SARS-CoV-2 update

February 2021

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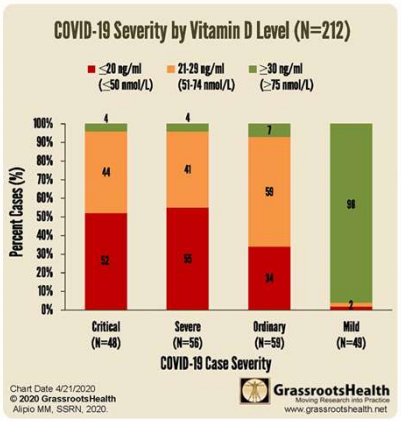
What do we know?

1. Common Symptoms
- Fever
- Cough
- Headaches
- Fatigue
- Muscle or body aches
- Loss of taste or smell
- Sore throat
- Nausea
- Diarrhea

2. How it spreads
- By respiratory droplets from an infected person or surface

3. Are masks effective?
- Generally, no.

4. There is a negative correlation between vitamin D levels and severity of infection



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What do we know?

5. SARS-Cov-2 binds to ACE2 receptors

6. Vitamin D increases expression of ACE2 receptors, maintains immune system homeostasis, and prevents development of autoimmune processes

7. As seen with other coronaviruses, having COVID once results in long-term immunity in most people.

8. Children are spared due to immature respiratory epithelium.

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Immune system support

- **Vitamin D3 (Bio D Mulsion Forte)** - Receptors for vitamin D are found on the surface B cells, T cells, and white blood cells. These cells are capable of synthesizing the active vitamin D metabolite. Vitamin D can modulate both the TH1 and the TH2 arms of the immune system.
- **Zinc (Zn Zyme Forte)** - This mineral is a co-factor for up to 300 enzyme systems. It has been shown to be clinically effective in protecting against coronavirus infections. "Some 90% of the population consume diets deficient in zinc," according to Denham Harmond M.D., Ph.D. considered to be the Father of the Free -Radical Theory of Aging.
- **Vitamin C (Bio C Plus)** - This is one of the most powerful and important nutrients for humans. It is a water-soluble, chain-breaking antioxidant that interacts with glutathione and alpha-lipoic acid, and regenerates Vitamin E, leading to increased activity of macrophages, the white blood cells that remove pathogens from your system.
- **Quercetin (Bio FCTS)** - This is a plant-based antioxidant that works to drive zinc into the cell. It has a similar mechanism of action as HCQ to improve immune system functioning. https://pubs.acs.org/doi/full/10.1021/jf5014633
- **N-acetyl-L-cysteine** - NAC has antioxidant, anti-inflammatory and immune-modulating characteristics that may prove beneficial in the treatment and prevention of SARS-Cov-2. https://pubmed.ncbi.nlm.nih.gov/33177829/

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What do other doctors say?

Dr. Simone Gold, MD - Prophylactic HCQ protocol:

- Hydroxychloroquine 400 mg. twice a day on the first day + elemental zinc 50 mg. daily then
- Hydroxychloroquine 400 mg. weekly + zinc 50 mg. daily

Dr. Teryn Clark, MD - Wellness protocol:

- Quercetin 500 mg twice daily
- Zinc 50 mg daily
- Vitamin D 2000 IU daily
- Melatonin 3-6mg nightly

https://www.americasfrontlinedoctors.com/treatment-protocols/

Dr. Dietrich Klinghardt, MD, PhD also suggests the above lists and:
Vitamin D, Propolis spray, Calendula, Liquorice, Skullcap, Rosemary, Andrographis, Artemisinin (Dysbiocide)
Dandelion
https://klinghardtinstitute.com/wp-content/uploads/2020/03/Dr-Klinghardt-Corona-2020-UK-19th-March-2020.pdf

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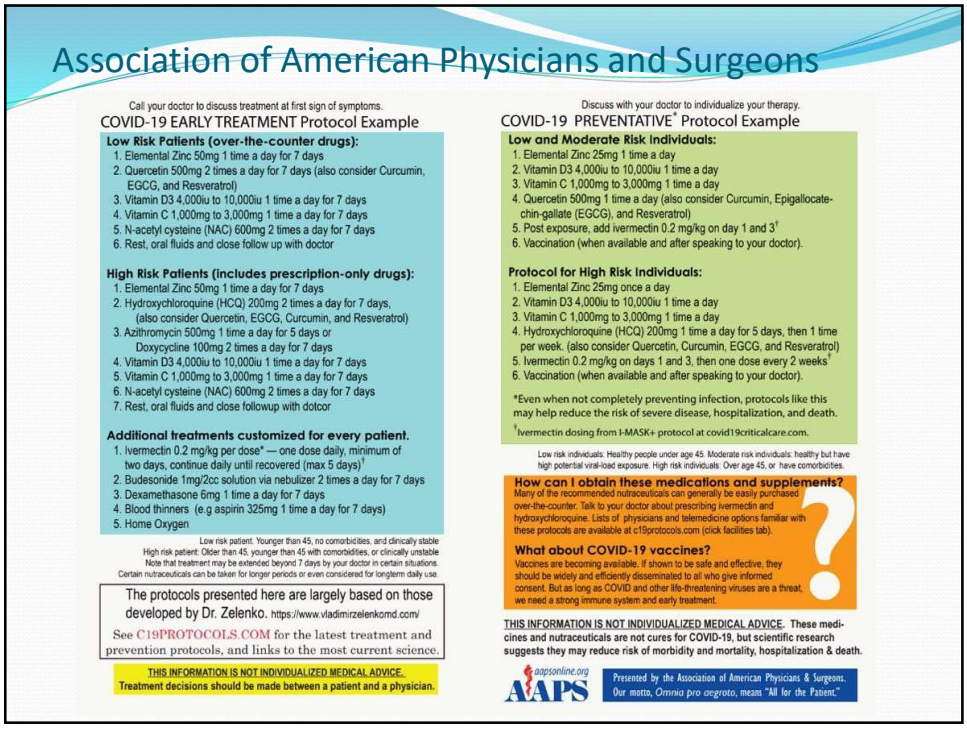
Association of American Physicians and Surgeons
Call your doctor to discuss treatment at first sign of symptoms.
COVID-19 EARLY TREATMENT Protocol Example
Low Risk Patients (over-the-counter drugs):
1. Elemental Zinc 50mg 1 time a day for 7 days
2. Quercetin 500mg 2 times a day for 7 days (also consider Curcumin, EGCG, and Resveratrol)
3. Vitamin D3 4,000iu to 10,000iu 1 time a day for 7 days
4. Vitamin C 1,000mg to 3,000mg 1 time a day for 7 days
5. N-acetyl cysteine (NAC) 600mg 2 times a day for 7 days
6. Rest, oral fluids and close follow up with doctor
High Risk Patients (includes prescription-only drugs):
1. Elemental Zinc 50mg 1 time a day for 7 days
2. Hydroxychloroquine (HCQ) 200mg 2 times a day for 7 days, (also consider Quercetin, EGCG, Curcumin, and Resveratrol)
3. Azithromycin 500mg 1 time a day for 5 days or Doxycycline 100mg 2 times a day for 7 days
4. Vitamin D3 4,000iu to 10,000iu 1 time a day for 7 days
5. Vitamin C 1,000mg to 3,000mg 1 time a day for 7 days
6. N-acetyl cysteine (NAC) 600mg 2 times a day for 7 days
7. Rest, oral fluids and close followup with dotcor
Additional treatments customized for every patient.
1. Ivermectin 0.2 mg/kg per dose* — one dose daily, minimum of two days, continue daily until recovered (max 5 days)†
2. Budesonide 1mg/2cc solution via nebulizer 2 times a day for 7 days
3. Dexamethasone 6mg 1 time a day for 7 days
4. Blood thinners (e.g aspirin 325mg 1 time a day for 7 days)
5. Home Oxygen
Low risk patient: Younger than 45, no comorbidities, and clinically stable
High risk patient: Older than 45, younger than 45 with comorbidities, or clinically unstable
Note that treatment may be extended beyond 7 days by your doctor in certain situations.
Certain nutraceuticals can be taken for longer periods or even considered for longterm daily use.
The protocols presented here are largely based on those developed by Dr. Zelenko. https://www.vladimirzelenkomd.com/
See C19PROTOCOLS.COM for the latest treatment and prevention protocols, and links to the most current science.
THIS INFORMATION IS NOT INDIVIDUALIZED MEDICAL ADVICE.
Treatment decisions should be made between a patient and a physician.
Discuss with your doctor to individualize your therapy.
COVID-19 PREVENTATIVE* Protocol Example
Low and Moderate Risk Individuals:
1. Elemental Zinc 25mg 1 time a day
2. Vitamin D3 4,000iu to 10,000iu 1 time a day
3. Vitamin C 1,000mg to 3,000mg 1 time a day
4. Quercetin 500mg 1 time a day (also consider Curcumin, Epigallocate-chin-gallate (EGCG), and Resveratrol)
5. Post exposure, add ivermectin 0.2 mg/kg on day 1 and 3†
6. Vaccination (when available and after speaking to your doctor).
Protocol for High Risk Individuals:
1. Elemental Zinc 25mg once a day
2. Vitamin D3 4,000iu to 10,000iu 1 time a day
3. Vitamin C 1,000mg to 3,000mg 1 time a day
4. Hydroxychloroquine (HCQ) 200mg 1 time a day for 5 days, then 1 time per week. (also consider Quercetin, Curcumin, EGCG, and Resveratrol)
5. Ivermectin 0.2 mg/kg on days 1 and 3, then one dose every 2 weeks†
6. Vaccination (when available and after speaking to your doctor).
*Even when not completely preventing infection, protocols like this may help reduce the risk of severe disease, hospitalization, and death.
†Ivermectin dosing from I-MASK+ protocol at covid19criticalcare.com.
Low risk individuals: Healthy people under age 45. Moderate risk individuals: healthy but have high potential viral-load exposure. High risk individuals: Over age 45, or have comorbidities.
How can I obtain these medications and supplements?
Many of the recommended nutraceuticals can generally be easily purchased over-the-counter. Talk to your doctor about prescribing ivermectin and hydroxychloroquine. Lists of physicians and telemedicine options familiar with these protocols are available at c19protocols.com (click facilities tab).
What about COVID-19 vaccines?
Vaccines are becoming available. If shown to be safe and effective, they should be widely and efficiently disseminated to all who give informed consent. But as long as COVID and other life-threatening viruses are a threat, we need a strong immune system and early treatment.
THIS INFORMATION IS NOT INDIVIDUALIZED MEDICAL ADVICE. These medicines and nutraceuticals are not cures for COVID-19, but scientific research suggests they may reduce risk of morbidity and mortality, hospitalization & death.
aapsonline.org
AAPS
Presented by the Association of American Physicians & Surgeons.
Our motto, Omnia pro aegroto, means "All for the Patient."

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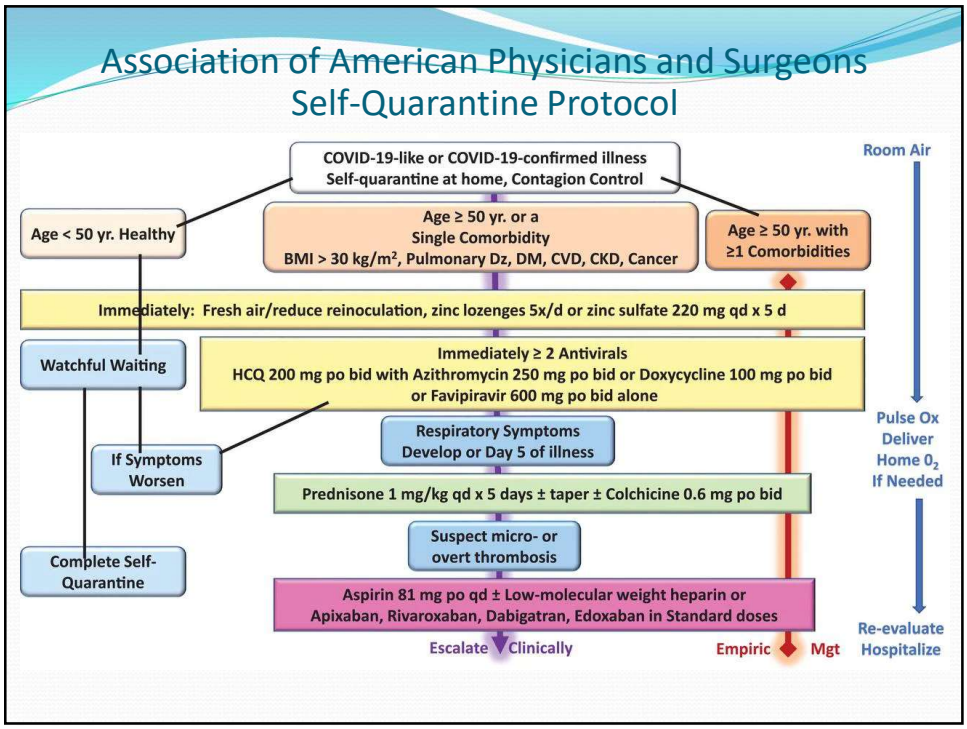
Association of American Physicians and Surgeons
Self-Quarantine Protocol
COVID-19-like or COVID-19-confirmed illness
Self-quarantine at home, Contagion Control
Room Air
Age < 50 yr. Healthy
Age ≥ 50 yr. or a
Single Comorbidity
BMI > 30 kg/m², Pulmonary Dz, DM, CVD, CKD, Cancer
Age ≥ 50 yr. with
≥1 Comorbidities
Immediately: Fresh air/reduce reinoculation, zinc lozenges 5x/d or zinc sulfate 220 mg qd x 5 d
Watchful Waiting
Immediately ≥ 2 Antivirals
HCQ 200 mg po bid with Azithromycin 250 mg po bid or Doxycycline 100 mg po bid
or Favipiravir 600 mg po bid alone
Respiratory Symptoms
Develop or Day 5 of illness
Pulse Ox
Deliver
Home O2
If Needed
If Symptoms
Worsen
Prednisone 1 mg/kg qd x 5 days ± taper ± Colchicine 0.6 mg po bid
Suspect micro- or
overt thrombosis
Complete Self-
Quarantine
Aspirin 81 mg po qd ± Low-molecular weight heparin or
Apixaban, Rivaroxaban, Dabigatran, Edoxaban in Standard doses
Re-evaluate
Hospitalize
Escalate Clinically
Empiric Mgt

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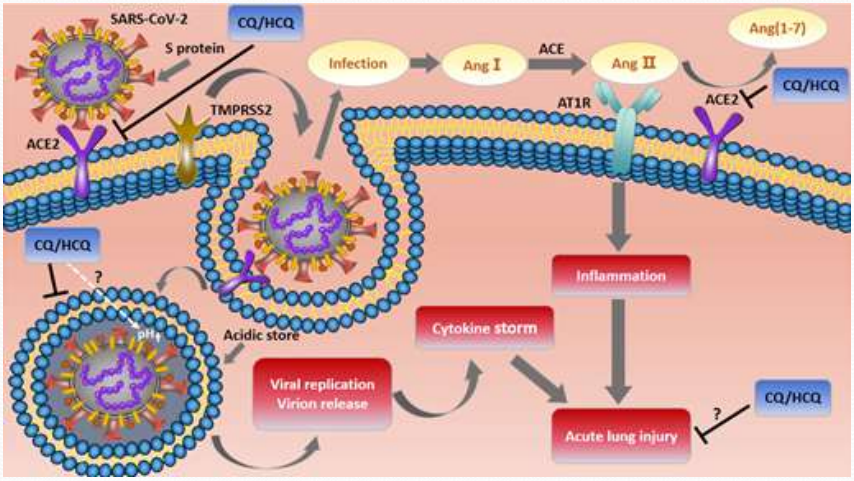
How does HCQ / CQ work?



https://academic.oup.com/function/article/1/2/zqaa012/5876834)

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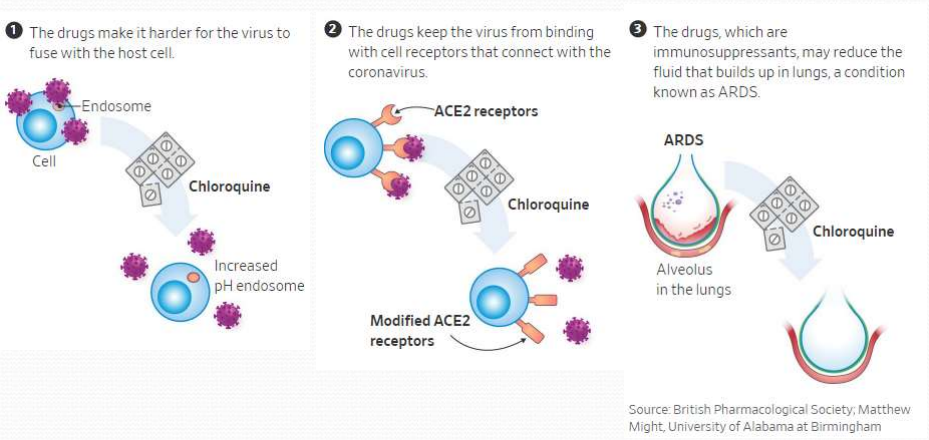
How does chloroquine work?



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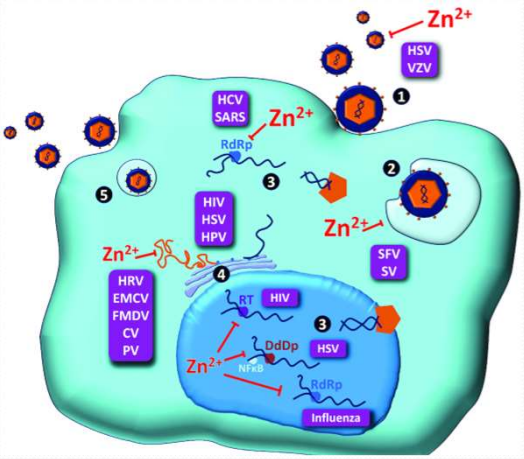
HCQ / CQ acts as a zinc ionophore



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Chloroquine is a Zinc Ionophore

- "Free zinc ions are more concentrated in the lysosomes after addition of chloroquine, which is consistent with previous reports showing that chloroquine inhibits lysosome function. The combination of chloroquine with zinc enhanced chloroquine's cytotoxicity and induced apoptosis in A2780 cells. Thus chloroquine is a zinc ionophore."
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4182877/
- The main function of lysosomes is to help with cell metabolism by ingesting and dissolving unwanted parts of the cell, cell debris, or foreign substances that have entered the cell.
- A zinc ionophore is a chemical which carries zinc ions through the cell membrane. Elemental zinc cannot pass through the cell membrane on its own. Once zinc is inside the cell, it can inhibit the RNA polymerase activity of coronaviruses, i.e. it blocks viral replication.

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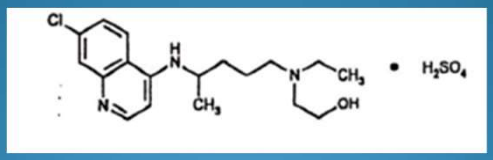
Data on HCQ/CQ



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S. Korea and China used chloroquine

- March 13, 2020
- "Recent guidelines from South Korea and China report that chloroquine is an effective antiviral therapeutic treatment against Coronavirus disease 2019. The use of chloroquine (in tablet form) is showing favorable outcomes in humans infected with Coronavirus, including faster recovery times and a shorter hospital stay."

An effective treatment for coronavirus (COVID-19)

- Presented by: James M. Todaro, MD (Columbia MD, jtodaro2@gmail.com) and Gregory J. Rigano, Esq. (Grigano1@jhu.edu)
- **In consultation with researchers from Stanford University School of Medicine, UAB School of Medicine and the National Academy of Sciences.**
- https://docs.google.com/document/d/e/2PACX-1vSjPNh_WX6FXUIE3OaA3ScsW7yIH3-SpZyYzElNQUNuJvDmD9eFzM29mVXeaYRY-rjGv52wkrZNa7tb/pub

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Clinical study of HCQ + Azithromycin

- International Journal of Antimicrobial Agents
- June 30, 2020
- "Our survey shows that hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in COVID-19 patients and its effect is reinforced by azithromycin."
- 100% of patients that received a combination of HCQ and Azithromycin tested negative and were virologically cured within 6 days of treatment.
- Azithromycin added to HCQ was significantly more efficient for virus elimination
- https://www.sciencedirect.com/science/article/abs/pii/S0924857920300996?via%3Dihub

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Hydroxychloroquine

European Journal of Clinical Microbiology & Infectious Disease, June 2020:

- "In a preliminary clinical study, we observed that the combination of hydroxychloroquine and azithromycin was effective against SARS-CoV-2 by shortening the duration of viral load in Covid-19 patients."

https://pubmed.ncbi.nlm.nih.gov/32342252/

The Lancet, Nov. 5, 2020:

- "Hydroxychloroquine has been shown to inhibit entry of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) into epithelial cells in vitro."

https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913%2820%2930378-7/fulltext

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Problems with most HCQ studies:

- Huge, toxic doses given
- No Zinc is given
- The combination is given to patients too late, i.e. after the cytokine storm has begun
- Issues with data collection

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HCQ + Azithromycin + Zinc:

Outcomes in hospitalized Covid-19 patients

- May 8, 2020
- "Zinc sulfate increased the frequency of patients being discharged home, and decreased the need for ventilation, admission to the ICU, and mortality or transfer to hospice for patients who were never admitted to the ICU."
- NYU Grossman School of Medicine

https://www.medrxiv.org/content/10.1101/2020.05.02.20080036v1.full.pdf

This further confirms the theory that the combination of HCQ and Zn has an antiviral effect. Antiviral medications work by blocking the replication of viruses. Once the cytokine storm begins, and the virus has reached its peak in an individual, antiviral medications are useless.

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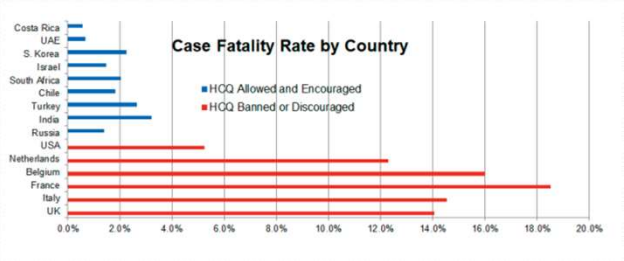
HCQ

- • Countries where HCQ is widely available, which are typically third world countries that have malaria or citizens who travel to malaria-endemic regions, have 1-10% of the death rates of first world nations where HCQ is severely restricted.
- • HCQ availability correlates with COVID-19 death rates. We see this across the world and amongst USA states.
- • A typical headline from the Washington Post April 6, 2020 was that Africa was going to be decimated by this virus. "Coronavirus presents a crisis for Africa" and per the UN: "Pandemic crisis may kill up to 3.3 million Africans." (It is 1-2% of that.)
- • Contrary to expert predictions and media headlines, the lowest death rates from COVID-19 are in the poorest countries with no masking, no social distancing, limited medical care, no ICUs … but with easy access to hydroxychloroquine/chloroquine.



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There is a dramatic difference in saving lives in countries allowing early and prophylactic use of hydroxychloroquine compared with the United States:

Country	HCQ Policy	Mortality rate per COVID-19 case	COVID-19 deaths per 1M population
U.K.	HCQ is discouraged and mostly unavailable	14%	628
Italy	HCQ's value was not known for the many initial casualties	14.5%	573
France	HCQ is officially disfavored	18.5%	454
U.S.A.	FDA interferes with access to HCQ	5.2%	370
Russia	HCQ is encouraged	1.4%	56
India	HCQ is used prophylactically	3.2%	10
Turkey	HCQ is used as early treatment	2.6%	59
Israel	HCQ is encouraged	1.5%	33
South Korea	HCQ is encouraged	2.3%	5

https://aapsonline.org/judicial/aaps-v-fda-hcq-6-22-2020.pdf

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What is more risky?

Being infected with Covid-19 or being inoculated with the experimental "vaccines"?

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See for most up-to-date values: https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html

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Genetic Vaccines – mRNA

Vaccines that deliver one or more of the coronavirus's own genes into our cells to provoke an immune response.

PHASE 2 | PHASE 3 | COMBINED PHASES

APPROVED IN SEVERAL COUNTRIES | EMERGENCY USE IN U.S., ELSEWHERE

Pfizer BIONTECH

Pfizer-BioNTech: ages ≥16 years

VACCINE NAME: Comirnaty (also known as tozinameran or BNT162b2)
EFFICACY: 95%
DOSE: 2 doses, 3 weeks apart
TYPE: Muscle injection
STORAGE: Freezer storage only at −94°F (−70°C)

PHASE 3

APPROVED IN SWITZERLAND | EMERGENCY USE IN U.S., E.U., ELSEWHERE

moderna NIH National Institutes of Health Turning Discovery Into Health

Moderna: ages ≥18 years

VACCINE NAME: mRNA-1273
EFFICACY: 94.5%
DOSE: 2 doses, 4 weeks apart
TYPE: Muscle injection
STORAGE: 30 days with refrigeration, 6 months at −4°F (−20°C)

*This is the FIRST "vaccine" EVER by Moderna.

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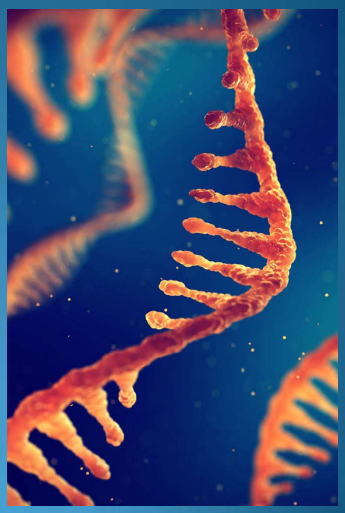
What is mRNA?



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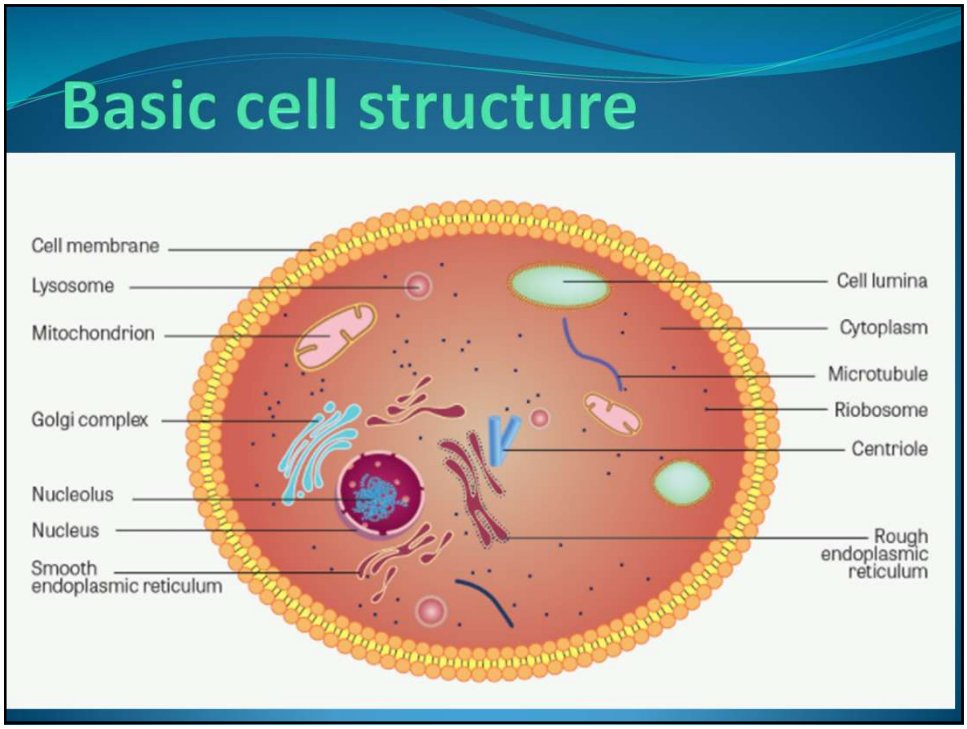

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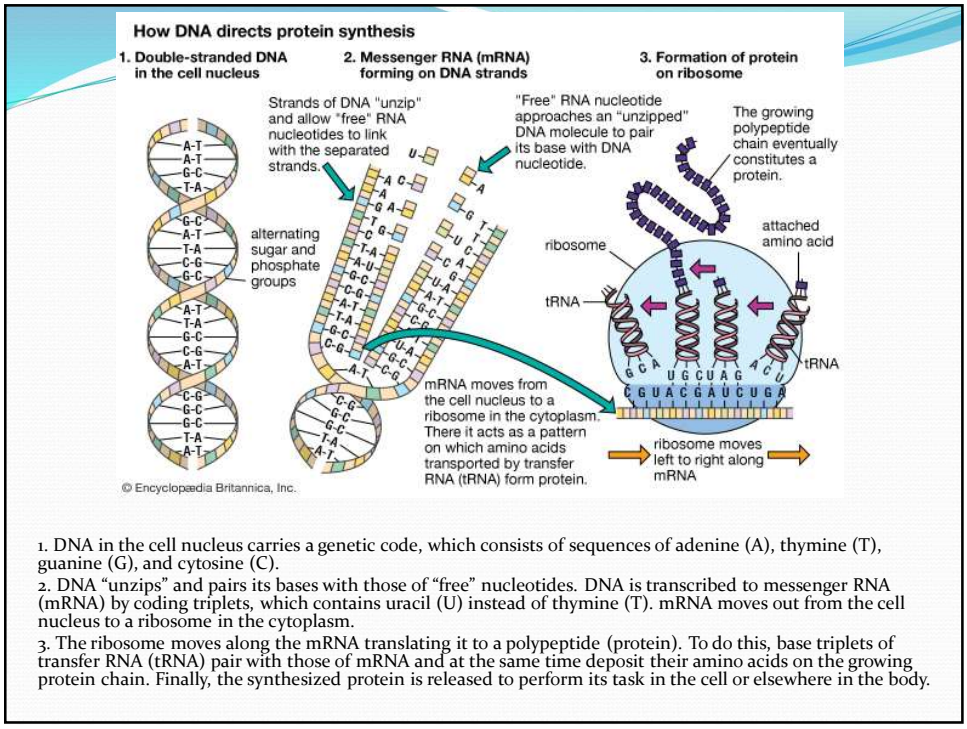

1. DNA in the cell nucleus carries a genetic code, which consists of sequences of adenine (A), thymine (T), guanine (G), and cytosine (C).
2. DNA "unzips" and pairs its bases with those of "free" nucleotides. DNA is transcribed to messenger RNA (mRNA) by coding triplets, which contains uracil (U) instead of thymine (T). mRNA moves out from the cell nucleus to a ribosome in the cytoplasm.
3. The ribosome moves along the mRNA translating it to a polypeptide (protein). To do this, base triplets of transfer RNA (tRNA) pair with those of mRNA and at the same time deposit their amino acids on the growing protein chain. Finally, the synthesized protein is released to perform its task in the cell or elsewhere in the body.

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Will mRNA from "vaccines" permanently alter the body's DNA?

- The official narrative is that mRNA is a temporary molecule that quickly becomes destroyed in the cell

HOWEVER

- RNA can be "reverse transcribed" into DNA
- Enzymes called "reverse transcriptases" can convert RNA into DNA
- This happens with retroviruses such as HIV and Hepatitis B
- Some viruses become hard-wired into our DNA
- (called endogenous retroviruses)
- There is NO evidence to support whether this will or will not happen with the experimental mRNA "vaccines"

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Will mRNA from "vaccines" permanently alter the body's DNA?

- A new study by MIT and Harvard scientists demonstrates that segments of the RNA from the coronavirus itself are most likely becoming a permanent fixture in human DNA.
- There exists a viable cellular pathway whereby snippets of SARS-CoV-2 viral RNA could become integrated into our genomic DNA after natural infection
- The modified genomic DNA is transcriptionally active meaning DNA is being converted back into RNA.
- The study noted that a number of people tested positive for Covid-19 long after the infection was gone, even though they were not re-infected.

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Will mRNA from "vaccines" permanently alter the body's DNA?

- The RNA in "vaccines" is different than the viral RNA, because it is artificially engineered
- "Vaccine" RNA is engineered to be efficient in translating into protein, thereby staying in the cell for a longer period of time
- This increases the probability that it will be integrated into our DNA
- This also increases the probability that negative effects from the "vaccine" are more pronounced than natural infection

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Will mRNA from "vaccines" permanently alter the body's DNA?

- Further, the study found that the nucleocapsid "N" protein was the most likely protein to be integrated into human DNA
- The "vaccine", on the other hand, encodes for the spike "S" protein
- If the "vaccine" mRNA becomes permanently affixed to our DNA through the "reverse transciptase" process, we would be coding for the spike protein
- This could lead to serious autoimmune problems

Zhang, Liguo, Alexsia Richards, Andrew Khalil, Emile Wogram, Haiting Ma, Richard A. Young, and Rudolf Jaenisch. "SARS-CoV-2 RNA reverse-transcribed and integrated into the human genome." *bioRxiv* (2020).
https://sciencewithdrdoug.com/2021/02/15/breaking-study-sheds-more-light-on-whether-an-rna-vaccine-can-permanently-alter-dna/

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Dr. Alexandra Henrion-Caude, French geneticist Director of Research, French Institute of Health and Medical Research, Unit of Genetics and Epigenetics:

- We "cannot anticipate" what may happen with mRNA from "vaccines", because there are many interactions between proteins and various RNA types in the cell
- Take honeybees as an example:
- The queen bee is long and thin, while the worker bees are quite short. Also, their behavior is very different.
- YET, their DNA is the SAME. The only difference between them is their epigenetic settings. Epigenetic modifications can define how genetic information is expressed and used by cells.

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Dr. Alexandra Henrion-Caude, French geneticist

- The official narrative of vaccine manufacturers has "overlooked" this fact in every presentation of how their mRNA "vaccines" will act once inside the cell
- "Maybe it will not have direct genomic consequences, but because inheritance is not only your genome but also the modification around the genome (epigenetic setting), it is biased to only report about the genome."
- Our understanding of the family of RNA molecules in the cell is far beyond the "archaic…simplistic…biased" model being presented by the vaccine manufacturers
- "There is no artificial intelligence tool that can anticipate the variety of molecules ["vaccine" mRNA] can encounter."

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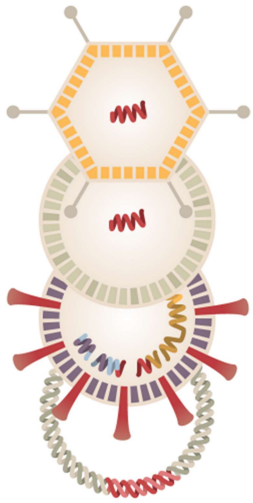
The Vaccine Testing Process

The development cycle of a vaccine, from lab to clinic.



PRECLINICAL TESTING: Scientists test a new vaccine on cells and then give it to **animals** such as mice or monkeys to see if it produces an immune response.

PHASE 1 SAFETY TRIALS: Scientists give the vaccine to a **small number of people** to test safety and dosage, as well as to confirm that it stimulates the immune system.

PHASE 2 EXPANDED TRIALS: Scientists give the vaccine to **hundreds of people** split into groups, such as children and the elderly, to see if the vaccine acts differently in them. These trials further test the vaccine's safety.

PHASE 3 EFFICACY TRIALS: Scientists give the vaccine to **thousands of people** and wait to see how many become infected, compared with volunteers who received a placebo. These trials can determine if the vaccine protects against the coronavirus, measuring what's known as the efficacy rate. Phase 3 trials are also large enough to reveal evidence of relatively rare side effects.

EARLY OR LIMITED APPROVAL: Many countries have given emergency authorization based on preliminary evidence that they are safe and effective. China, Russia and other countries have begun administering vaccines before detailed Phase 3 trial data has been made public. Experts have warned of serious risks from jumping ahead of these results.

APPROVAL: Regulators review the complete trial results and plans for a vaccine's manufacturing, and decide whether to give it full approval.

COMBINED PHASES: One way to accelerate vaccine development is to combine phases. Some vaccines are now in Phase 1/2 trials, for example, which this tracker would count as both Phase 1 and Phase 2.

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Leading Experimental "Vaccines"

Leading vaccines

Developer	How It Works	Phase	Status
Pfizer-BioNTech	mRNA	2 3	Approved in several countries. Emergency use in U.S., E.U., other countries.
Moderna	mRNA	3	Approved in Switzerland. Emergency use in U.S., U.K., E.U., others.
Gamaleya	Ad26, Ad5	3	Early use in Russia. Emergency use in other countries.
Oxford-AstraZeneca	ChAdOx1	2 3	Emergency use in U.K., E.U., other countries.
CanSino	Ad5	3	Limited use in China.
Johnson & Johnson	Ad26	3	
Vector Institute	Protein	3	Early use in Russia.
Novavax	Protein	3	
Sinopharm	Inactivated	3	Approved in China, U.A.E., Bahrain. Emergency use in Egypt, other coutries.
Sinovac	Inactivated	3	Approved in China. Emergency use in Brazil, other countries.
Sinopharm-Wuhan	Inactivated	3	Limited use in China, U.A.E.
Bharat Biotech	Inactivated	3	Emergency use in India.

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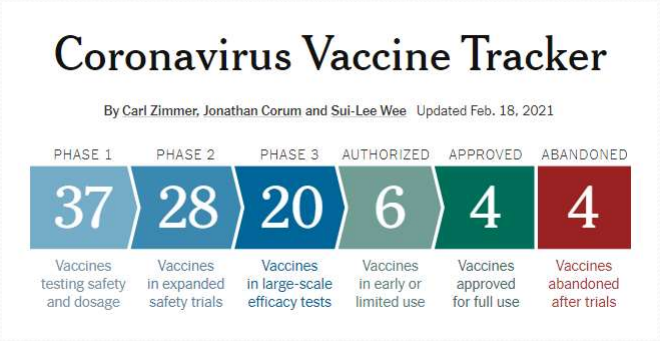
- In December 2020, the first "vaccines" for SARS-CoV-2 were granted Emergency Use Authorization by the FDA and recommended by the Advisory Committee on Immunization Practices: Pfizer-BioNTech and Moderna



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Preclinical animal testing skipped

- "Due to the urgent need for a vaccine in a surging pandemic, Pfizer and Moderna were given approval to simultaneously test their vaccines on animals while they were conducting Phase 1 trials on humans." (Associated Press)
- There is potential for "pathogenic priming" by a vaccine. Also referred as "immune enhancement" or "antibody-dependent enhancement" (ADE), this is where a vaccinated person, after later being exposed to the same virus, has the risk of exhibiting an extremely exaggerated and sometimes deadly immune reaction.
- In ADE, a virus leverages antibodies to aid infection. In short, the anti-viral antibodies, stimulated by a vaccine, amplify the infection rather than prevent its damage. It may only be seen after months or years of use in populations around the world.

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Why were previous coronavirus vaccine attempts abandoned?

- "Failure of SARS and MERS vaccines in animal trials involved pathogenesis consistent with an immunological priming that could involve autoimmunity in lung tissues due to previous exposure to the SARS and MERS spike protein."

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7142689/

ADE demonstrated in studies on SARS-CoV-1 (which is 78% identical to SARS-CoV-2) on:

Humans: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4018502/

Ferrets: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC525089/

Primates:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6478436/

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- It is not known what percent of the population may suffer pathogenic priming or antibody-dependent enhancement (ADE) after vaccination with a COVID vaccine. Estimates of Americans who already have an autoimmune disease range from 14.7 million to 23.5 million. They are likely more susceptible to pathogenic priming and ADE.

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Current trials are not designed to find ADE

- "Neither principles of immunity nor preclinical studies provide a basis for prioritizing among the COVID-19 vaccine candidates with respect to safety at this time. Rigorous clinical trial design and postlicensure surveillance should provide a reliable strategy to identify adverse events, including the potential for enhanced severity of COVID-19 disease, after vaccination."
- https://pubmed.ncbi.nlm.nih.gov/33077678/

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Experimental "vaccines"

According to the Food and Drug Administration, "An investigational drug can also be called an experimental drug and is being studied to see if your disease or medical condition improves while taking it." The Pfizer and Moderna and AstraZeneca applications properly identify their new agents as "investigational," which is normal at this very early stage of development. All the vaccine candidates are categorized as experimental for the following four reasons:

- the pharmaceutical companies have applied for investigational use status
- adverse events will be settled under the legal standard for experimental medications
- recipients are enrolled as subjects in a medical trial to gather data on side effects.
- many groups of persons have not been studied at all, including: prior COVID-19 patients, pregnant women, youths, elderly
- no published animal studies data
- persons are enrolled in a pharmacovigilance tracking system for at least two years

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Pharmacovigilance tracking

- 2 official Operation Warp Speed documents state that vaccine recipients would be monitored for 24 months after the first dose of a Covid-19 vaccine by a "pharmacovigilance system"

- https://www.nejm.org/doi/full/10.1056/NEJMp2027405
- https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf

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Pharmacovigilance tracking

- ***The Department of Health and Human Services (HHS) and the Department of Defense (DOD) stated that, because Warp Speed vaccine candidates use new unlicensed vaccine production methods that "have limited previous data on safety in humans . . . the long-term safety of these vaccines will be carefully assessed using pharmacovigilance surveillance and Phase 4 (post-licensure) clinical trials."***
- ***The vaccination effort itself (Operation Warp Speed) is being managed by the military with the Department of Homeland Security (DHS) and the National Security Agency (NSA) as opposed to what is usually done, which is civilian health agencies.***

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- The quickest vaccine ever developed previously was for mumps. It took 4 years.
- The Pfizer-BioNTech Covid-19 vaccine was developed and cleared for emergency use in only **8 months**!!
- Experimental mRNA gene technologies have never before been approved for widespread use in healthy populations.

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This has never been done before!

- No vaccine based on messenger RNA has ever been approved for any disease, or even entered final-stage trials until now
- there's no peer-reviewed published human data to compare how mRNA stacks up against older technologies
- a vaccine candidate had to be halted because test subject had 'false positive' HIV test results – in other words, unexpected things must be expected with brand new experimental technology

https://www.americasfrontlinedoctors.com/wp-content/uploads/Vaccine-PP.pdf

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Flawed trial design

- Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine in Houston, said, "Ideally, you want an antiviral vaccine to do two things . . . first, reduce the likelihood you will get severely ill and go to the hospital, and two, prevent infection and therefore interrupt disease transmission."
- HOWEVER
- None of the trials currently under way are designed to detect a reduction in any serious outcome such as hospital admissions, use of intensive care, or deaths. Nor are the vaccines being studied to determine whether they can interrupt transmission of the virus.

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- US DCD data April 2020 reported:
- Symptomatic case hospitalization ratio 3.4% overall
- 1.7% in 0-49 year olds
- 4.5% in 50-64 year olds
- 7.4% in those over 65

http://web.archive.org/web/20200709001525/https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html

Tal Zaks, chief medical officer at Moderna, told *The BMJ* that the company's trial lacks adequate statistical power to assess those outcomes. "The trial is precluded from judging [hospital admissions], based on what is a reasonable size and duration to serve the public good here," he said.

Hospital admissions and deaths from covid-19 are simply too uncommon in the population being studied for an effective vaccine to demonstrate statistically significant differences in a trial of 30 000 people. The same is true of its ability to save lives or prevent transmission: the trials are not designed to find out.

https://www.bmj.com/content/371/bmj.m4037#T1

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What about Hotez's second criterion, interrupting virus transmission, which some experts have argued should be the most important test in phase III studies?

https://www.nytimes.com/2020/08/24/opinion/coronavirus-vaccine-prevention.html

Tal Zaks, chief medical officer at Moderna said:
"Our trial will not demonstrate prevention of transmission, because in order to do that you have to swab people twice a week for very long periods, and that becomes operationally untenable."

Moderna, like Pfizer, has designed its study to detect a relative risk reduction of at least 30% in participants developing laboratory confirmed covid-19, consistent with FDA and international guidance.
https://www.fda.gov/media/139638/download

"In addition to the primary efficacy endpoints evaluating confirmed COVID-19 cases accruing from 7 days after the second dose, the final analysis now will include, with the approval of the FDA, new secondary endpoints evaluating efficacy based on cases accruing 14 days after the second dose as well."
https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against

Bottom line: These trials were not DESIGNED to detect whether vaccines reduce disease outcomes or prevent transmission.

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- 100% of those injected with two doses of Moderna's mRNA vaccine (100 mcg) experienced systemic adverse events

https://www.nejm.org/doi/full/10.1056/NEJMoa2022483

- 50% of those aged 18-55 in Pfizer's trial had systemic adverse events

https://www.nejm.org/doi/10.1056/NEJMoa2027906?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

- Systemic adverse events experienced by participants in all trials include chills, fever, muscle pain and headache, which participants claim last about 24 hours. One man with chills chattered his teeth so badly that he broke a tooth.

https://www.cnbc.com/2020/10/01/coronavirus-vaccine-trial-participants-exhaustion-fever-headaches.html

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- Over the last 5 years, the Vaccine Adverse Event Reporting System (VAERS) has recorded an average of 45,000 adverse events each year.
- According to the Dept. of Health & Human Services' records, that number represents 1% of all adverse events due to the large majority going underreported or unidentified.
- These adverse events need to be investigated, so any causal relationship between the vaccine and these events can be identified.
- Vaccine injuries and deaths DO occur, and the government has paid out over $4.4 billion to the vaccine-injured through its National Vaccine Injury Compensation Program (VICP).
- Under the 2005 PREP Act, vaccine companies have total immunity from liability if something goes wrong with their vaccines. This protection lasts until 2024.
- You cannot sue Pfizer-BioNTech, Moderna, or the FDA.
- The VICP has compensated less than 6% of claims filed in the past decade.

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Mechanism of action

- COVID-19 mRNA Vaccine BNT162b2 is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced by cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.
- The nucleoside-modified messenger RNA in COVID-19 mRNA Vaccine BNT162b2 is formulated in lipid nanoparticles, which enable delivery of the RNA into host cells to allow expression of the SARSCoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19 disease.
- Simple breakdowns of the mechanism can be found here:

https://www.nytimes.com/interactive/2020/health/pfizer-biontech-covid-19-vaccine.html
https://www.nytimes.com/interactive/2020/health/moderna-covid-19-vaccine.html

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Lipid nanoparticles (LNPs)

- Novel pharmaceutical drug deliver system
- Used to coat fragile mRNA strands
- Promote the uptake of mRNA
- PEGylated LNPs
  - PEGylation is the process of attachment of polyethylene glycol (PEG) to a protein or drug. PEG is synthetic and non-degradable.
  - Published, peer reviewed scientific studies have documented that 72% of the US population has anti-PEG antibodies, 8% of that group having high levels putting them at risk for anaphylaxis. The immune system reaction ranges from localized to systemic, and not dangerous to life threatening.
    - (analyphyaxis = severe allergic reaction or shock)

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Ingredients

Active: BNT162B2 mRNA (Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2)

Inactive:

- ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate),
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine,
- cholesterol,
- potassium chloride,
- potassium dihydrogen phosphate,
- sodium chloride,
- disodium hydrogen phosphate dihydrate,
- sucrose,
- water for injections
- (contains polyethylene glycol/macrogol (PEG) as part of ALC-0159)
- First two inactive ingredients have NEVER BEEN USED BEFORE

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/955899/Temporary_Authorisation_HCP_Information_BNT162_6_0_UK_editclean.pdf

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moderna NIH National Institutes of Health Turning Discovery Into Health

Ingredients

Active:

- Nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus, 100 mcg
  - **IMPORTANT:** The Moderna patent states that the mRNA also encodes for the protein, **flagellin, an unapproved vaccine adjuvant** used to stimulate the pro-inflammatory Toll-like receptor 5 (TLR5)

Inactive:

Lipid: (SM-102, 1,2-dimyristoyl-rac-glycero3-**methoxy-polyethylene glycol-**2000 [PEG2000-DMG]

- Lipid: 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 93 mg
- Lipid: cholesterol
- **Tromethamine**, 31 mg – this is a prescription medication used to treat metabolic acidosis
- tromethamine hydrochloride, 18 mg
- acetic acid, 0.42 mg
- sodium acetate, 0.12 mg
- sucrose, 43.5 mg

https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

https://www.modernatx.com/sites/default/files/US10702600.pdf

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The Moderna mRNA encodes for two things:
the *COVID spike protein* AND *bacterial flagellin*.

- Flagellin is a protein found in bacteria such as *Salmonella*, which use it in their tails, or flagella, to propel themselves around. Sometimes it's made by detaching the tails from bacteria – though more recently it's become common to grow it in genetically modified cells.
- Flagellin isn't licensed for use in human vaccines, but if the vaccine merely contains the instructions, and you technically are making the flagellin, it appears the vaccine companies can get around that detail!
- Flagellin is a potent PAMP (pathogen associated molecular pattern), which is used as an immunostimulatory signal that can instantiate an immune response. PAMPs are conserved patterns that the immune system inherently knows is dangerous.

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Lawsuit

- Allele Biotechnology and Pharmaceuticals, Inc. (Allele) has accused Regeneron Pharmaceuticals, Inc. Pfizer, Inc.; and BioNTech SE and BioNTech US, Inc. for allegedly infringing U.S. Patent No. 10,221,221 (the '221 patent)
- The '221 patent is directed to an artificial flourescent protein, i.e. mNeonGreen, which according to Allele "facilitates quick, targeted, and precise receptor research, including for potential therapeutics to treat COVID-19." mNeonGreen is essentially a biomarker.
- Allele argues that Regeneron, Pfizer and BioNTech have been infringing the '221 patent by using mNeonGreen throughout their COVID-19 vaccine trials without authorization. Allele asserted that "[o]nly through use of mNeonGreen were Defendants able to develop and test the BNT162 vaccine candidate at lightspeed making them first to market, earning them an immediate $400 million in grants and over $4 billion in sales of the vaccine."
- https://jolt.law.harvard.edu/digest/allele-v-regeneron-allele-v-pfizer-and-biontech-the-cases-of-a-protein-a-patent-and-a-pandemic

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Pfizer BIONTECH

- Pfizer and BioNTech found that the antibodies are somewhat less effective against another variant called B.1.351. It's not clear whether those results mean that people who get the vaccine will be at greater risk of developing Covid-19 from that variant. But the companies are moving ahead with creating a version of the vaccine based on the B.1.351 spike protein.
- Currently, the Centers for Disease Control says pregnant women who become eligible may choose to get vaccinated, while pointing out the lack of data from trials.
- Spike proteins contain syncytin-homologous proteins, which are essential for the formation of the placenta. The question arises whether vaccines may train the female body to attach syncytin-1 thereby sterilising the female. Syncytin-1 is also present in sperm.
- There is no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion.

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- Most vaccines are only monitored for side effects for a period of 2 to 5 days (stated on vaccine insert literature)
- However, side effects can sometimes take months to years to be detected
  - Autoimmune, neurodevelopmental, chronic conditions

Ex. Merck's hepatitis B vaccine given to 1 day old infants was only safety tested for 5 days.

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CDC:

- Cases of Bell's palsy were reported following vaccination in participants in both the Pfizer-BioNTech and Moderna COVID-19 vaccines clinical trials. However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination.

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

- According to trials in the UK, cases of acute peripheral facial paralysis (palsy) was reported following the Pfizer-BioNTech vaccine. Onset was Day 37 after Dose 1.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/955899/Temporary_Authorisation_HCP_Information_BNT162_6_0_UK_editclean.pdf

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CDC data Dec. 2020:
2.8% of vaccinated experienced "Health impact events" such that they were "unable to perform normal daily activities, unable to work, required care from doctor"

	Dec 14	Dec 15	Dec 16	Dec 17	Dec 18*
Registrants with recorded 1st dose	679	6,090	27,823	67,963	112,807
Health Impact Events**	3	50	373	1,476	3,150
Pregnancies at time of vaccination	5	29	103	286	514

*Dec 18, 5:30 pm EST
**unable to perform normal daily activities, unable to work, required care from doctor or health care professional

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Potential problems:

- 1. Brand new technology. mRNA has never been used before
- 2. Failure of previous coronavirus vaccines.
- 3. No independently published animal studies. No published data on safety studies.
- Permanent addition to epigenetic settings
- 4. Known complications –
  - Pathogenic priming – Immune enhancement - Antibody-dependent enhancement (ADE) - (overreaction in a negative way after exposure to a virus after having receiving vaccine)

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Potential fertility problems:

- The question remains whether this "vaccine" will affect the syncytiotrophoblast – the outer layer of the placenta.
- Infection with COVID seems to affect the syncytiotrophoblast.
- We don't know how it will affect pregnant women.

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Unanswered questions

- Does the vaccine prevent the infection or only lessen a patient's symptoms?
- Does it keep them from spreading the virus? If so, why do we still need to distance and wear a mask?
- How long will the antibody last? In otherwords, how long to we have to worry about viral re-exposure?
- What if you already have a co-morbidity such as an autoimmune disease?
- How well does it protect the elderly, many of whom have received a flu vaccine?

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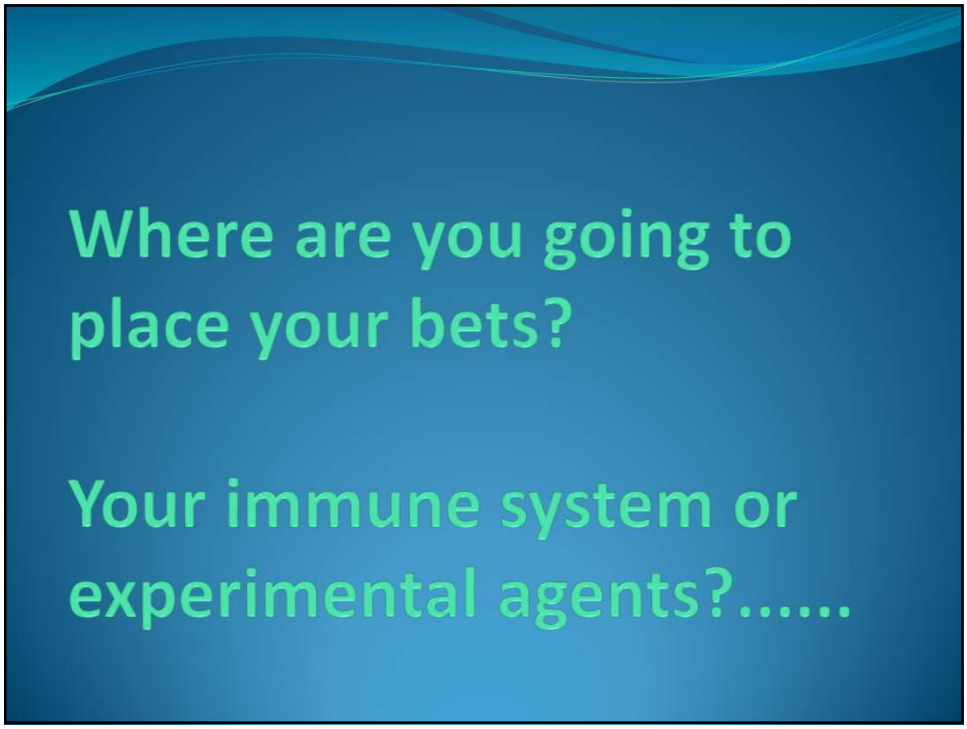
Where are you going to place your bets?
Your immune system or experimental agents?.....

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