From: John Hines [John.Hines@oann.com]
Sent: 4/13/2020 9:54:02 AM
To: Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissione]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
CC: John Hines [John.Hines@oann.com]
Subject: interview request

Dear all,

Looking to do an on-camera TV interview for One America News (a 24 hour TV cable news channel) about the following:

Why hasn't the US been able to do the necessary testing (double sided blind testing) to determine whether hydroxy-chloroquine (sulfate) with a Z-pak (and Zinc) is or is not proven to be scientifically beneficial to treat Covid-19.

Thank you.

John

.....
John Hines
DC Bureau Chief One America News
101 Constitution Ave., NW, DC
John.Hines@oann.com 202-368-4696
YouTube - One America News_John Hines

From: Natalie Mooney [Natalie.Mooney@oann.com]
Sent: 4/1/2020 1:39:56 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Interview Inquiry - One America News Network

Dear Stephen Hahn,

My name is Natalie Mooney, a producer for the show After Hours with Alex Salvi on One America News Network. I'm contacting you today to see if you would be interested in appearing as a guest next week.

OANN is a growing cable channel that reaches 35 million homes—the fourth largest in the news category behind only Fox News, MSNBC, and CNN. For 20 hours a day, the network runs the top headlines of the day without opinion or commentary; the other 4 hours are made up of two conservative-leaning talk shows (Tipping Point with Liz Wheeler and the Daily Ledger with Graham Ledger). However, After Hours is a down-the-middle news/talk show.

The show is taped from 3:30-4:30pm EST and will air at 10:00pm EST. The appearances could be conducted through Skype. Each appearance shouldn't take longer than 10-15 minutes.

If this seems like something you'd be interested in, please don't hesitate to contact me with any questions or comments.

Thank you,

Natalie Mooney

Booking Producer

One America News Network

Cell (b) (6) [redacted]

oann.com | Streaming on klowdtv.com

From: vladimir zelenko (b) (6)
Sent: 4/7/2020 9:45:25 AM
To: rudolphgiulian (b) (6); (b) (6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Mark Meadows (b) (6)
Subject: For President Trump

>
> Dear Mr. President:
>
> I humbly suggest the following:
>
> 1. It is essential to start treatment against Covid-19 immediately upon clinical suspicion of infection and not to wait for confirmatory testing. There is a very narrow window of opportunity to eliminate the virus before pulmonary complications begin. The waiting to treat is the essence of the problem.
>
> 2. Emphasis must be to prevent complications in the outpatient setting and not to wait until the patient needs to be admitted in the hospital and put on a respirator. This will elevate the respirator shortness and lower mortality significantly.
>
> 3. The risk of side effects is over exaggerated. The theoretical risk of QT prolongation is 1 in 1000. The actual risk of death in the high risk population is between 5 to 10%. The risk vs benefit analysis overwhelmingly favors treatment.
>
> 4. This is World War lll (virus vs humanity). We don' t have time to wait for the results of a long study. Millions will die while we wait. We need to initiate immediate treatment of high risk patients in the outpatient setting.
>
> 5. Any obstruction to life saving medication (HCQ) should be viewed has crimes against humanity.
>
> 6. Prophylaxis should be considered in the very high risk patients (i.e. nursing homes).
>
> 7. We need an immediate supply of 1.5 billion pills of HCQ 200mg, 500 million pills of Azithromycin 500mg, 500 million pills of zinc sulfate 220mg (or its equivalent - we need 50mg elemental zinc).
>
> 8. I suggest the following immediate treatment regimen of high risk patients with symptoms:
>
> Hydroxychloroquine 200mg twice a day for 5 days
> Azithromycin 500mg once a day for 5 days
> Zinc sulfate 220mg once a day for 5 days
>
> 9. I suggest the following prophylactic regimen for very high risk patients:
>
> Hydroxychloroquine 200mg once a day for 5 days, and then 1 pill a week until immunity can be shown or a vaccine becomes available.
> Zinc Sulfate 220mg once a day for 5 days, and then 1 pill a week until immunity can be shown or a vaccine becomes available.
>
> 10. We need an executive order to override any state obstacles and allow all physicians to prescribe the medication without the fear of liability or retribution. Pharmacies must be permitted to dispense this medication without the fear of liability or retribution.
>
> 11. The Task force must announce that physicians must treat patents early and aggressively, even without confirmatory testing. If test comeback negative, the patient could be advised to stop the medication.
>
> With much respect,
>
> Dr. Vladimir (Zev) Zelenko
> Cell number (b) (6)
>
>
>
>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/7/2020 7:11:07 AM
To: Zelenko Family (b) (6)
Subject: Re: Dr Rosy Joseph outcomes data

Thx Dr. Zelenko
We are identifying an appropriate point of contact for you to send these data to. In the meantime, please hold them. We'll let you know later today.
Thanks
Steve

From: Zelenko Family (b) (6)
Date: April 6, 2020 at 10:13:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Dr Rosy Joseph outcomes data

Please see the outcome data of my colleague. She is a Columbia med graduate with 40 years experience in internal medicine and nephrology. She is at Hackensack hospital. Extremely well respected

Sent from my iPhone

Begin forwarded message:

From: "R. Joseph" (b) (6)
Date: April 6, 2020 at 8:54:52 PM EDT
To: Zelenko Family (b) (6)
Subject: my latest data with names removed

Rosy E. Joseph, M.D.
Suite 304
360 Essex Street
Hackensack, NJ 07601
Tel:201)646-0110
Fax:(201)646-0219

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/8/2020 10:04:54 AM
To: vladimir zelenko (b) (6)
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Contact person

Dr. Zelenko,
Thanks for touching base. Keagan Lenihan, will be providing that information.
Steve

From: vladimir zelenko (b) (6)
Date: April 8, 2020 at 10:03:11 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Contact person

Hi Dr. Hahn

Have you chosen a contact person for me to send data, as it comes is? Any comments on the data that I provided?

Thanks

Dr. Zelenko

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/6/2020 2:48:42 PM
To: Stephen M. Smith, MD (b) (6)
CC: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Subject: Re: HCQ

Thanks, Stephen, very much. We are reviewing all available data and appreciate your willingness to share. Our team will be in touch.
Best
Steve

From: Stephen M. Smith, MD (b) (6)
Date: April 5, 2020 at 1:59:59 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: HCQ

Hello Stephen,

Let me now if you need me to explain what each column means.
Since Friday, we have added many more pts.
I can send you today's updated list later, if you're interested.

Trying to be devil's advocate and also just to find good prognostic indicators, we have been trying to figure out who gets intubated and why, separately from the HCQ/azithro treatment.
The NEWS2 scores aren't particularly helpful.
So, we haven't found anything, except maybe persistent, poor glycemic control.
Maybe you can suggest a lab like blood type or something else, maybe even a creased earlobe, for us to add.
We are open to anything.

Stephen

On Sun, Apr 5, 2020 at 1:16 PM Hahn, Stephen <SH1@fda.hhs.gov> wrote:

> Hi Stephen,
> Thanks for the message. I most definitely want to review the data and thought you would be sending. My apologies. We'll review.
> (b) (6) is a great guy and a good friend.
> Steve

From: Stephen M. Smith, MD (b) (6)
Date: April 5, 2020 at 12:24:57 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: HCQ

Hello Stephen,

I am emailing you, because (b) (6) (aka (b) (6)) is one of my best friends and he says you're a good guy and I trust (b) (6).

The meeting the other day was...interesting. I assume you have not looked at my data yet, but that's fine. Trust me, I get it. Some local ID doc with a spreadsheet. But please consider the following.

First, I want to point out to you the absurdity of the FDA approving the same HCQ dose for every adult.

We now have >100 pts.

- The weight range is from 40.7 - 157 kg.
- Over 34% weigh >90 kg.
- Only 12% weigh < 70 lg, including 6% who weight < 60 kg.

The FDA chose the HCQ dose based on computer PK modeling.

The FDA needs to model pts with vastly different weights.

We were giving a 40 kg, 94 yo woman the same dose as 45 yo man who literally weight more than 3 times her. Even if I didn't have a degree in mathematics, I could figure out that that makes no sense.

Every critically ill COVID pt has DM and/or uncontrolled sugars.

- 23 pts have been intubated.
- 21 had DM and
- 2 had PreDM.
- 4 presented in DKA. What virus causes DKA like?
- 22 of 23 had uncontrolled sugars.

These data are simply overwhelming. They tell us there is a unique pathophysiology, which may point to future preventive measures. The data also suggest that tight glycemic control may improve outcomes.

Regarding therapy -

Efficacy:

62 pts received who received at least 2,400 mg of HCQ; 0 of these 64 has been intubated.

Said another way, none of the 23 intubated pts received 2,400 mg or more of HCQ.

By any statistical analysis, that's pretty tough for anyone, regardless of their biases, to explain by chance. Tom Frieden, who I had admired immensely, messed up Ebola and got away with it. Clearly, we are not going to get away with any mishandling of this pandemic.

Before the Marseilles' clinical trial came out, I noticed that after the 5-day, 2,400 mg total HCQ regimen, several pts lingered like I have never seen before. Some needed high-flow oxygen for several days AFTER completing the HCQ. 2 pts bounced back after being sent home.

Each was male and each weighed > 90 kg.

We were able to re-test a few and each was still positive.

Last week, any pt who had only received the 2,400 mg total dose and still needed oxygen therapy, we re-started on HCQ. Each improved quickly. One pt had his HCQ/azithro reduced or held, but he was improving. After finishing the 2,400 mg HCQ, he oxygen needs increased and then his fever returned. We didn't add any abx; we just gave him more HCQ. 2 days later, I saw he was "grayed out" meaning no longer in the hospital. I feared he had died. No, we had discharged him.

Safety:

Because of my fear of hurting someone. For those on HCQ/azithro combo therapy, we have been monitoring EKGs daily or nearly daily. Dr. David Dobesh, an excellent EP cardiologist, has reviewed them. A summary of his data is attached as a pdf.

Dave's conclusions are:

1) This is highly encouraging that a 5 days course of therapy will not cause potentially harmful changes on the ECG for most patients.
2) Medication list should be reviewed prior to starting regimen to assess for conflicts.
3) If baseline ECG, baseline labs look good, daily testing may not be warranted.
4) This may lead to initiation of therapy as an outpatient.

This disease is unique. The patterns of this disease are far different than anything we have seen before. The cumulative dose matters more than the daily dose. At a minimum, weight based dosing needs to considered and then implemented.

Stephen, we have the tools and enough information now to improve outcomes in COVID pts. Ironically, your approval of the lower dose of HCQ actually interfered with my use of the only dose supported by clinical data at the time. Half of ID is off-label, including ceftriaxone for strep endocarditis, metronidazole for C diff and meropenem for HCAP or UTI. When you approved that lower dose, the hospital fought with me about using the only dose with clinical trial data. I had to threaten them before they would let me give the higher dose. BTW, go back to the PK paper, even the authors opined that a 10-day course (3,400 mg total) might work better than a 5-day course (2,400 mg).

Sincerely,

Stephen

P.S. – The data are no longer anecdotal, well, at least, the data are becoming no more anecdotal than the tetanus toxoid vaccine data. These data are FAR, FAR less anecdotal than those Drs. Fauci and Wolff presented in 1973 on the treatment of Wegener's.

Stephen M. Smith, M.D.

Cellphone: (b) (6) [redacted]

COVID Data 4/4/2020

Caveats

1) This is an early, first run assessment of the available data.
2) Limited as it is a single site and single group assessment.
3) Some patients in the midst of ongoing therapy (more data points to evolve and hope to achieve 4-5 days therapy)
4) ECG performance has not been done daily on all patients due to staff exposure concern issues.
5) Some patients will not have 5 day follow-up ECG (range 1-10) as some treatment ongoing, some are treated and discharged within 5 days and patient demise.

All 5 day of therapy	49	patients
At least 4 days (11)	60	patients
At least 3 days (9)	69	patients

Full 5 day QT data available	39
At least 4 days QT data available (8)	47
At least 3 days QT data available (9)	56

Prolongation >50 from baseline: 2

1) developed bundle branch block conduction with raid AFib
2) One had IVCD <110-120
   (degree of prolongation in progress)

Developed Abnl QT:

1: amiodarone and low potassium
2: PiCe persistent hypocalcemia and acute renal failure/intubated/DM/ACS.
3: AlSo DM/DKA/ACS/intubated
4: BrGr - ARF/Intubated/DM
5: Two patients with ACS: intubated andDM

All patients who developed abnormal QT had DM and were intubated

Average QT prolongation: xxx (in progress)
Degree of prolongation above 500 in the sick individuals who did prolong (in progress)

Clearly thought provoking and encourages further investigation.

My impressions:

This is all very preliminary and needs further investigation!!

1) This is highly encouraging that a 5 days course of therapy will not cause potentially harmful changes on the ECG for most patients.
2) Medication list should be reviewed prior to starting regimen to assess for conflicts.
3) If baseline ECG, baseline labs look good, daily testing may not be warranted.
4) This may lead to initiation of therapy as an outpatient.

From: Stephen Smith (via Google Sheets) (b) (6)
Sent: 4/3/2020 2:46:24 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Patient list 04-02

(b) (6) has shared a link to the following spreadsheet:

Patient list 04-02

Open in Sheets

Google Sheets: Create and edit spreadsheets online.
Google LLC, 1600 Amphitheatre Parkway, Mountain View, CA 94043, USA
You have received this email because (b) (6) shared a spreadsheet with you from Google Sheets.

From: Zelenko Family (b) (6)
Sent: 4/14/2020 6:04:58 AM
To: Rudy Giuliani (b) (6); Mark Meadows (b) (6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Jerome Corsi Ph. D. (b) (6)
Subject: Fwd: Detailed Patient Trials from Dr. Zelenko (part 1)
Attachments: pt tx hcq.pdf; ATT00001.htm; masterpatientlistpdf.pdf; ATT00002.htm; Coronas letter-april13.pdf; ATT00003.htm; Zelenko-detailed-patients1.zip; ATT00004.htm

Subject: Detailed Patient Trials from Dr. Zelenko (part 1)

To All Concerned:
President Donald J.Trump; Mr. Mark Meadows, Chief of Staff, Prime Minister Benjamin Netanyahu; Israel Health Ministry; FDA;

This is a very important update from Dr. Zelenko as it includes detailed patient trails and results of those with Covid-19. We have included approximately 250 complete patient charts who were treated as high risk, along with followup positive results when treated by the combination drugs, Hydroxychloroquine, Azithromycin and Zinc Sulfate. The Doctor has seen approximately 1500 Covid-19 patients to date.

We want to reemphasize the importance of treating patients quickly in the outpatient setting. Dr. Zelenko's success comes from the immediate treatment of patients who are deemed high risk and not waiting for them to be admitted to hospitals or ICU's. By implementing Dr. Zelenko's recommendations, deaths would be reduced by more than 95% in a matter of days. This is proven by the included documents where almost no high risk patients with Covid-19 were admitted to hospitals after treatment because almost all improved in only a matter of days in quarantine at home.

The governments of Brazil, Peru, Ukraine, Russian and others have asked him to lead their covid-19 task force. The Doctor is available to help in anyway possible. He seeks no position of honor or credit, only to help save lives. Call him anytime 1-845-238-4214.

Thank you,
Rabbi Moshe Steinerman
On behalf of Dr. V. Zelenko

-Please note, there are two emails with attachments

Dr. Vladimir (Zev) Zelenko M.D.
Board Certified Family Practitioner
501 Rt 208, Monroe, NY 10950
845-782-0000

April 12, 2020

To all medical professionals around the world:

For the last 16 years, I have cared for approximately 75% of the adult population of Kiryas Joel, which is a very close knit community of approximately 35,000 people in which the Covid-19 infection spread rapidly and unchecked prior to the imposition of social distancing.

As of today my team has tested hundreds of people from this community for Covid-19, and approximately 61% of the results have been positive. If extrapolated to the entire community, that means more than 20,000 people are infected at the present time. Of this group, I estimate that there are 1,500 patients who are in a generally accepted high-risk category (e.g. above 60, immunocompromised, comorbidities, underlying respiratory issues).

Given the urgency of the situation, I developed the following treatment protocol in the pre-hospital setting and have seen only positive results:

1. Any patient with shortness of breath is treated.
2. Any patient in a high-risk category with mild symptoms is treated.
3. Young, healthy and low risk patients even with symptoms are not treated (unless their circumstances change and they fall into category 1 or 2) (as is well known, these patients likely self resolve).

My outpatient treatment regimen is as follows:

1. Hydroxychloroquine 200mg twice a day for 5 days
2. Azithromycin 500mg once a day for 5 days
3. Zinc sulfate 220mg once a day for 5 days

The rationale for my treatment plan is as follows. I combined the data available from China and South Korea with the recent study published from France (sites available on request). We know that hydroxychloroquine helps Zinc enter the cell. We know that Zinc slows viral replication

within the cell. Regarding the use of azithromycin, I postulate it prevents secondary bacterial infections. These three drugs are well known and usually well tolerated, hence the risk to the patient is low.

Since 3/15/20, my team has seen approximately 1354 patients in Monroe, New York with either test proven or clinically suspected coronavirus infection. The majority of the patients were treated with only supportive care. The patients with shortness of breath or who are in the high risk category were treated with the above regimen (approximately 405 patients at this point)..

Of this group and the information provided to me by affiliated medical teams, we have had two deaths, six hospitalizations for pneumonia, and four intubations (all extubated now). In addition, I have not heard of any negative side effects other than approximately 10% of patients with temporary nausea and diarrhea.

In sum, **my urgent recommendation is to initiate treatment in the outpatient setting as soon as possible** in accordance with the above. Based on my direct experience, it prevents acute respiratory distress syndrome (ARDS), prevents the need for hospitalization and saves lives.

With much respect,

Dr. Vladimir (Zev) Zelenko

P.S. Please see attached excel spreadsheets of total patients seen and total patients treated with my three drug protocol. Also attached are the bioreference Covid-19 results and the majority of the redacted and Hippa compliant patient records..

From: Zelenko Family (b) (6)
Sent: 4/13/2020 12:28:00 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Dr Zelenko outcomes. Please review
Attachments: Coronas letter.pdf.pdf.pdf.pdf.pdf.pdf; ATT00001.txt

Dr. Vladimir (Zev) Zelenko M.D.
Board Certified Family Practitioner
501 Rt 208, Monroe, NY 10950
845-782-0000

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From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/11/2020 2:30:53 PM
To: Stephen M. Smith, MD (b) (6)
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: HCQ

Thanks Dr. Smith - Patti (b) (6) at the NIH is working to collect this kind of information. She would be the best person to share this information with going forward.

Thanks,
Keagan

Sent from my iPhone

On Apr 11, 2020, at 2:10 PM, Stephen M. Smith, MD (b) (6) wrote:

Hello Keagan & Stephen,

As I may have mentioned, I noticed that several pts developed recurrent disease after the HCQ was stopped or held.

I am collecting and organizing data on 5 COVID pts who had recurrence of disease and symptoms after the HCQ was discontinued by them after discharge (3 cases) or was by us in the hospital (2 cases).

After the HCQ of these 5 pts was stopped, each worsened clinically. Below I describe two of these five cases.

After the HCQ of these 5 pts was stopped, each worsened clinically.
Each was then put back on HCQ and five of five improved.
I discuss two patients below.
Of note, each had very high ferritin, LDH and D-dimer, a pattern unique to COVID.
If measured during both admissions, each went up further.

The first case or patient demonstrates very well that HCQ effectively treats COVID-19.

(b) (6) with cognitive deficits and seizure disorder, was admitted on March 28th.
(b) (6) COVID test from that day was positive.
(b) (6) was started on HCQ monotherapy. (b) (6) bloodwork and presentation were entirely and completely consistent with COVID.
(b) (6) improved.
On (b) (6), the (b) (6) back to (b) (6) nursing home without any HCQ.
On (b) (6) the nursing home sent (b) (6) back to the ER, because of dark urine. (b) (6) was evaluated and sent back to the nursing home after (b) (6) was given only IV fluids.

On (b) (6) was sent back to the ER for high fever, decreased mental status, high pulse and increased respiratory or respiratory distress.

(b) (6) labs and presentation were so entirely consistent with COVID, the ER didn't even order a repeat COVID test.
I ordered a repeat COVID test (b) (6)
Regardless of the repeat COVID test result, this patient has recurrent COVID, no doubt about it all.
(b) (6) ferritin, D-dimer and LDH are markedly elevated.
Only one disease causes fever, hypoxia, and very high levels of ferritin, D-dimer and LDH.
There is not other disease that can cause (b) (6) illness or syndrome.

(b) (6) while (b) (6) is still very ill, (b) (6) condition has improved considerably.
(b) (6) was never given azithromycin, because azithro interacted with one of (b) (6) other medications.

The table below shows the Date, Place, Total or cumulative HCQ dose in milligrams, oxygen saturation, oxygen therapy needed, and the maximum temperature, maximum pulse, and maximum respiratory rate of that day.

For oxygen therapy, RA = room air, 4L or 5L refer to the flow rate of oxygen via nasal cannula, NRB means non-rebreather and NRB 15HF means non-rebreather with high flow oxygen at a flow rate = 15 (flow rates for high flow range from 15-40).
These are listed in rank order, meaning RA is best, nasal cannula, etc.

Date	Place	Daily HCQ Dose	Total HCQ	Oxygen Saturation	Oxygen Therapy	Tm	Pulsem	RRm
(b) (6)	ER			(b) (6)				
	Hospital	800	800					
	Hospital	400	1200					
	Hospital	200	1400					
	Hospital	200	1600					
	ER/dark urine	0	1600					
	Nursing Home	0	No change					
	ER	800	2400					
	Hospital	600	3000					
	Hospital	600	3600					

Second case -
(b) (6) admitted on (b) (6) with hypoxia, fever, shortness of breath and (b) (6) COVID test was positive.
(b) (6) was given HCQ/azithro. (b) (6) initially required significant oxygen therapy, including high flow on (b) (6), (b) (6) was sent home off oxygen therapy on room air.
(b) (6) was discharged at noon on (b) (6) and was given a prescription for HCQ, but didn't fill it.

On (b) (6) PM, (b) (6) came back into the ER.
(b) (6) hypoxia and tachycardia (fast heart rate) had required.
(b) (6) was re-started on HCQ.
As before, (b) (6) initially required significant oxygen therapy, but again, (b) (6) need for supplemental oxygen quickly resolved.
(b) (6) was discharged on HCQ to finish a 10-day course.
(b) (6) has not returned.

Date	Place	Daily HCQ	Total HCQ	Daily Azithro	Total Azithro	Oxygen Saturation	Oxygen Therapy	Tm	Pulsem	RRm
(b) (6)	ER	0	0	0	0	(b) (6)				
	Hospital	800	800	500	500					
	Hospital	600	1400	250	750					
	Home at 12 PM	400	1800	250	1000					
	ER 9 PM	0	No change	0						
	Hospital	800	2400	0						
	Hospital	600	3000	0						
	Hospital	600	3600	0						
	Hospital	200	3800	0						

As in (b) (6) case, in (b) (6) case, there is no other explanation for improvement on HCQ, deterioration off of it and then improvement once put back on it.
Tangentially, I have never seen such rapid respiratory deterioration as in COVID cases.
I also have never seen such rapid improvement.
(b) (6) went from HF on (b) (6) to home on room air a day later.
That kind of rapid deterioration and then improvement doesn't happen in any other disease.

The other 3 cases show similar responses after HCQ was re-started.

If you or anyone else can think of any other explanation for these pts' disease courses, please let me know.
I have been practicing ID for many years.
In these cases, the responses are quite dramatic.
We clinicians, of course, call this response, a "therapeutic response" and a very good therapeutic response at that.
Again, I am open to suggestions and theories, but can anyone think of a legitimate reason other than the obvious one?
That well beyond any reasonable doubt, HCQ effectively treats COVID.

SMS
P.S. - I didn't use either pts' real initials.

On Wed, Apr 8, 2020 at 12:57 PM Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Hi Dr. Smith,

Patti Brennan, the Director of the National Library of Medicine at the NIH has been identified as the appropriate lead for this type of data. Please work with her going forward. Thank you!

Her email is: (b) (6) [redacted]

Keagan Lenihan

FDA Chief of Staff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 12:23 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: HCQ

From: Stephen M. Smith, MD (b) (6) [redacted]
Date: April 5, 2020 at 1:59:59 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: HCQ

Hello Stephen,

Let me now if you need me to explain what each column means.

Since Friday, we have added many more pts.

I can send you today's updated list later, if you're interested.

Trying to be devil's advocate and also just to find good prognostic indicators, we have been trying to figure out who gets intubated and why, separately from the HCQ/azithro treatment.

The NEWS2 scores aren't particularly helpful.

So, we haven't found anything, except maybe persistent, poor glycemic control.

Maybe you can suggest a lab like blood type or something else, maybe even a creased earlobe, for us to add.

We are open to anything.

Stephen

On Sun, Apr 5, 2020 at 1:16 PM Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Hi Stephen,

Thanks for the message. I most definitely want to review the data and thought you would be sending. My apologies. We'll review.

(b) (6) is a great guy and a good friend.

Steve

From: Stephen M. Smith, MD (b) (6)
Date: April 5, 2020 at 12:24:57 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: HCQ

Hello Stephen,

I am emailing you, because (b) (6) (aka (b) (6)) is one of my best friends and he says you're a good guy and I trust (b) (6).

The meeting the other day was...interesting. I assume you have not looked at my data yet, but that's fine. Trust me, I get it. Some local ID doc with a spreadsheet. But please consider the following.

First, I want to point out to you the absurdity of the FDA approving the same HCQ dose for every adult.

We now have >100 pts.

- The weight range is from 40.7 - 157 kg.
- Over 34% weigh >90 kg.
- Only 12% weigh < 70 lg, including 6% who weight < 60 kg.

The FDA chose the HCQ dose based on computer PK modeling.

The FDA needs to model pts with vastly different weights.

We were giving a 40 kg, 94 yo woman the same dose as 45 yo man who literally weight more than 3 times her. Even if I didn't have a degree in mathematics, I could figure out that that makes no sense.

Every critically ill COVID pt has DM and/or uncontrolled sugars.

- 23 pts have been intubated.
- 21 had DM and
- 2 had PreDM.
- 4 presented in DKA. What virus causes DKA like?
- 22 of 23 had uncontrolled sugars.

These data are simply overwhelming. They tell us there is a unique pathophysiology, which may point to future preventive measures. The data also suggest that tight glycemic control may improve outcomes.

Regarding therapy -

Efficacy:

62 pts received who received at least 2,400 mg of HCQ; 0 of these 64 has been intubated.

Said another way, none of the 23 intubated pts received 2,400 mg or more of HCQ.

By any statistical analysis, that's pretty tough for anyone, regardless of their biases, to explain by chance. Tom Frieden, who I had admired immensely, messed up Ebola and got away with it. Clearly, we are not going to get away with any mishandling of this pandemic.

Before the Marseilles' clinical trial came out, I noticed that after the 5-day, 2,400 mg total HCQ regimen, several pts lingered like I have never seen before. Some needed high-flow oxygen for several days AFTER completing the HCQ. 2 pts bounced back after being sent home.

Each was male and each weighed > 90 kg.

We were able to re-test a few and each was still positive.

Last week, any pt who had only received the 2,400 mg total dose and still needed oxygen therapy, we re-started on HCQ. Each improved quickly. One pt had his HCQ/azithro reduced or held, but he was improving. After finishing the 2,400 mg HCQ, he oxygen needs increased and then his fever returned. We didn't add any abx; we just gave him more HCQ. 2 days later, I saw he was "grayed out" meaning no longer in the hospital. I feared he had died. No, we had discharged him.

Safety:

Because of my fear of hurting someone. For those on HCQ/azithro combo therapy, we have been monitoring EKGs daily or nearly daily. (b) (6), an excellent EP cardiologist, has reviewed them. A summary of his data is attached as a pdf.

(b) (6) conclusions are:

1) This is highly encouraging that a 5 days course of therapy will not cause potentially harmful changes on the ECG for most patients.

2) Medication list should be reviewed prior to starting regimen to assess for conflicts.

3) If baseline ECG, baseline labs look good, daily testing may not be warranted.

4) This may lead to initiation of therapy as an outpatient.

This disease is unique. The patterns of this disease are far different than anything we have seen before. The cumulative dose matters more than the daily dose. At a minimum, weight based dosing needs to considered and then implemented.

Stephen, we have the tools and enough information now to improve outcomes in COVID pts. Ironically, your approval of the lower dose of HCQ actually interfered with my use of the only dose supported by clinical data at the time. Half of ID is off-label, including ceftriaxone for strep endocarditis, metronidazole for C diff and

meropenem for HCAP or UTI. When you approved that lower dose, the hospital fought with me about using the only dose with clinical trial data. I had to threaten them before they would let me give the higher dose. BTW, go back to the PK paper, even the authors opined that a 10-day course (3,400 mg total) might work better than a 5-day course (2,400 mg).

Sincerely,

Stephen

P.S. – The data are no longer anecdotal, well, at least, the data are becoming no more anecdotal than the tetanus toxoid vaccine data. These data are FAR, FAR less anecdotal than those Drs. Fauci and Wolff presented in 1973 on the treatment of Wegener's.

Stephen M. Smith, M.D.

Cellphone(b) (6) [redacted]

From: Zelenko Family (b) (6)
Sent: 4/5/2020 3:44:59 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fwd: Dr. Zelenko protocol and outcome date
Attachments: 315-43.pdf; outcomes date 3_15 - 4_3 (1).pdf; Coronas letter.pdf

Begin forwarded message:

From: vladimir zelenko (b) (6)
Subject: Dr. Zelenko protocol and outcome date
Date: April 5, 2020 at 1:34:30 PM EDT
To: Sam Sandowski (b) (6), (b) (6), adi Gast (b) (6), Moshe (b) (6), (b) (6).

This document was exported from Numbers. Each table was converted to an Excel worksheet. All other objects on each Numbers sheet were placed on separate worksheets. Please be aware that formula calculations may differ in Excel.

Numbers Sheet Name	Numbers Table Name	Excel Worksheet Name
Patients seen with icd codes		
	Table 1	Patients seen with icd codes

Dr. Vladimir (Zev) Zelenko M.D.
Board Certified Family Practitioner
501 Rt 208, Monroe, NY 10950
845-782-0000

4/6/20

To all medical professionals around the world:

Please see attachment with my outcomes data for 3/15/20 - 4/3/20

The table consists of:

DOB / gender / risk factors / outcomes

The main points:

929 total patients seen with corona - diagnosed with test or clinically. My community of 35000 people has >75% positive. We ran out of tests.

349 high risk patients were treated with three drug regimen. The remainder of low risk patients were only treated with supportive care.

Outcomes

1 dead - patient had CLL
4 intubated - 1 is extubated already
5 admitted for iv antibiotics for pneumonia

I am in direct daily contact with the white house via Mr. Mark Meadows (the president's chief of staff) and Mayor Rudy Guliani (the president's private legal counsel). They are supportive of my recommendations and the FDA approved the use of hydroxychloroquine for use against Covid-19.

I was interviewed by Mayor Guliani on his recent podcast. Please see the attached link.

https://www.youtube.com/watch?v=1TJdjhd_XG8&feature=youtu.be

My protocol has been endorsed by

Dr. Robert Susskind, Dean and founder of University of California School of Medicine. His cell number is (b) (6).

Dr. William Grace, Oncology Lenox Hill Hospital, NY. His cell number is (b) (6).

Dr. Rosy Joseph, Nephrology and Internal Medicine, Hackensack University Medical Center, Hackensack, NJ. Her cell number is (b) (6).

Dr. Bushra Mina, Head of Pulmonary and Critical care, Lenox Hill Hospital, NY

Dr. Israel Brekowitz, Cardiology and Critical care, Lenox Hill Hospital

Dr. Michael Poon, Cardiology and Advanced Cardiac Imaging, North Shore / LIJ

I have been contacted by the governments of Ukraine, Russia, Brazil, and Belgium, who are interested in this protocol.

In summary, it is imperative to **initiate aggressive and early treatment of Covid-19 in the primary care setting,** before the patient develops pulmonary complications. According to my data, prompt treatment will reduce hospitalizations, intubations, and death.

I humbly and respectfully request that you consider this outpatient treatment against Covid-19.

Sincerely,

Dr. Vladimir (Zev) Zelenko
Cell number is (b) (6)

Dr. Vladimir (Zev) Zelenko M.D.
Board Certified Family Practitioner
501 Rt 208, Monroe, NY 10950
845-782-0000

March 31, 2020

To all medical professionals around the world:

For the last 16 years, I have cared for approximately 75% of the adult population of Kiryas Joel, which is a very close knit community of approximately 35,000 people in which the Covid-19 infection spread rapidly and unchecked prior to the imposition of social distancing.

As of today my team has tested hundreds of people from this community for Covid-19, and approximately 65% of the results have been positive. If extrapolated to the entire community, that means more than 20,000 people are infected at the present time. Of this group, I estimate that there are 1,500 patients who are in a generally accepted high-risk category (e.g. above 60, immunocompromised, comorbidities, underlying respiratory issues).

Given the urgency of the situation, I developed the following treatment protocol in the pre-hospital setting and have seen only positive results:

1. Any patient with shortness of breath is treated.
2. Any patient in a high-risk category with mild symptoms is treated.
3. Young, healthy and low risk patients even with symptoms are not treated (unless their circumstances change and they fall into category 1 or 2) (as is well known, these patients likely self resolve).

My outpatient treatment regimen is as follows:

1. Hydroxychloroquine 200mg twice a day for 5 days
2. Azithromycin 500mg once a day for 5 days
3. Zinc sulfate 220mg once a day for 5 days

The rationale for my treatment plan is as follows. I combined the data available from China and South Korea with the recent study published from France (sites available on request). We know that hydroxychloroquine helps Zinc enter the cell. We know that Zinc slows viral replication

within the cell. Regarding the use of azithromycin, I postulate it prevents secondary bacterial infections. These three drugs are well known and usually well tolerated, hence the risk to the patient is low.

Since 3/15/20, my team has seen approximately 911 patients in Monroe, New York with either test proven or clinically suspected coronavirus infection. The majority of the patients were treated with only supportive care. The patients with shortness of breath or who are in the high risk category were treated with the above regimen (approximately 350 patients at this point)..

Of this group and the information provided to me by affiliated medical teams, we have had ZERO deaths, six hospitalizations for pneumonia, and three intubations. In addition, I have not heard of any negative side effects other than approximately 10% of patients with temporary nausea and diarrhea.

In sum, my urgent recommendation is to initiate treatment in the outpatient setting as soon as possible in accordance with the above. Based on my direct experience, it prevents acute respiratory distress syndrome (ARDS), prevents the need for hospitalization and saves lives.

With much respect,

Dr. Vladimir (Zev) Zelenko

From: Zelenko Family (b) (6)
Sent: 4/5/2020 3:44:13 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fwd: Follow up - CHS/Dr Zelenko - Covid-19 Clinical Trial
Attachments: Mail Attachment.ics

Please below emails. These are the principals that will run the clinical trial from the Catholic Health System, NY (St. Francis hospital)

From: "Thakore, Avni" (b) (6)
Subject: Follow up - CHS/Dr Zelenko - Covid-19 Clinical Trial
Date: April 3, 2020 at 4:03:00 PM EDT
To: "Levine, Joseph" (b) (6), "Haag, Elizabeth" (b) (6), "Muehlbauer, Stefan" (b) (6), "(b) (6)" (b) (6)

From: Thakore, Avni (b) (6)
To: Levine, Joseph (b) (6) ; Haag, Elizabeth (b) (6) ; Muehlbauer, Stefan (b) (6)]; (b) (6) ' (b) (6)

Subject: Follow up - CHS/Dr Zelenko - Covid-19 Clinical Trial
Location: 1-866-305-0232 Access Code (b) (6) Host Pin (Avni only) (b) (6)

Start: 4/13/2020 2:00:00 PM
End: 4/13/2020 2:45:00 PM
Show Time As: Tentative

Recurrence: (none)

From: Zelenko Family (b) (6)
Sent: 4/7/2020 8:40:34 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Mark Meadows (b) (6); rudolphgiulian (b) (6); (b) (6)
Subject: Zelenko Updates - important / Please show to the President
Attachments: Lettre au preèsident pour extension ATU -JCG-OK.pdf; A reasoned COVID strategy adapted to the here and now JC GHALEB - EN.pdf

Thanks, please provide any further guidance on what I can do. I am attempting to generate as much data as fast as possible.

FYI -

1- The government if Brazil has adopted my protocol and is advising all doctors to initiate treatment immediately in the outpatient setting and not to go to the hospitals which are overwhelmed. Ambassador Ernesto Araujo (Foreign minister of Brazil) has reach out to me and I will be talking to them today.

2- I have been fighting with Israel's minister of health (Prof. Litzman) for 2 weeks. Yesterday Israel approved the use of the hcq, and Dr. Alon Moses, Israel's leading ID doctor (Hadassah hospital), has started a clinical trial already using the protocol.

3- One day after I gave an interview to their biggest media outlet, Italy began using hcq on a broad scale this week, lets keep an eye on their mortality figures.

4- I am leading a pilot project to prophylax the city of dnipropetrosk, Ukraine (3.2 million people in metro and surrounding areas). If successful, it may be scaled country wide.

5- The government of Peru reached out to me yesterday. I hope to connect today.

6- I have been contacted by officials from Moscow and had a conference with the country's leading doctors. Im not sure what they have decided.

7- Leading doctors in France have petitioned the French president 2 days ago to adopt my protocols. Not sure of the impact.

Dear Doctor Zelenko,

I am writing on behalf of Ambassador Ernesto Araújo, Foreign Minister of Brazil.

We would very much like to establish contact between you and Brazil´s team of doctors who are on the forefront of the coronavirus treatment, for the purpose of sharing findinds and other relevant information. Doctors in Brazil have administered hydroxicloroquin to over 60 thousand patients.

Please let me know if you would be interested in this and what channel of communication would be most convenient. I understand how busy you must be at this time. Feel free to reach me via whatsapp on the number listed here.

Best regards,

Flavio Sapha
Advisor to the Minister
Ministry of Foreign Affairs of Brazil

+[redacted]

Information from France

Dr. Jerome Corsi / Dr. Zelenko - national podcast

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fyoutu.be%2FZ7SDemHGl8U&data=02%7C01%7C%7Cccf4839c1c764955c70008d7dae82eaa%7C84df9e7fe9f640afb435aaaaaaaaaaaa%7C1%7C0%7C637218563051737584&sdata=TwSM4OffZVfIrP8LZPZuq0eWaPSHuHiQzhjVy12AbjY%3D&reserved=0

Mayor Giuliani / Dr. Zelenko - Podcast

https://www.youtube.com/watch?v=1TJdjhd_XG8

Recent Reuters article

https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmobile.reuters.com%2Farticle%2Famp%2FidUSKBN21O2VO&data=02%7C01%7C%7Cb4504a2c3c3f4118593308d7daef5376%7C84df9e7fe9f640afb435aaaaaaaaaaaa%7C1%7C0%7C637218593733416902&sdata=8JiwFOg9E6LCkYY32MwoMI1BtCq7ARj3Zh%2Fshvm3NRo%3D&reserved=0

On-line physician petition / rational for treatment

https://docs.google.com/document/d/1ka76CL50hR_a0b5oIhEAVY4gfyqkJcBxXBcP0r2nrz0/edit?fbclid=IwAR0ss1p0lsPhLkSFhO6_8vJK19BUispAREVcn0oi09iajG-Pq4HDCMFTQdg

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Israel approval of use hcq

https://www.ynet.co.il/articles/0,7340,L-5696160,00.html

Ukraine proposal

Dr Zelenko,

This is the original idea that we sent Rabbi Kaminetzki in Ukraine.

Please understand it was a proposal and obviously we did not make any commitment to them regarding you and your time. All we said is that we will endeavor to have a call with Dr Zelenko. Of course if a longer term relationship is envisioned, compensation should certainly be part of it. Just wanted to get that out of the way!

This is going to hit Ukraine.
To save Ukraine's elderly, it is urgent that a task force be formed to utilize private resources to deploy Dr. Zelenko's drug regimen.

The needs are as follows:
• Test kits
• Personal protection for front line medical personal
• Zelenko drug regimen

Re the Drug regimen
Dr Zelenko will remotely oversee the drug program; meaning he will make a video in Russian/Ukrainian explaining his methods so Ukrainian doctors can follow and Zelenko is to be availble for consultations.

Community of Dnipro will be responsible to distribute drugs, PPE and test kits to the local hospital and clinics.

A register of elderly high risk patients will be created that will be monitored and overseen by a team of doctors overseen by Zelenko.
Data will have to be updated daily so that Zelenko and his team can do virtual rounds...
A procurement team needs to be setup and endowed with resources to acquire the neccessary drugs and equiment

If you think the above is possible you would need to get the following:
Buy-in from Ukrainian govt
Manage the distribution

Once this program to save the elderly of Ukraine is anounced, it is likely other oligarchs will line up to contribute.

There are 7.4 million people ages 65+
Zelenko guestimates that his drug regimen costs $20 per person. Say together with increase in drug price and PPE it's $30 per person. That's a total of $222 million. Private contributions should be sources for half of the amount I.E. 111 million and the government matches them.

Being that not everybody becomes infected and not all infected are in need of hospital. This can end up benefiting the entire Ukraine....but for marketing purposes we focus only the elderly .

Best, Mendel

PS I am thinking big. Though I must say It's possible that group in Dnipro will want to limit this to just the Jewish population they serve.

Lettre ouverte à Monsieur le Président de la République[1]

Monsieur le Président de la République,

La pandémie Covid-19 est foudroyante dans notre pays. Le nombre de patients infectés et de décès double tous les trois jours. L'hydroxychloroquine, qui était en vente libre en France depuis 40 ans, a fait la preuve empirique de son efficacité et les autorités de nombreux pays dont les USA autorisent sa prescription en ambulatoire.

Vos meilleurs atouts sont aussi nos médecins de ville, pour autant qu'ils soient en capacité d'agir. Le préalable exigé d'un *"Gold Standard"* de la preuve nous paraît incompatible avec la déferlante que nous subissons.

Nous savons que la précocité d'un traitement chez les personnes à risque est la clé pour prévenir une pneumonie quasi-incurable. En se propageant de la rhinite à la pneumonie, la réplication du virus devient immaîtrisable.

La contagiosité de ce virus s'est avérée bien plus importante qu'imaginé initialement, tout comme la distance de transmission aujourd'hui sous-évaluée, à un mètre. Le confinement physique, sauf à être très strict, est aujourd'hui insuffisant et il faut y ajouter un confinement chimique par la réduction de la période de portage.

Traiter les malades précocement permet donc dans le même temps de circonscrire la transmission du virus en diminuant la durée de portage, donc de contagiosité,

Les médecins généralistes sont aujourd'hui interdits de prescrire des médicaments curatifs à leurs patients, alors qu'ils sont autorisés (décret du 28 mars) à utiliser le clonazépam injectable.

En restituant aux médecins leur liberté de prescrire en leur âme et conscience, vous leur témoignerez votre confiance.

Qui oserait vous reprocher d'avoir remis la responsabilité de la décision médicale à sa vraie place ? Faut-il se résigner aux aléas du désordre civil, aux risques de l'automédication voire au trafic de médicaments contrefaits et parfois mortels ?

Le traitement ambulatoire précoce incluant l'hydroxychloroquine en bithérapie avec l'azithromycine (voire mieux, en trithérapie avec un complément de Zinc) est maintenant

[1] Propager cette lettre à d'autres médecins avec l'URL: https://bit.ly/extensionATU

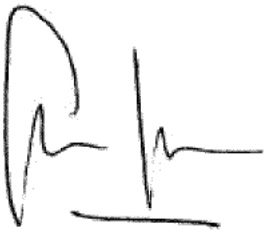
recommandé dans presque tous les autres pays touchés, pour tout patient dyspnéique ou présentant une comorbidité identifiée comme facteur aggravant.

Les médecins chinois ont ouvert la voie de l'utilité des chloroquines. Une équipe française - référence mondiale en matière d'épidémies - a optimisé cette voie de traitement curatif précoce par l'ajout d'azithromycine, et les résultats sont prometteurs. Réserver ce traitement aux formes avancées voire critiques est incompréhensible aux cliniciens de terrain.

Au vu des circonstances et de ce qui précède, et dans le but d'éviter toute perte de chances aux Français, nous vous demandons de prendre en considération l'urgence d'étendre à la médecine de ville l'autorisation temporaire d'utilisation pour l'hydroxychloroquine, l'azithromycine, et le Zinc, ainsi que d'autres antiviraux.

Dans cette attente, nous vous prions d'agréer, Monsieur le Président de la République, l'expression de notre profond respect.

Au nom des signataires[2]: Docteur Gérard BAPT, le 2 Avril 2020



Je demande l'extension à la médecine de ville de l'ATU "Covid-19"

Le bouton vous redirige vers un formulaire qui exige d'être enregistré avec un compte google. Ceci permet de vérifier l'identité des signataires et l'unicité des signatures.
En l'absence de compte google, votre nom pourra figurer sur une liste séparée. Nous demandons dans ce cas un numéro de téléphone portable.
Vos coordonnées ne seront en aucun cas communiquées à des tiers et seront exclusivement utilisées pour soutenir cette demande urgente et vous informer des suites. ***Seuls seront accessibles publiquement les informations suivantes: Prénom, Nom et spécialité***

112 Signataires

[2] Note: cette lettre est le résultat d'une rédaction participative par une centaine de médecins d'un groupe Whatsapp ad hoc, sur la base du texte proposé par le Dr Jean-Claude Ghaleb, qui en a aussi coordonné la mise au point finale avec le Dr Gérard Bapt, avec l'aide de M. Philippe Tarbouriech.
La signature de cette lettre ouverte est maintenant proposée à tout médecin qui le souhaite.
Si vous n'êtes pas médecin il existe des pétitions en ligne à ce sujet par exemple https://www.petition-chloroquine.fr/

A PROPOSAL FOR AN ALTERNATIVE COVID-19 STRATEGY FOR FRANCE

NOTE: this document initiated by the author is now a collaborative tool open to remarks and suggestions for improving it

Inspiration: **"ONE MUST WORK"** (Pr. Didier RAOULT's motto)

Here are a few ideas for a strategy to control the French Covid epidemic, taking into account the tools available and their respective strengths and deficiencies, **HERE and NOW**. We cannot at this stage aim for the response of countries such as Taiwan, Singapore, South Korea, Germany, Marseille or Morocco to name a few.

COMMUNITY MEDICINE:

At this stage, the role of general practitioners, exposed to severe illnesses by repeated virus inoculum, is restricted by decree to prescribe paracetamol (acetaminophen) instead of doing their job, often having to apologize (while sometimes being harrassed) for not being able to treat the sick.

As long as there is no TUA (Temporary Use Authorisation) and restoration of freedom of prescription, GPs transformed into health officers should REFUSE to receive in their office any suspicious Covid cases, except obviously in "Covid centres (for example out-of-hours GP service where you only do that BUT which are equipped for that).

It is the only currently ETHICAL solution because, despite all the Standard Infection Control Precautions, you cannot in a GP practice guarantee the absence of inter-patient contamination

WHAT TESTING STRATEGY

Unless it is to deploy a Korean type strategy, which France has proved incapable of until now, it is preferable to give up PCR testing, except in the context of clinical trials.

These tests expose the personnel who carry them out to unwarranted risks. Let's follow clinical signs:

- In the presence of symptoms, we treat, taking the risk of treating people not affected by Covid19. The circumstances and the almost non-toxic nature of the treatment make this risk ethically acceptable
- In the absence of any symptom, we do not treat (see below)

If we restore primacy to the clinical exam, the decisional imperative to use PCR tests is nullified, except the context of clinical trials with a scientific aim.

Given its rarity, the delay in reporting results (> 3 days in some clusters), the cost of PCR tests and their low sensitivity (60% most often), they are no longer worth a clinical examination followed by a possible decision to treat.

In fact, clinical signs are now fairly well known including by the public (cough and/or fever and/or dyspnea and/or chest pain and/or diarrhoea without cause, with higher evidence criteria if a pathognomonic sign is associated: anosia (loss of sense salty taste), ageusia or unobstructed-nose anosmia).

In addition, the ZELENKO tri-therapy has demonstrated safety and effectiveness both individually and collectively, since it combines 100% healing/survival AND the acquisition of group immunity in the cluster.

Our best option is certainly to treat based on physical, the examination limited to eliminating another cause requiring another treatment (in particular pneumococcal pneumonia requiring amoxicillin, non-Covid pericarditis, spontaneous pneumothorax, lung cancer, peritonitis, etc.).

If in doubt, the chest CAT scan or even thoracic-abdominal scan will decide.

WHAT TREATMENT?

The treatment from Marseille, invented by Didier RAOULT's team (hydroxychloroquine and azithromycin combination), seems sufficient at the population level (breaking the pandemic exponential by reducing the duration of contagiousness from 20 to 6 days and by reducing the viral mass of the cluster).

The therapeutic strategy, established on this basis by Dr ZEV ZELENKO, GP in the state of New York, is a comprehensive and effective approach to constrain the overall viral mass, AND AT THE SAME TIME enable group immunity building within a cluster:

- first-line treatment: focus only on at-risk patients, and allow others to develop the disease by confining themselves,

- from THE first symptom: tri-therapy combining ZINC (hydroxychloroquine is a Zinc ionophore) with Marseille dual therapy is currently the most effective, since this general practitioner's team (himself in isolation because of a pneumonectomy) treated 350 patients in his cluster with ZERO hospitalizations and ZERO deaths!) .

IT IS ESSENTIAL TO CROSS CHECK THE INFORMATION ABOUT THE ZELENKO ET AL SERIES.

- ECG (QT corrected) and a serum potassium concentration prior to the initiation of treatment are indicated regardless of age. A blood group can be added (group A is more prone to severe forms)

- In case of contraindication (allergies, interactions, long QT, ;-) etc.) we can switch to Kaletra (+ Zinc?) at the cost of painful side effects.

WHAT CONTAINMENT?

This is the only point that becomes obsolete:

- if we apply the right treatment (Zelenko inspired by IHU / Marseille)

- at the right time (first symptom)

- to the right people (classified as at risk by the Chinese)

- while building group immunity by letting the virus run its course in healthy young people

- provided they avoid meeting fragile people and if necessary self-isolate

WHAT MEDICAL CARE SYSTEM?

France should immediately prioritize the use of the intensive care and care capacities of all hospitals, both public AND private, rather than transporting seriously ill patients from one region to another. Let's optimize our resources!

Dr Jean-Claude GHALEB

March 28, 2020

“"A GP IS A DOCTOR WHO KNOWS ALMOST NOTHING ABOUT ALMOST EVERYTHING”

From: Zelenko Family (b) (6)
Sent: 4/26/2020 3:17:25 AM
To: Jerome R. Corsi (b) (6); David Shmuel Greenstein (b) (6); 'Joe Levine' (b) (6); Larisa Zelenko (b) (6); Moshe (b) (6); (b) (6); Mark Meadows (b) (6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; morris steinberg (b) (6); Thakore, Avni (b) (6)
Subject: new paper published my world famous German researchers

https://www.preprints.org/manuscript/202004.0124/v1

From: Zelenko Family (b) (6)
Sent: 4/30/2020 11:08:34 PM
To: Jerome Corsi Ph. D. (b) (6); morris steinberg (b) (6); Moshe (b) (6); (b) (6); mark Meadows (b) (6); (b) (6); David Shmuel Greenstein (b) (6); Gregory Rigano (b) (6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Martin Scholz (b) (6); Roland Derwand (b) (6)
Subject: Fwd: WCBS-TV NEWS EXCLUSIVE REPORT ON Dr. Zelenko and Hydroxychloroquine
Attachments: clip_image001.png; ATT00001.htm; S. Korea Study of Prophylaxis.pdf; ATT00002.htm; Brazil 2020.04.15 journal manuscript final.pdf; ATT00003.htm

Sent from my iPhone

Begin forwarded message:

From: Alexander Roberts (b) (6)
Date: April 30, 2020 at 10:17:11 PM EDT
Subject: WCBS-TV NEWS EXCLUSIVE REPORT ON Dr. Zelenko and Hydroxychloroquine

Dear Friends:

Some of you have been following my efforts to allow doctors, **if they choose**, to prescribe Dr. Vladimir Zelenko's treatment of hydroxychloroquine, azithromycin and zinc for early treatment of COVID-19 because of his excellent results in keeping elderly and high risk patients out of the hospital. I have been dismayed at some media reports on the Left and the Right, which have made the drug a political football, conflating the science with President Trump's promotion of the drug ("Take it. What do you have to lose?"). The fact is that hydroxychloroquine is a drug prescribed hundreds of millions of times over 50 years and which the FDA considers safe and effective for Malaria, Lupus and Rheumatoid Arthritis.

Tonight, Carolyn Gusoff of WCBS-TV News did a fair report on Dr. Zelenko and the FDA's approval of a clinical trial at a hospital on Long Island for his three-part therapy:

https://newyork.cbslocal.com/2020/04/30/coronavirus-exclusive-meet-the-doctor-behind-the-hydroxychloroquine-treatment-for-covid-19/

Instead of allowing use of the drug cocktail when Dr. Zelenko and some clinical studies say it is most effective—taken early upon symptoms of COVID-19 by a high risk individual—Governor Cuomo has made it nearly impossible for patients to obtain the drug early by requiring them to enroll in a clinical trial at a hospital after a test that can take several days. Dr. Zelenko feels it is not effective once the disease has time to damage the lungs, and that is consistent

with some of the studies. In addition, he says that the zinc is critical, since it's a proven anti-viral.

While the three-drug cocktail including hydroxychloroquine is still unquestionably an "unproven" treatment, there is **no approved treatment** and as such, should patients with a potentially fatal disease be denied the choice of **something** that may help? According to Dr. Richard Zeckhauser, a professor of economics and decision theory at Harvard's Kennedy School, and *M*aryaline Catillon, formerly a hospital director in France, waiting for results of Randomized Clinical Trials "is inappropriate" with 1,500 people dying every day…

https://www.hks.harvard.edu/centers/mrcbg/news-events/COVID_Zeckhauser

I am perplexed as to why, with so many people dying of COVID-19, Governor Cuomo and his Health Commissioner Howard Zucker have shown no interest in verifying or debunking Dr. Zelenko's claims, even after he released all of his patient data at my request. If it turns out that this well studied drug IS effective taken early in the disease, our leaders will have to answer for the deaths of thousands by preventing doctors from prescribing the drug "off-label," which is frequently allowed for other drugs.

If you are interested, I've attached two **recent clinical studies** on hydroxychloroquine (one in South Korea and another from Brazil) that got no play in the media.

All the best,

Alec

Alexander H. Roberts

Executive Director

Community Housing Innovations, Inc.

75 South Broadway, Suite 340

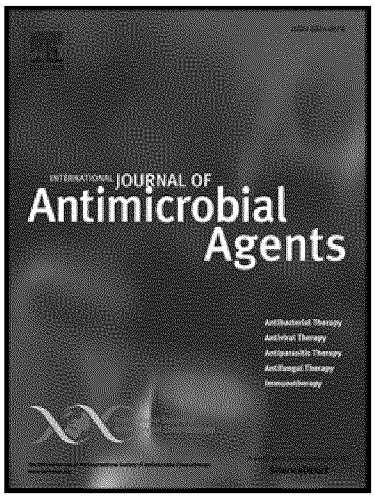
White Plains, NY 10601

Office: (914) 683-1010 ext. 1227

Fax: (914) 683-6158

To Donate: https://interland3.donorperfect.net/weblink/weblink.aspx?name=E341690&id=1

Alexander Roberts
(b) (6)
(b) (6)



Can post-exposure prophylaxis for COVID-19 be considered as one of outbreak response strategies in long-term care hospitals?

Sun Hee Lee , Hyunjin Son , Kyong Ran Peck

PII: S0924-8579(20)30145-X
DOI: https://doi.org/10.1016/j.ijantimicag.2020.105988
Reference: ANTAGE 105988

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From: Stephen M. Smith, MD (b) (6) [redacted]
Sent: 4/16/2020 8:17:42 PM
To: Brennan, Patti F (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb26df910bc248c29413116e2bf67cdf-HHS-patti.b]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Who vetted the HCQ dosing article

Hello Patti, Keagan & Stephen,
I, quite by unintentionally, ended up reviewing the article, published by CID on March 9th by Yao et al. You all apparently used to set the dosing regimen for HCQ.
This decision was a very bad one for many reasons, the simplest of which is that you have US docs giving the same dose to 88 lbs. 90 year-old women as 360 lbs. 45 year-old men. I have treated over 3 in each group. One definitely is and both may be receiving the wrong dose.
Many studies on HCQ in preDM used and use weight based dosing.
These are FDA-approved studies.
There are other FDA-approved clinical studies which use much higher daily and very much greater total HCQ doses than that you approved for COVID-19. For instance, the FDA approved 1 gram per day of HCQ in some stage 4 cancer trials.

I would like to know how you vetted this dosing regimen for COVID-19.
Did you simply rely on Yao et al.?
Hopefully not.
By the way, did anyone from the FDA ask the authors about their comment that Yao et al. wrote "In a recent clinical trial 500 mg of chloroquine phosphate given twice daily was shown to be effective on study day 5".

My background in virology is in HIV-1 and HIV-2/SIV. I don't remember PK specialists relying on EC50's to assess compounds, which had activity against HIV-1.
Yet, that's only one of the things Yao et al. did wrong.
I cannot remember ever reading a serious scientific article that used both molarity and mass concentration in different figures or tables. Yao et al. didn't use both; they used either. Yao et al. used a logarithmic scale for his presentation of linear data on HCQ plasma and whole blood levels from 1988 articles. That demonstration of linear data makes no sense. Again, these figures used ng/ml, while the EC50s were calculated in µM.

Next, Yao et al. determined two EC50's - one at 24 hours and one at 48 hours. The former was 8.5 times the latter. The authors, without explanation, chose the much lower one.
Then, the authors used data from two articles done over 37 years ago in rats estimate the HCQ in lungs. They then used some multiplier to determine the concentration of HCQ in lung tissue in their PBK modeling of "therapeutic" levels in the lungs, based on the 48-hour EC50, which, as far as anyone knows lacks clinical relevance. The authors multiplied the expected plasma or blood HCQ level by some factor, not stated in the article or supplemental information, to estimate lung tissue levels and then presented data on these levels as ratios to the EC50. In other words, they multiplied the expected HCQ blood levels by some factor to find the lung tissue concentration. They then divided the lung concentration, which is in mg/kg, by the EC50, which is µM, to determine the ratio of lung:EC50 at several times during the 5-day dosing regimen.
More problems, the 1983 study showed that the HCQ slowly built up slowly over weeks lung and other tissues. The physiologic activity of this build-up is not known. How much, for instance, of the lung HCQ is in the lysosomes and how much is elsewhere?
The other reference was from 1982 and used IP administration HCQ at 10 mg/kg, quite a dose. This article's lung: blood ratio increased more rapidly. Again, the physiologic relevance of the tissue concentration is not

known. The tissue concentration, of course, is mg/kg of tissue, since lung is solid, so it is unclear how Yao et al. used mg/kg to estimate the lung's concentration above their EC50, which is μM.
The authors are right about one thing – HCQ does build up. The total dose of HCQ is the most important over this short time frame.
Hopefully, I am very wrong. Please tell me I am.
Stephen M. Smith, MD

From: Kenneth Fisher (b) (6)
Sent: 9/1/2020 12:03:00 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Make thorough testing at certified labs a requirement for companies that produce sanitizer with alcohol from outside sources

Stephen Hahn
FDA Commissioner

RE: Make thorough testing at certified labs a requirement for companies that produce sanitizer with alcohol from outside sources

null

FDA Commissioner Stephen Hahn:

The number of hand sanitizer brands that have potentially been contaminated with toxic methanol is now at 80 and counting. It's clear we need stronger measures to prevent this public health threat from growing even worse.

I urge you to require companies that produce sanitizer with alcohol from outside sources to conduct product tests in labs that have previously been inspected by the FDA and are compliant. Currently, this testing is only recommended -- but it needs to be mandatory to protect consumers and keep potentially dangerous hand sanitizers off store shelves.

Sincerely,
Kenneth Fisher
(b) (6)

From: Zelenko Family (b) (6)
Sent: 8/16/2020 8:20:45 PM
To: gacdds (b) (6); George Fareed (b) (6); Harvey Risch (b) (6); Don Pompan (b) (6); Karladine Graves (b) (6); Jerome Corsi (b) (6); (b) (6); Robert Kanner (b) (6); Craig Campbell (b) (6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Suggestion from the nation's leading doctors

Dear Dr. Hahn

Prediction is for 200,00 USA deaths by Labor Day from the 167,000 as of today.

Dr Hahn, we respectfully ask that you instruct the FDA to make the following statement:

"While we wait for the "Gold Standard" clinical trials to be done on HCQ, there is sufficient and enough information to help guide doctors in their practice of prescribing a medication like HCQ. This decision is between the doctor and patient and FDA does not regulate the practice of medicine. HCQ is already an FDA approved medication and although this approval does not include a specific treatment for Covid-19, there is sufficient and enough information to justify it's "off-label" use until a company submits data to FDA for an additional use in Covid-19 patients." If this action is taken promptly, 30,000 or more USA lives can still be saved and many more than that number spared the agony of prolonged hospitalizations and probable permanent disabilities.

Respectfully,

Dr. Vladimir Zelenko