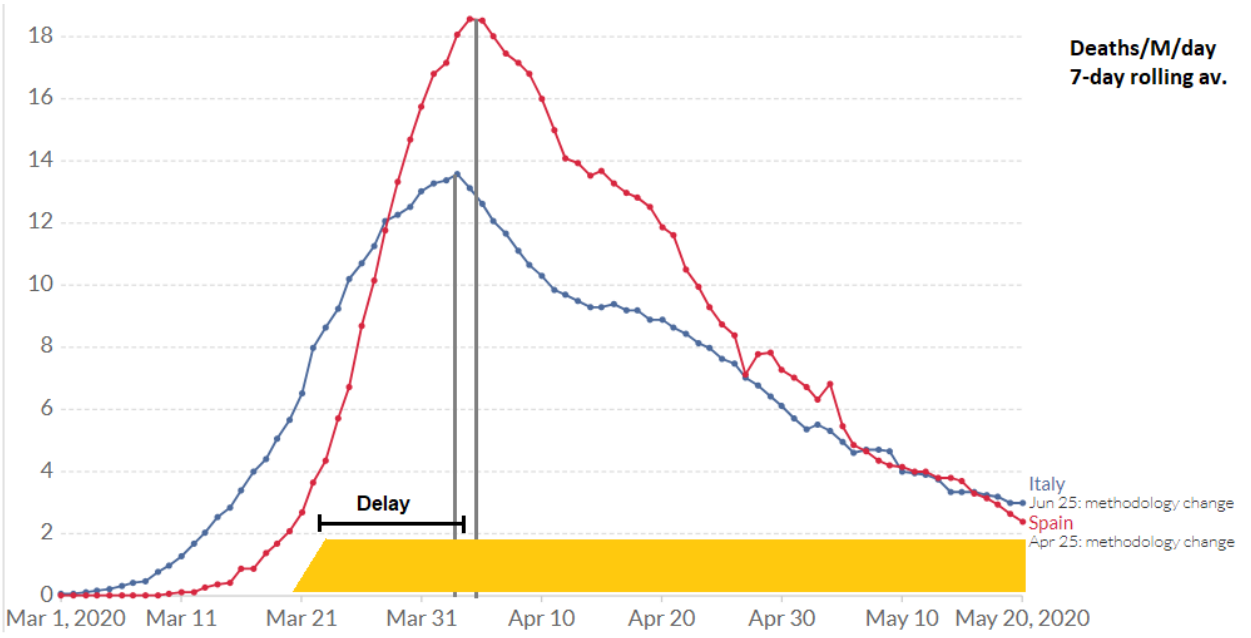
Sorted by the number of deaths per million of population. San Marino, Andorra & Sint Maarten are removed from the table because of their small sizes. Netherlands, Ireland, Chile, and Peru are removed because of the lack of information about them. https://archive.is/wip/EYFj9

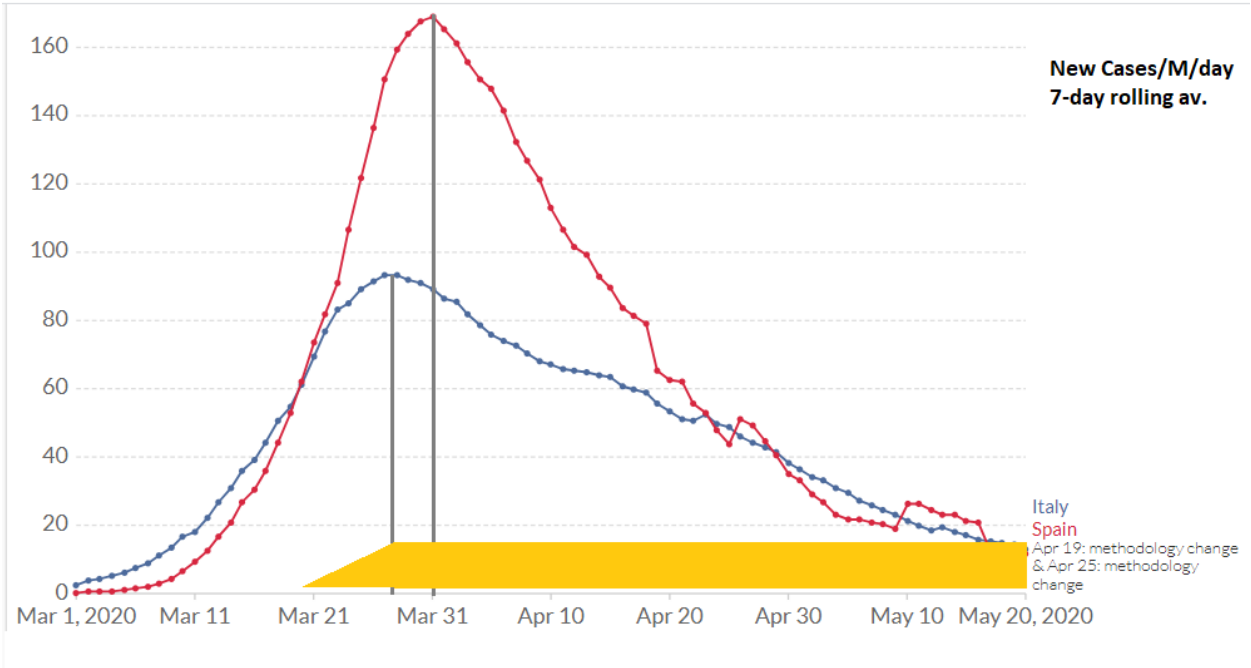
HCQ is not the only factor. The results are confounded by other anti-epidemic measures taken by the countries.

The information about the use of HCQ is from Sermo (https://app.sermo.com/covid19-barometer), the data from Week 3 through Week 10. The Sweden data is not statistically sufficient.

Italy and Spain adopted HCQ+AZ almost simultaneously. The daily deaths in Italy and Spain peaked before going down almost simultaneously, on April 3 and April 4-5, respectively. The daily new confirmed cases in Italy and Spain also peaked almost simultaneously – on March 28-29 and March 31. Notice only 5 days difference between peaks of cases and deaths. Early outpatient HCQ treatment decreases both transmission (seen as confirmed cases 7 – 14 days after the treatment adoption) and deaths (on average, 18.5 days after symptoms appear, about 12 – 16 days after the window for HCQ treatment was missed). There is quite a good match.

Fig. 1. Trend reversal in Italy and Spain, following the early HCQ+AZ treatment for COVID-19





It is winter in Australia now, but there is no COVID-19 epidemic. Australia uses HCQ.

No "herd immunity"

Most countries of Western Europe overcame COVID-19 epidemic and re-opened at least partly. None of them reached anything close to "herd immunity," by the seroprevalence ratio. The recent survey of Spain shows only 5% of the population have COVID-19 antibodies (*Prevalence of SARS-CoV-2 in Spain (ENE-COVID): a nationwide, population-based seroepidemiological study*, Marina Pollán et al., https://www.thelancet.com/journals/lancet/article/PIIS0140-

6736(20)31483-5/fulltext). This is an average between a few worst hit cities, having 10%-15%, and coastal areas, some of which have less than 1%. This matches other studies. COVID-19 does not end because of "herd immunity". It is not being eradicated. COVID-19 epidemic ends when a country widely uses HCQ. It starts or restarts when it does not. Of course, when COVID-19 epidemic ends, the new cases still occur, like flu and common cold.

Scientific Evidence

HCQ+AZ Studies and Testimonies

Studies of HCQ+AZ (with or without Zinc) treatment, given to COVID-19 early, universally show safety and outstanding effectiveness in reducing mortality and need for hospitalization, and fast clearance of the viral load. See a list of studies at https://c19study.com/

Anonymous surveys of physicians have shown the wide use and remarkably high opinion physicians have of HCQ for COVID-19 treatment. See https://wattsupwiththat.com/2020/07/07/hydroxychloroquine-based-covid-19-treatment-a-systematic-review-of-clinical-evidence-and-expert-opinion-from-physicians-surveys/ (which includes the data from Sermo)

Alleged Studies Showing Lack of Positive Results

By design or by chance, the clinical studies of HCQ in the US were conducted in hospitals, with patients in a late stage of the disease. At that time, antiviral effect of HCQ is useless. Frequently, HCQ was given to the patients in the worst conditions. Some "studies" compared outcome of the most desperate patients who received HCQ with the outcome of average ones and claimed that HCQ does not help or even harms.

Another mistake was giving a wrong dose of HCQ. When clinical trials of a new drug are conducted, the company that has developed it knows the optimal regimen and conducts the trial accordingly, to prove that its drug works. HCQ trials have been conducted with disregard to the regimen, and without intent to make it work.

Huge clinical trial RECOVERY, conducted in the Britain, would be comical if it were not tragical. The clinical researchers confused HCQ with another drug and gave their patients 6x higher dose than normal one (2,400 instead of 400 mg/day). It was tolerated well, but, on the balance, did not improve odds.

Then there was an anti-HCQ paper by *Mehra et al.*, based on non-existing patients' records. Despite the obviously fake data, the paper was published in The Lancet around May 22. It was retracted in the early June. Nothing is off limit in the was on HCQ.

Of note, the recently published Henry Ford Hospitals study was also conducted on late stage hospitalized patients, but competently, and reported with integrity. HCQ cut mortality by half.

Alleged Safety Issues

The late stage of COVID-19 typically includes cytokine storm. HCQ still helps for the cytokine storm as an immunomodulator, although there are other alternatives at that time. The coronavirus and/or cytokine storm can also damage multiple organs. Not unfrequently, the damage includes arrhythmia and/or cardiac arrest. These outcomes were blamed on HCQ and HCQ+AZ, although they happen without it. HCQ and AZ are known as mild QT prolongers, so they might be contributors at the later stages of the disease. This is just another reason to use HCQ+AZ early.

HCQ is one of the most used prescription drugs. AZ is one of the most prescribed drugs. Contra-indications and drug interactions exist, are well known, and should be respected.

Alleged Shortage of HCQ for "legitimate users"

Of all excuses not to use HCQ, this is the nastiest one. About 3 million lupus and rheumatoid arthritis patients take HCQ daily. A COVID-19 patient needs HCQ for 5 days only. If each of ~50,000 daily new cases are treated with HCQ, it would increase the demand only 8%, for a few weeks. The near-shortages of HCQ in the late March were triggered by a media campaign, that sent lupus patients to fill their 90-day prescriptions. The complaints about difficulties to fill their prescriptions are about limits to 30 days.

Suboptimal Experience

By design or by accident, many state governments and other factors discouraged and made impossible the most effective, early use of HCQ for COVID-19 treatment. One was the requirement for a positive test. In 20%-40% of the cases, symptoms appear before the viral load achieves levels confirmed in a PCR test. Another requirement was hospitalization. Dr. Zev Zelenko stressed, that HCQ treatment should be started as early as possible, on clinical suspicions.

Real Causes

There is no scientific basis to doubt CQ or HCQ effectiveness for COVID-19 treatment. In early April, some people even complained that it is too efficient and would not give a chance to other drugs. The politization started when the media attacked Trump for recommending them. Then it became personal for many powerful individuals and organizations. They have got too much at stake.

More Information

The petition asking the FDA not to interfere with physicians' use of Hydroxychloroquine

http://hcqpetition.com/

http://hcqpetition.com/EUA-Support-Letter.pdf

Hydroxychloroquine Saves Lives, States AAPS

https://aapsonline.org/new-study-shows-that-hydroxychloroquine-saves-lives-states-aaps/

AAPS sued FDA to release Hydroxychloroquine from the National Strategic Supply to the public. It is not necessary. There is enough of its in the commercial channels. Somebody must override the opinions of the FDA and NIH, and to investigate how they issued them.

https://aapsonline.org/preliminary-injunction-sought-to-release-hydroxychloroquine-to-the-public/

A recent article on the subject

https://wattsupwiththat.com/2020/07/05/hypothesis-restrictions-on-hydroxychloroquine-contribute-to-the-covid-19-cases-surge/

The FDA revocation letter with the memorandum, and FAQ

https://www.fda.gov/media/138945/download

https://www.fda.gov/media/138946/download

v. 1.1

[i] Belgium was using HCQ only in hospitals (i.e., too late), at too low doses (200 instead of 400 mg/day), and without AZ. It counts as not using.