SARS-CoV-2 mRNA Vaccines: Is the Risk Worth the Benefit?

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Rational Responses to Pandemic Challenges Symposium

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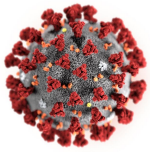

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Overview

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"Worse than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19"*

The mRNA vaccines are a poorly evaluated unprecedented technology with many unknowns

Some potential adverse consequences:

- Pathogenic priming, multisystem inflammatory disease and autoimmunity
- Allergic reactions and anaphylaxis
- Emergence of novel variants of SARS-CoV-2
- Antibody dependent enhancement
- Activation of latent viral infections
- Neurodegeneration and prion diseases

*S Seneff and G Nigh. IJVTPR 2021; 2(1): 38-79.

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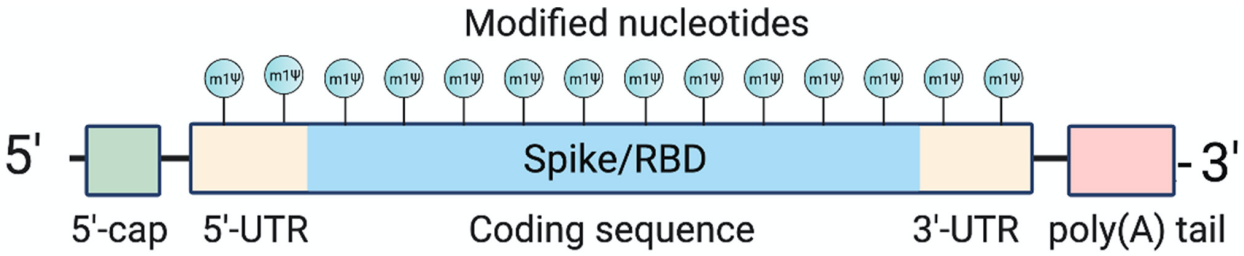

- mRNA vaccines contain the genetic code to make spike protein
- The mRNA is incorporated into a lipid particle that simulates a human LDL particle
- A synthetic cationic (positively charged) lipid is added to act as an adjuvant – very toxic to the cells
- Large quantities of polyethylene glycol (PEG) are added to further protect the mRNA from breakdown
- The RNA is carefully engineered to resist breakdown and to produce spike protein at high rate

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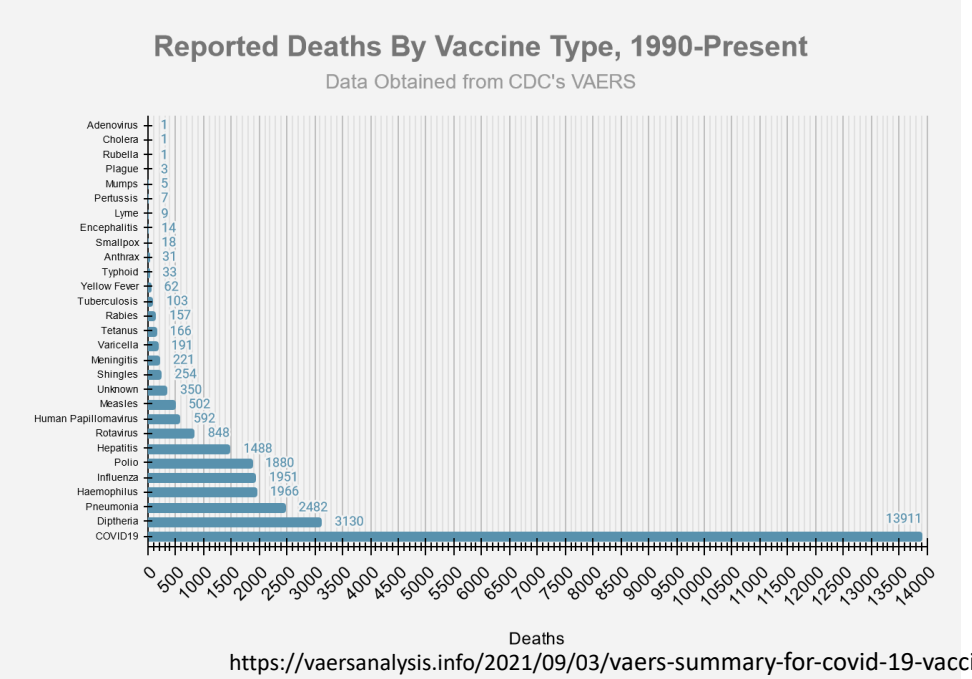

As of August 27,2021

https://vaersanalysis.info/2021/09/03/vaers-summary-for-covid-19-vaccines-through-8-27-2021/

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"Substantial Differences in SARS-CoV-2 Antibody Responses Elicited by Natural Infection and mRNA Vaccination"*

- After the second dose of the vaccine, antibody titers were *up to 10 times higher* than those of patients who had recovered from natural COVID-19 infection
- In patients with COVID-19, the most severe disease is associated with the highest number of antibodies**
- High antibody titers lead to autoimmune disease

*Rafael Assis et al. bioRxiv preprint. May 19, 2021. doi: https://doi.org/10.1101/2021.04.15.440089

**Vincent Legros et al., Cellular & Molecular Immunology 2021; 18: 318-327.

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Rogue antibodies could be driving severe COVID-19*

Evidence is growing that self-attacking 'autoantibodies' could be the key to understanding some of the worst cases of SARS-CoV-2 infection.

I predict that a massive vaccination campaign against COVID-19 may result in a dramatic increase in all sorts of autoimmune diseases

*Nature News Feature. https://www.nature.com/articles/d41586-021-00149-1

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Antibody-Dependent Enhancement (ADE) and Breakthrough Variants

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Antibody-Dependent Enhancement (ADE)*

The vaccine has the potential to backfire:

- Non-neutralizing antibody enhances uptake into macrophages via Fcγ receptors leading to increased viral infection and replication
- Antibody increases release of cytokines causing enhanced risk of excessive inflammation and cytokine storm

"ADE has been observed in SARS, MERS and other human respiratory virus infections including RSV and measles, which suggests a real risk of ADE for SARS-CoV-2 vaccines and antibody-based interventions."*

"Thus, the absence of ADE evidence in COVID-19 vaccine data so far does not absolve investigators from disclosing the risk of enhanced disease to vaccine trial participants, and it remains a realistic, non-theoretical risk to the subjects."**

*Wen Shi Lee et al., Nature Microbiology 2020; 5: 1185-1191.
**T Cardozo and R Veazey, Int J Clin Pract 2021; 75(3): e13795.

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"SARS-CoV-2 evolution during treatment of chronic infection"*

- Cancer patient being treated for recurrent lymphoma with a drug that depletes antibody-producing B cells caught COVID-19
  - Persistent viral RNA shedding and risk of transmission in the hospital
  - Patient died 101 days after diagnosis, after being given two rounds of plasma from recovered patients, *which contained antibodies against the virus*
  - Following antibody exposure, SARS-CoV-2 had acquired several mutations that might have allowed it to elude the antibodies.
- This is a good model for what happens when you vaccinate an immune-compromised person

*SA Kemp et al., Nature 2021; 592: 277-282.

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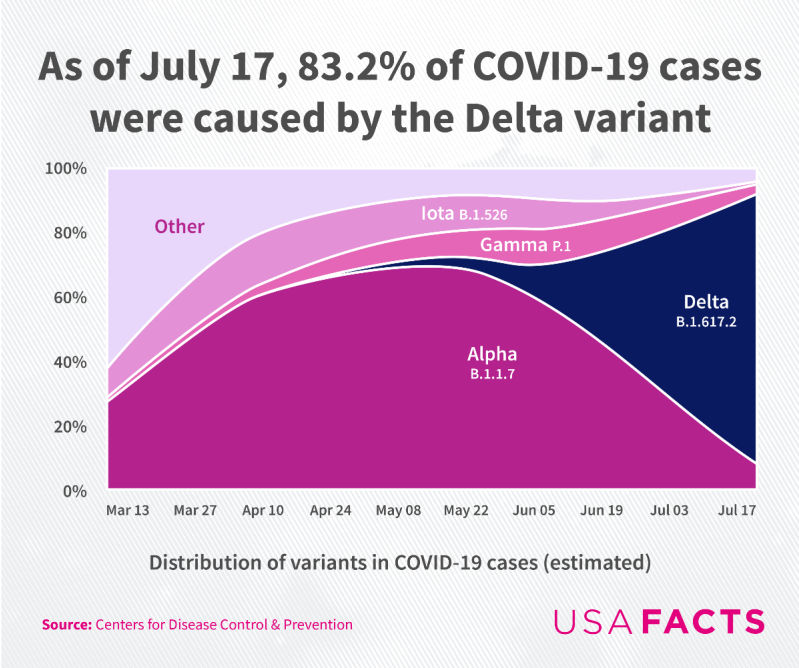

As of September 20, the number had risen to over 99%

Delta variant binds less well to neutralizing antibodies and it binds better to facilitating antibodies*

*Nouara Yahi et al. Journal of Infection August 9, 2021 [Epub ahead of print] doi: 10.1016/j.jinf.2021.08.010

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"An Effective COVID-19 Vaccine Needs to Engage T Cells"*

- All the vaccines currently on the market are specific to the spike protein
  - Natural infection induces antibodies to many other viral proteins
- T cells exposed to *internal* viral proteins can become *memory T cells* that respond very quickly to a new infection
  - They are much more long lasting than memory B cells (up to 17 years!)
- These memory T cells can induce a rapid antibody response *in B cells* to a mutated form of the spike protein
- Memory B cells can lose their effectiveness because their antibodies are specific to an obsolete version of the spike protein
- Conclusion: natural infection induces far better protection than the vaccines

*Karsten Sauer and Tim Harris. Frontiers in Immunology 2020; 11: 581807.

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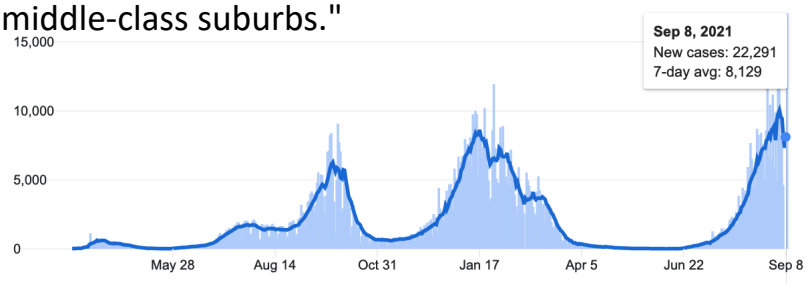
The New York Times August 18,2020

Israel, Once the Model for Beating Covid, Faces New Surge of Infections

One of the most vaccinated societies, Israel now has one of the highest infection rates in the world, raising questions about the vaccine's efficacy.

"Unlike previous epicenters of infection in Israel's crowded, less-vaccinated ultra-Orthodox communities, this scourge primarily took hold in well-vaccinated, middle-class suburbs."



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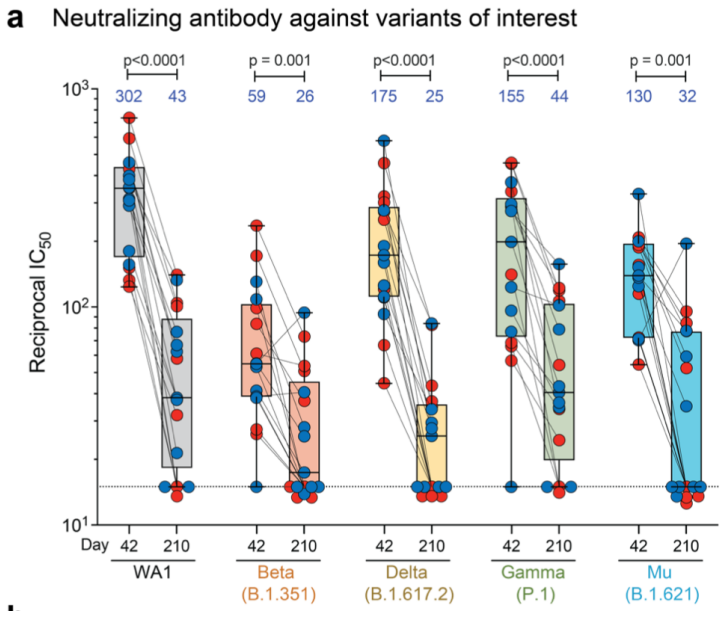

Neutralizing antibodies fall dramatically in six months*

Red: males; Blue: females

*Mehul S. Suthar et al. bioRxiv preprint Sept. 20, 2021. Doi: 10.1101/2021.09.30.462488.

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Figure 2a.

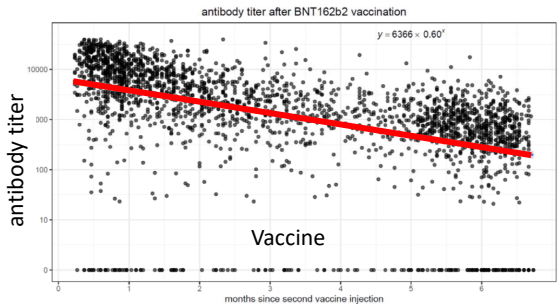
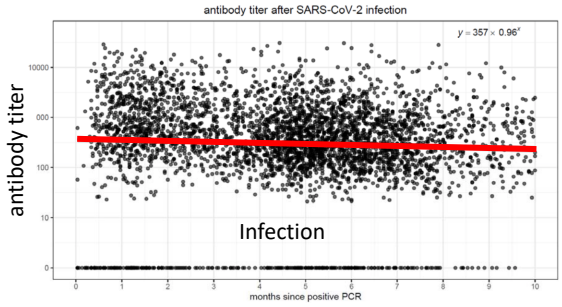


Figure 2b.



"Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection"*

Initial levels of antibody are much higher in vaccinated patients (Pfizer mRNA vaccine), but they decrease faster.

*Ariel Israel et al. medRxiv preprint Aug. 22, 2021. doi: 10.1101/2021.08.19.21262111.

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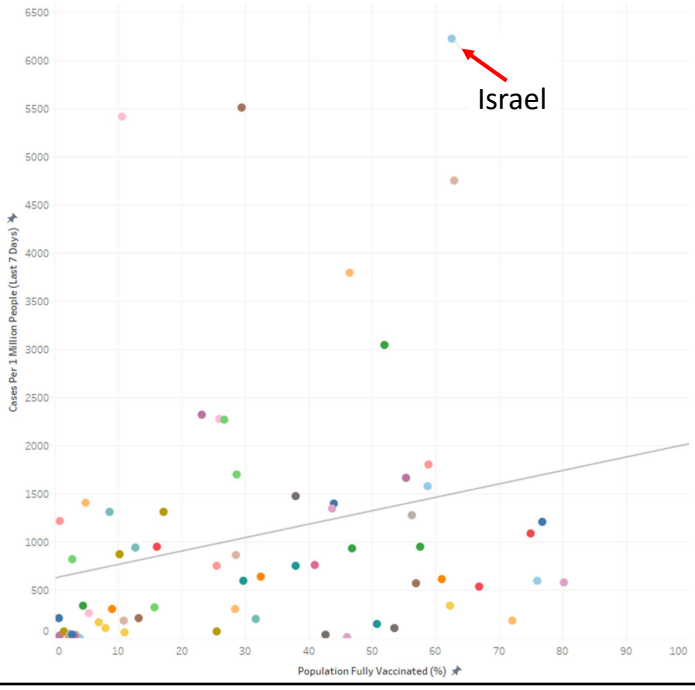
Positive trend between vaccination rate and infection rate*

Number of cases during one week before September 3. 2021

*S. V. Subramanian et al. European Journal of Epidemiology Sept 30, 2021 [Epub ahead of print]



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Outbreak in Israeli Hospital, July 2021*

- 24% of the patients (23 people) were infected
  - An additional 19 people (staff and family members) were also infected
- 39 out of 42 cases were fully vaccinated.
  - Median time of 25 weeks after vaccination
- Index patient was fully vaccinated
- Several transmissions occurred among people wearing face masks
- 14/23 patients became severely sick or died (five deaths)
- The two unvaccinated patients had mild disease
- Warning about waning immunity

*Pnina Shitrit et al. Euro Surveill 2021; 26(39): 2100822.

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Myocarditis and Cardiovascular Disease

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The Big Picture

- The mRNA vaccines are causing inflammation in the heart in young people who have near zero risk of dying from COVID-19
  - This can lead to permanent damage to the heart
- The spike protein S1 subunit detaches and becomes free to bind to ACE2 receptors which are present at high levels in the heart
  - The suppression of ACE2 by spike S1 causes upregulation of angiotensin II, which induces inflammation (myocarditis) and cardiovascular disease
- S1 has been found in COVID-19 patients long after the virus is cleared, and is believed to play a critical role in "long-haul COVID"
- S1 has also been found in the vasculature following vaccination

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S1 detected in the blood following vaccination*

Eleven out of 13 health care workers had detectable levels of spike protein and/or S1 in their blood plasma as early as 1 day and up to 28 days following the first mRNA vaccine, with a peak level on average after five days

*Ogata et al. Clinical Infectious Diseases 2021; ciab465. [Epub ahead of print] doi: 10.1093/cid/ciab465.

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S1 is toxic to mice*

S1 alone caused COVID-19-like lung symptoms in mice humanized with ACE2 receptor: Immune cell infiltration, cytokine storm, impaired barrier function

*Ruben M. L. Colunga Biancatelli et al. Am J Physiol Lung Cell Mol Physiol 2021; 321: L477–L484

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SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis"*

- Rate of myocarditis after two shots of Pfizer vaccine was 162 cases per million in boys 12-15 years old
  - About 86% required hospitalization
  - May lead to permanent damage and heart failure
- Risk of a healthy adolescent being taken to hospital with COVID-19 in the next three months is 44 per million

*Tracy Beth Høeg et al. medRxiv preprint. August 30, 2021. doi: https://doi.org/10.1101/2021.08.30.21262866

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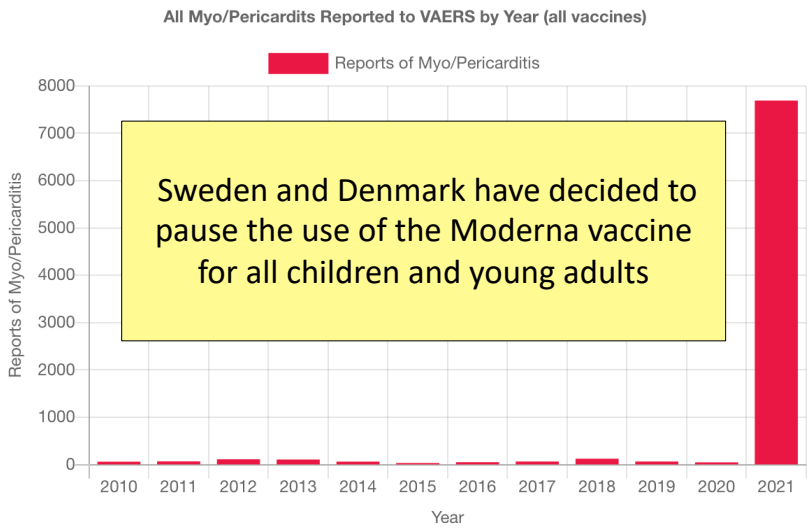
Myocarditis Reports in VAERS*



Through September 24, 2021

- 16-and-over vaccination began December 14, 2020
- 12-15-year-old vaccination began May 10, 2021

*https://openvaers.com/covid-data/myo-pericarditis

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Conclusion

- The mRNA vaccines against COVID-19 are neither safe nor effective
  - Reports of adverse reactions in the VAERS database are much higher than for any other vaccine
- The vaccine induces exposed cells to produce large amounts of spike protein, which is toxic
  - This causes myocarditis in young people who are very safe from COVID-19
- The vaccine induces a very high antibody response, which however can lead to autoimmune disease
- Vaccine-based immunity fades quickly over time; frequent booster shots may become routine
- The vaccines may be responsible for the rapid emergence of vaccine-resistant mutants
- Antibody Dependent Enhancement (ADE) is a real risk that may make the vaccinated susceptible to worse symptoms than the unvaccinated

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