

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized

A vaccine is unnecessary

COVID-19 severity is itself a vaccine-induced disease (Arumugham 2020a). We have understood the immunological mechanism of COVID-19 severity and have proven treatments. COVID-19 severity is due to an allergic reaction to the SARS-CoV-2 proteins. We have safe, cheap, proven treatments such as histamine H1/H2 antagonists (famotidine/cetirizine). Hydroxychloroquine (HCQ) when appropriately dosed and timed has also been shown to work. HCQ has anti-IgE effect (Arumugham 2020a).

Vaccines in general are unsafe, new, unproven mRNA Pfizer/BioNTech vaccine, more so

Vaccinologists admit they have no understanding of the immunological mechanisms involved in vaccines (Pulendran and Ahmed 2011; Cohen 2019), 200 years after Jenner. The hypodermic needle defeated millions of years of evolutionary protection, introduced alien proteins into humans and created an epidemic of brand new diseases (Arumugham 2020b). mRNA vaccines are new and even less understood. They defeat another protective barrier evolved over millions of years. The cell wall keeps out alien RNA. mRNA vaccines destroy that barrier and inject alien mRNA into the cell. The consequences are unknown. But the second law of thermodynamics allows us to predict that the outcome will be highly undesirable.

Products must be designed for safety (Arumugham 2019a). Vaccines are not designed at all. So they are all unsafe by definition. It is utterly ridiculous to rely on testing alone to determine safety as is being done now for all vaccines. A vaccine may cause type 1 diabetes 10 years later. Are you going to test for 10 years? You regulators have learned nothing from the Pandemrix vaccine-induced narcolepsy disaster (Ahmed et al. 2015; Arumugham 2018b, c).

Pfizer/BioNTech failed to design for safety, failed to perform a Failure Modes and Effects Analysis (FMEA) for this safety critical product. An FMEA would have allowed them to determine safety problems, design modifications needed for safety and would have informed proper trial design for safety evaluation (Arumugham 2019b). Lipid nanoparticle (LNP) safety is poorly understood. Lipids for LNP are derived from plant/animal sources and are contaminated with plant/animal proteins. This will result in numerous diseases such as allergies and autoimmune diseases (Arumugham 2020b). Bioinformatics analysis and autoimmune serology in vaccine trials has been proposed to check for this problem (Verdier 2003; Wraith et al. 2003). Pfizer/BioNTech failed to perform such checks. Similarly, de novo IgE synthesis directed against contaminating proteins and the spike protein encoded by the mRNA, needs to be checked which they failed to do. Allergic reactions in recipients of higher doses in the Moderna trial following the second dose, provides clear evidence of a textbook case of sensitization followed by elicitation (Jackson et al. 2020).

The latest fiasco is the AstraZeneca/Oxford vaccine trials where a “half-dose” was unintentionally administered and was serendipitously determined to be more effective than the standard dose. This illustrates the complete lack of understanding of the immunological mechanisms involved. This is like Boeing claiming their aircraft performed better after one of the engines fell off during tests. Will you certify that plane for airworthiness? This complete lack of understanding of mechanisms and a lack of a design for safety process, is common to all vaccine makers. The AstraZeneca fiasco is the latest reminder that these vaccines are unsafe by definition.

Effectiveness against severe disease, duration of protection and transmission blocking

The trial does not demonstrate protection against severe disease (Doshi 2020). The ability of the vaccine to prevent transmission has not been studied at all. Duration of protection has not been studied at all. So just like the influenza vaccines and the Dengvaxia vaccine, the vaccinated could be infected by wild virus, transmit disease (more so when protection wanes), turning into super spreaders and/or suffer severe COVID-19 disease (Arumugham 2018a, d). The first in line to get the vaccines are healthcare workers. What happens when they turn into super spreaders?

Corruption of science

The general corruption of medical science (Gyles 2015; Moynihan et al. 2019; Abbasi 2020) by the pharmaceutical industry and the lack of product liability has made it impossible to trust safety claims. The Pfizer/BioNTech EUA application must be rejected for all the above reasons.

References

- Abbasi K (2020) Covid-19: politicisation, “corruption,” and suppression of science. *BMJ* 371:m4425
- Ahmed SS, Volkmuth W, Duca J, et al (2015) Antibodies to influenza nucleoprotein cross-react with human hypocretin receptor 2. *Sci Transl Med* 7:294ra105-294ra105.
<https://doi.org/10.1126/scitranslmed.aab2354>
- Arumugham V (2018a) Influenza vaccines and dengue-like disease. In: *BMJ*.
<https://www.bmj.com/content/360/bmj.k1378/rr-15>. Accessed 14 Oct 2020
- Arumugham V (2020a) Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations.
<https://doi.org/10.5281/zenodo.4100663>. Accessed 28 Oct 2020
- Arumugham V (2020b) Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020
Covering over 125 conditions. <https://doi.org/10.5281/zenodo.2582634>. Accessed 23 Apr 2020
- Arumugham V (2019a) Vaccine safety: Learning from the Boeing 737 MAX disasters.
<https://doi.org/10.5281/zenodo.2648251>. Accessed 2 May 2019
- Arumugham V (2018b) Pandemrix and Arepanrix vaccine safety analysis and scrutiny fell short. In: *BMJ*. <https://www.bmj.com/content/363/bmj.k4152/rr-14>
- Arumugham V (2018c) Pharmacovigilance is no substitute for good vaccine design. In: *BMJ*.
<https://www.bmj.com/content/362/bmj.k3948/rr-11>
- Arumugham V (2019b) ERVEBO Ebola vaccine will create a rice allergy epidemic, add to numerous autoimmune diseases, cancer and make Ebola disease even more severe. Design for safety and

vaccine safety regulation remain abject failures. Incompetence or indifference?
<https://doi.org/10.5281/zenodo.3595020>. Accessed 17 Jan 2020

Arumugham V (2018d) Irrational dengue vaccine designs that ignore IgE and IgG4 mediated effects are destined to follow in Dengvaxia's disastrous direction?
<https://doi.org/10.5281/zenodo.1476291>

Cohen J (2019) How long do vaccines last? The surprising answers may help protect people longer. *Science* (80-). <https://doi.org/10.1126/science.aax7364>

Doshi P (2020) Opinion | Coronavirus Vaccine Trials Could Suffer From Shortcuts - The New York Times. <https://www.nytimes.com/2020/09/22/opinion/covid-vaccine-coronavirus.html>. Accessed 21 Nov 2020

Gyles C (2015) Skeptical of medical science reports? *Can Vet J = La Rev Vet Can* 56:1011–1012

Jackson LA, Anderson EJ, Roupheal NG, et al (2020) An mRNA Vaccine against SARS-CoV-2 — Preliminary Report. *N Engl J Med*. <https://doi.org/10.1056/nejmoa2022483>

Moynihan R, MacDonald H, Heneghan C, et al (2019) Commercial interests, transparency, and independence: A call for submissions. *BMJ* 365

Pulendran B, Ahmed R (2011) Immunological mechanisms of vaccination. *Nat Immunol* 12:509–517

Verdier F (2003) Chapter 14 - Preclinical Safety Evaluation of Vaccines. In: Thomas JA, Fuchs RL (eds) *Biotechnology and Safety Assessment (Third Edition)*, Third Edit. Academic Press, San Diego, pp 397–412

Wraith DC, Goldman M, Lambert P-H (2003) Vaccination and autoimmune disease: what is the evidence? *Lancet (London, England)* 362:1659–1666. [https://doi.org/10.1016/S0140-6736\(03\)14802-7](https://doi.org/10.1016/S0140-6736(03)14802-7)