Supplemental Material

Presented at Southwest District Health Board of Health meeting on July 25, 2023 for agendized topic of Vaccine Technology and Outcomes

Provided by guest presenter(s) Laura Demaray, et. al.

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The opinions and views of guest speakers and attendees expressed in Board of Health meetings are those of the guest speakers and attendees and do not necessarily reflect the views or positions of Southwest District Health. No endorsement of material shared or opinions or views expressed is to be implied.

The Honorable Raul Labrador

Office of the Attorney General, State of Idaho.

700 W. Jefferson Street, Suite 210

PO Box 83720

Boise, Idaho 83720-0010

Dear Attorney General Raul Labrador,

We are requesting an immediate recall of all genetic biologic "vaccine" platform technology in the state of Idaho due to adulteration, contamination, and misbranding of the products. We ask for an immediate recall due to the potential adverse effects to Idaho residents, and especially children as they prepare to start school this fall and may receive school shots. This harmful biologic has already been placed on the child vaccine schedule. 1,2.

Idaho residents have been injured by Genetic Biologic "Vaccine" Platform technology making it more injurious than any other vaccine mechanism in US history with 31 deaths and 94 permanent disabilities, 33 cases of myocarditis in the State of Idaho. The total deaths US are underreported at over 35,000 deaths, 65,670 permanently disabled and 26,897 myocarditis/pericarditis, since their release in 2021, according to VAERS CDC database.

www.openvaers.com

The mRNA platform technology shots must be recalled and investigated due to the egregious number of adverse events, disabilities, and deaths to adults and children. Adversely affecting children in the womb, it increases rates of miscarriages, and adversely affects women's menstruation and fertility. 3,4,5.

Multiple labs demonstrate that both the Pfizer and Moderna's misbranding, and adulteration of consumer products, substandard production processes, leading to contaminated and adulterated products, and substandard and underpowered clinical trials violate Consumer Product Protection statutes and informed consent as well as multiple other laws that regulate pharmaceutical safety in the State of Idaho. 6,7.

The mRNA technology shots are adulterated with over a thousand times the allowable level of DNA from the DNA plasmids used to make the shots in E. Coli bacteria. They represent up to 10-35% of the shot genetic material. 7

Some of these shots have an undisclosed SV40 promoter sequence that allows them to infect human cells and go to the cell nucleus, where they are likely to integrate into the person's DNA. Insertion of foreign DNA can cause mutations to cellular DNA that results in dysfunction and/or

tumor formation. Once integrated into the DNA, the SV40 regulatory element can also act to turn on and off genes near it, causing dysregulation with unknown effects. [7]

Due to adulteration, there is the possibility that the "vaccines" are contaminated with E. Coli bacterial proteins and "endotoxins" which are known to cause auto immune reactions and sepsis in the recipients. The material in the shot that was not cleaned out during the production process (plasmid DNA) was designed to infect E.Coli, such as are present in the human gut. This contaminating plasmid DNA codes for the toxic spike protein. If gut bacteria become infected with this contaminating plasmid DNA, the gut may become a permanent spike protein factory through the E.Coli that are naturally present there. https://osf.io/b9t7m/

The mRNA in the shots is also broken and degraded and this can adversely and permanently affect our God given genetic structure. Contamination and degradation of the mRNA genetic sequences the formation of small RNA molecules which can aberrantly activate receptors of the immune system causing immune system dysfunction and runaway inflammation. These small RNA molecules also have the power to turn genes on or off in ways that are unforeseen, since they are not naturally occurring. The material in genetic injections can shed through breathing as well as bodily secretions and transfect through fluids and contact. It is also secreted through mother's milk. [9,10.]

The mRNA technology presents possible irreversible damage, disability and death to livestock and critical food supply in the State of Idaho. Reducing herd loss beyond acceptable limits. Sequivity swine mRNA jabs USDA 2020-2021 summaries highlighted that this technology created adverse effects on 29.8% of the herd and 11.5% herd loss to death and wasting disease. This can adversely affect Idaho's economy, food supply, and health. [11]

We can no longer support this product on the child vaccine schedule, and we urge an immediate halt and recall of this product until further investigation of its quality and safety.

We urge future legislation and regulation that bans the use of any genetic or mRNA technology which introduces genetic material to humans or animals. This includes imported food supply or pharmacological products, that use mRNA or any genetic technology for human pharmacological use or food consumption or use regarding any livestock or agricultural products. This technology is inherently unsafe as it may cause dysregulation at every level of the organism. It can integrate into DNA, possibly causing insertional mutagenesis, gene dysregulation and cancer. MicroRNA degradation products can turn genes on and off in an unregulated fashion and bind to immune system receptors causing immune dysregulation. The production of a foreign protein causes immune cells to infiltrate tissues and attack cells and tissues expressing the foreign protein. The duration of foreign protein production has yet to be quantified. [12,13,14,15.]

We urge future legislation and regulation that requires transparency of "vaccine" ingredients and excipients, and informed consent for any vaccine or biologic.

We also support legislation that ensures and identifies the corporate or agency liability for vaccine injuries linked products that have used mRNA, DNA, or any genetic technology for human pharmacological use or consumption, use regarding any livestock, or use regarding any

agricultural products that may adversely affect human health, animal health, or the food supply thereof.

Counties of Idaho support the Idaho State Statute 18-3323 Bioweapons Law with specific emphasis to section 18-3323 (4) (a,b,c,and d). According to this Idaho Statute, this product qualifies a bioweapon. 16,17,18,19,20.

We support future legislation that prohibits any and all mandates, local, state, national, or global, regarding forced medical procedures or vaccinations in any modality.

We support a third-party independent forensics audit on all future vaccine products, mRNA, DNA, or genetic biologic technology vaccine products and modalities.

Idaho is a life affirming state, and we support life affirming legislation and declare that Idaho adults and children, including the unborn, have the right to normal cell growth.

Thank you for your service to our state and for your time and consideration regarding this important matter.

Sincerely,

Commissioner:

Commissioner:

Commissioner:

1. https://swdh.id.gov/clinic-services/immunizations/
2. https://www.cdc.gov/vaccines/schedules/index.html
3. https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf
4. www.openvaers.com
5. https://www.jpands.org/vol28no1/thorp.pdf
6. https://osf.io/b9t7m/
7. https://www.fda.gov/animal-veterinary/resources-you/glossary-terms-related-fdas-regulation-animal-products
8. https://osf.io/b9t7m/
9. https://www.mdpi.com/1467-3045/44/3/73/htm?s=09&fbclid=IwAR3MHm_RVRc9qxfoObdk1lkr2vmaHKj32Ojf8WiLEyhlILtVkoOCEwf3KEc
10. https://www.biorxiv.org/content/10.1101/2022.12.19.517879v1 https://www.researchgate.net/publication/365361839_Current_state_of_knowledge_on_the_excretion_of_mRNA_and_spike_produced_by_anti-COVID-19_mRNA_vaccines_possibility_of_contamination_of_the_entourage_of_those_vaccinated_by_these_products

11. https://www.aphis.usda.gov/wcm/connect/74aac7d9-9f2b-4c04-a626-5800e0654ba5/165a-19a5r8.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPACE-74aac7d9-9f2b-4c04-a626-5800e0654ba5-o9BylMj
12. https://pubmed.ncbi.nlm.nih.gov/36006288/
13. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7324311/
14. https://pubmed.ncbi.nlm.nih.gov/36006288/
15. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7120417/
16. . https://josephsansone.substack.com/p/ban-the-jab-resolution-f6f
17. https://karenkingston.substack.com/p/the-term-mrna-vaccines-is-a-sham
18. https://karenkingston.substack.com/p/mrna-is-an-operating-system-technology
19. https://anamihalceamdphd.substack.com/p/self-assembly-microtechnology-pfizer
20. **http://ww.jar2.com/Files/MILITARY/US_BIOLOGICAL/nm.3985.pdf**

SECTION BREAK

Four minute testimony:

I am Laura Demaray from Washington county my words are my own opinion and not any organization or place of work. I appeal to you honorable commissioners utilizing the doctrine of the lesser magistrates a precedence with thousands of years of history and include the Madiburg confessions and Magna Carta that set precedence to empower the lesser magistrates to stand up, take righteous action to protect the citizens when the higher authorities of the land fail to do so.

I support a halt, recall, and ban of the genetic biologic platform technology due to contamination of the product as well as the unprecedented adverse effects to Idahoans and Americans.

My first subject matter expert is:

Dr. Kirk Milhoan

Dr. Janci Lindsey

Dr. Renata Moon

Sasha Latypova

I speak for three Idaho injured friends one military, one health care, and one health care executive, who were forced by threat of job loss to take the mRNa shot and now have over 34 debilitating symptoms like blood clots, brain fog, exhaustion, insomnia, muscle spasms, allergies, chest pain, serious hear issues, neuropathy, nausea, maddening tinnitus, high blood pressure, reactivated latent viruses, major loss of finances due to health care costs their lives will never be the same.

- **Vaers safety data** show **17 k US deaths, including 181children. 16 k permanently disabled** including **586 children.**
- **In Idaho 31 dead and 94 permanently disabled**

    - **We were Told shot would stay in the arm** but Japanese biodiversity study proves that in in fact it travels to all organs in every sacred space of the body including blood brain barrier the blood placenta barrier, ovaries and testes

- **We were told it leaves the body quickly** but studies show blood 28 days and 60 (catruita and rotlgen)

- **We were told it cannot change our** DNA but it through reverse transcription it was found nucleus of liver cell by Alden et al 2022

- **We were told its safe for pregnancy but Thorp et al showed 57% increase in miscarriages** Thorp et a Bridle et al 2021

- **We were told the shot will stop us from getting covid and from transmitting to grandma, BUT Walenski , Birx and Fauci all** admit it doesn't stop you from getting covid or transmission to grandma, and Pelech studies show the more shots the more immune compromised you and grandma are. Seneff and Nigh and Banoun highlight that the vaccine can shed through body fluids and breath, breast milk, cows milk and has the potential to be passed on to your children. Zhang and Zhang

- **Athletes have had over 1200 sudden deaths and pilots over 100 sudden deaths after mRNA shot roll out** . with Bille et al 2006 study . Airline pilot association magazine .

- Ed Dowd exp blackrock analyst and hedge fund manager proves that for the first time in history there is an excess of all cause mortality in group life policy holders who are working age healthy iindividuals with access to healthcare. Theis is not during covid., but only after the injections were rolled out.

- These contaminated shots are literally breaking our children's hearts. Mansaguan et al 2022 shows 29.2 % cardiac issues in their study of teen children

- **LTC Theresa Long proves Military ICD 10 codes show 300% increase in cancers, infertility, miscarriages**

- **Clinical trials were substandard, biased, underpowered, not validated**, and some **injured participants were dropped** to obscure data like Breanne Dressen and Maddie DeGaray.

- **There are no downstream safety studies for fertility, cancer, genetics, or transgenerational contamination**

- **Big pharma corporations serve their shareholders not your health , they have no liability if your are injured, and Government agencies can be industry captured or make errors in judgement. Like thalidomide, rotavirus vaccine, and the tuskeegee experiments**

- **The mrna shot technology is so failed the cdc and fda had to change the definition of vaccine with a definition that can now include yogurt or sludge at the bottom of a porta pottie because they elicit an immune response.**

- **Its so failed that citizens had to be bribed with donuts and lotteries or threated with job loss and poverty to get a needle in every arm.**

- **It is so failed that to help save humanity even morticians are speaking up about unprecedented and disturbing massive amyloid plaque like clots that 7/10 are finding post mortem.**

- **Our health districts and other state agencies in Idaho plan to give this unsafe genetic therapy to your children and grandchildren as its on their child vaccine schedule this fall and big pharma openly discuss on their website the plan to have this dangerous technology in your flu shot and other shots for both adutls and children.**

- **Big Pharma is already marketing their genetic platform to give to to your livestock, wild game including fish, and even your agriculture which will adversely affect our food supply.**

Idaho is a state that corporately values life including the unborn, also farming and ranching are a way of life for generations and all of that is about to adversely change forever.

Dietrich Bonhoeffer: **"We are not to simply bandage the wounds of victims beneath the wheels of injustice, we are to drive a spoke into the wheel itself."**

I implore you members of this honorable committee to please hold the line with me and protect our most valuable treasures.... our children, our health, and our food supply.

To ensure a healthy community, to protect our little ones, and to do the right thing, I ask that you pass a recall the shot resolution until a forensics investigation of the products can be done. And I ask that you sign and send an action letter to Governor Little and AG Raul Labrador in support of a recall of this adulterated product in accordance with FDA regulation.

Thank you so much for your public service, time and consideration.

"Action is the only remedy to indifference: the most insidious danger of all,"

Elie Wiesel Holocaust survivor

Silence in the face of evil is itself evil: God will not hold us guiltless. Not to speak is to speak. Not to act is to act."

SECTION BREAK

Republican Party Of Idaho Halt and Recall of Genetic Biologic "Vaccine" Platform Technology Resolution:

WHEREAS Idaho residents have been injured by Genetic Biologic "Vaccine" Platform technology making it more injurious than any other vaccine mechanism in US history with 31 deaths and 94 permanent disabilities, 33 cases of myocarditis in the State of Idaho. The total US deaths are underreported at over 35,000 deaths, 65,670 permanently disabled and 26,897 myocarditis/pericarditis, since their release in 2021, according to VAERS CDC database www.openvaers.com

WHEREAS the mRNA platform technology shots must be recalled and investigated due to the egregious number of adverse events, disabilities, and deaths to adults and children. Adversely affecting children in the womb, it increases rates of miscarriages, and adversely affects women's menstruation and fertility.

WHEREAS multiple labs demonstrate that both the Pfizer and Moderna's misbranding, and adulteration of consumer products, substandard products, and substandard and underpowered clinical trials violate Consumer Product Protection statutes and informed consent as well as multiple other laws that regulate pharmaceutical safety in the State of Idaho.

WHEREAS the mNRA technology shots are adulterated with over a thousand times the allowable level of DNA from the DNA plasmids used to make the shots in E. Coli bacteria. They represent up to 35% of the shot genetic material.

WHEREAS some of these shots have non-disclosed SV40 sequence that allows them to infect human cells and go to the cell nucleus. SV40 is known to grow tumors and cause cancer.

WHEREAS due to adulteration there is the possibility of contamination with E. Coli bacterial proteins and "endotoxins" and can cause auto immune reactions and sepsis in the recipients. The material in the shot was designed to infect E.Coli, such as present in the human gut. This can make the gut become a permanent spike protein factory through the E.Coli that are naturally present there.

WHEREAS the mRNA in the shots is also broken and degraded. Contamination and degradation of the mRNA genetic sequence can lead to changing our God given DNA, it can turn off genes that we need, like those that fight cancer, and these genetic changes can be passed on to our children. The material in genetic injections can shed through bodily secretions and transfect through fluids and contact, as well a through milk of a mother including cows milk.

WHEREAS the mRNA technology presents possible irreversible damage, disability and death to livestock and critical food supply in the State of Idaho. Reducing herd loss beyond acceptable limits. Sequivity swine mRNA jabs USDA 2020-2021 summaries highlighted that this technology created adverse effects on 29.8% of the herd and 11.5% herd loss to death and wasting disease. This can adversely affect Idaho's economy, food supply, and health.

THEREFORE the Counties of Idaho support legislation that halts, recalls, investigates, or creates corporate liability for products that use mRNA, DNA, or any genetic technology for human pharmacological use or consumption, use regarding any livestock, or use regarding any agricultural products that may adversely affect human health, animal health, or the food supply thereof.

THEREFORE the Counties of Idaho support The Idaho State Statute 18-3323 Bioweapons Law with specific emphasis to section 18-3323 (4) (a,b,c,and d).

THEREFORE the Counties of Idaho support future legislation that requires informed consent and transparency of any proposed product, including imported food supply or pharmacological products, that use mRNA or any genetic technology for human pharmacological use or food consumption, or use regarding any livestock or agricultural products.

THEREFORE we the Counties of Idaho support future legislation that prohibits any and all mandates, local, state, national, or global, regarding forced medical procedures or vaccinations in any modality.

THEREFORE we the Counties of Idaho support a third party independent forensics audit on all future vaccine products, mRNA, DNA, or genetic vaccine products and modalities.

THEREFORE we the Counties of Idaho support life affirming legislation and declare that Idaho adults and children, including the unborn, have the right to normal cell growth.

SECTION BREAK

TITLE 18
CRIMES AND PUNISHMENTS

CHAPTER 33
FIREARMS, EXPLOSIVES AND OTHER DEADLY WEAPONS

18-3323. BIOLOGICAL WEAPONS — DEFINITIONS. (1) Any person who knowir develops, produces, stockpiles, transfers, acquires, retains or possesses biological agent, toxin or delivery system for use as a weapon, or who knowir assists another person or group of persons in doing so, or attempts, threatens conspires to do so, shall be guilty of a felony and shall be punished imprisonment for a term of up to and including life imprisonment or by a fine exceeding fifty thousand dollars ($50,000), or by both.

(2) As used in this section, the term "for use as a weapon" does not incl the development, production, stockpiling, transfer, acquisition, retention possession of a biological agent, toxin or delivery system for prophylact protective or other peaceful purposes if such biological agent, toxin or deliv system is of a type and in a quantity that is reasonable for such purposes.

(3) The attorney general of the state of Idaho may obtain in a civil actior injunction against:

(a) The conduct prohibited under this section;

(b) The preparation, solicitation, attempt, threat or conspiracy to engage conduct prohibited under this section; or

(c) The development, production, stockpiling, acquisition, retention possession of any biological agent, toxin or delivery system of a type or i quantity that under the circumstances has no apparent justification prophylactic, protective or other peaceful purposes.

(4) As used in this section:

(a) "Biological agent" means any microorganism, virus, infectious substance biological product that may be engineered as a result of biotechnology, or naturally occurring or bioengineered component of any such microorganism, vir infectious substance or biological product that is capable of causing:

(i) Death, disease or other biological malfunction in any anin including humans, or any plant or other living organism;

(ii) Deterioration of food, water, equipment, supplies or material of kind; or

(iii) Deleterious alteration of the environment;

(b) "Toxin" means the toxic material of animals, plants, microorganis viruses, fungi, infectious substances or a recombinant molecule, whatever origin or method of production including:

(i) Any poisonous substance or biological product that may be enginee as a result of biotechnology produced from a living organism; or

(ii) Any poisonous isomer or biological product, homologue, or derivat of such substance;

(c) "Delivery system" means any apparatus, equipment, device, or means delivery specifically designed to deliver or disseminate a biological age toxin or vector;

(d) "Vector" means a living organism or molecule, including a recombir molecule, or a biological product that may be engineered as a result biotechnology capable of carrying a biological agent to a host.

History:

[18-3323, added 2002, ch. 222, sec. 2, p. 624.]

SECTION BREAK

The Rest of the Story:

Clinical Trials: https://www.canadiancovidcarealliance.org/

https://rumble.com/vobcg5-relative-vs-absolute-risk-reduction.html

https://worldcouncilforhealth.org/

3400 Studies that show the injection harm and confirm the risks do not outweigh the benefit:

1250+ COVID Vaccine Publications and Case Reports - React19

https://childrenshealthdefense.org/defender/

Athletes' death rate up over 1600%:

https://goodsciencing.com/covid/athletes-suffer-cardiac-arrest-die-after-covid-shot/

Mask harms:

https://brownstone.org/articles/studies-and-articles-on-mask-ineffectiveness-and-harms/

Natural Immunity superior to injections:

https://brownstone.org/articles/research-studies-affirm-naturally-acquired-immunity/

SECTION BREAK

Read The CDC Disclaimer

VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports.

As of 11-18-2022 VAERS has stopped putting free text field information in the public data for Europe/UK.

All VAERS COVID Reports | US/Territories/Unknown

959,637 Reports Through May 5, 2023

source: OpenVAERS.com

17,544
DEATHS

80,233
HOSPITALIZATIONS

115,789
URGENT CARE

193,165
DOCTOR OFFICE VISITS

2,437
ANAPHYLAXIS

6,123
BELL'S PALSY

2,020
Miscarriages

8,117
Heart Attacks

4,943
Myocarditis/Pericarditis

16,871
Permanently Disabled

3,501
Thrombocytopenia/Low Platelet

14,394
Life Threatening

33,540

8,103

Severe Allergic Reaction

Shingles

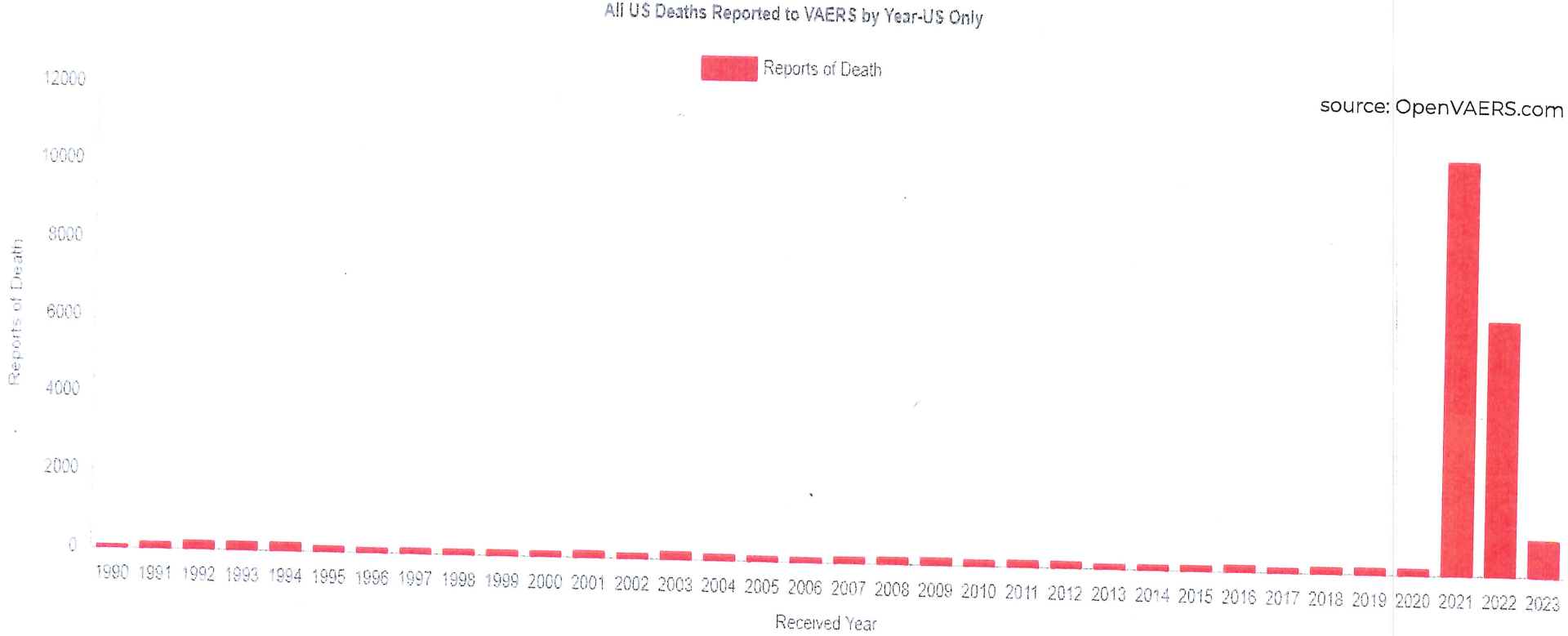
* As of November 18, 2022 VAERS has stopped putting free text field information in for Europe/UK.

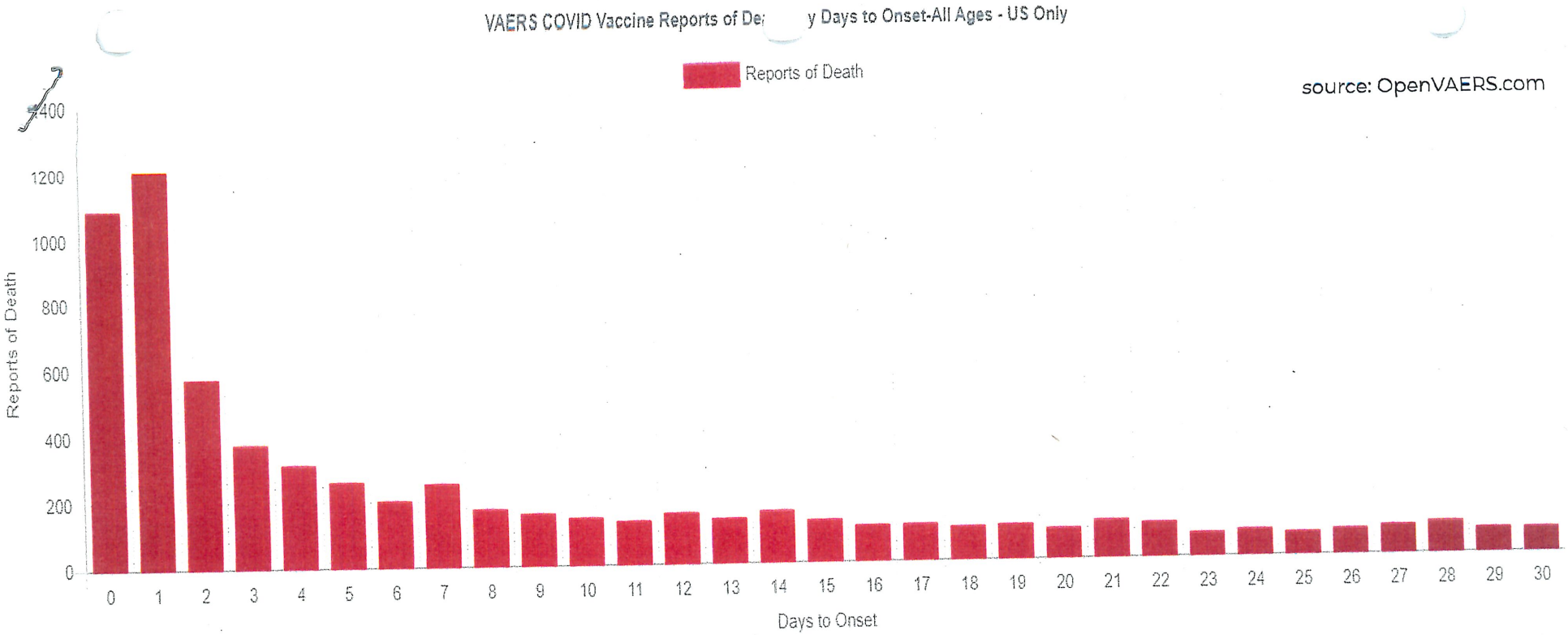
Read More →

Read COVID Child Reports

Read VAERS COVID Reports

Read All VAERS Reports


All US Deaths Reported to VAERS by Year-US Only
Reports of Death
source: OpenVAERS.com
12000
10000
8000
6000
4000
2000
0
Reports of Death
1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
Received Year



Questions? Comments? Bugs?

info@openvaers.com

Due to the high volume of inquiries, please be patient with response times.

AND PLEASE read the FAQ first.

OpenVAERS is a private organization that posts publicly available CDC/FDA data of injuries reported post-vaccination. Reports are not proof of causality.

OVERVIEW

PFIZER'S 6 MONTH REPORT DATA
LEVEL 1 EVIDENCE OF HARM

- Pfizer's most recent report indicates an **Efficacy of 91.3%.** (Which means **a reduction in positive cases** compared to placebo group.)
- **But it also showed**, compared to the placebo group, **an increase in illness and deaths.**
- There is **no benefit to a reduction in cases** if it comes at the cost of **increased sickness and death.**

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

S.J. Thomas, E.D. Moreira, Jr., N. Kitchin, J. Absalon, A. Gurtman, S. Lockhart, J.L. Perez, G. Perez Marc, F.P. Polack, C. Zeldis, R. Bailey, K.A. Swanson, X. Xu, S. Roychoudhury, K. Koury, S. Bouguermouh, W.V. Kalina, D. Cooper, R.W. Frenck, Jr., L.L. Hammitt, O. Türeci, H. Nell, A. Schaefer, S. Ünal, O. Yang, P. Liberator, D.B. Tresnan, S. Mather, P.R. Dormitzer, U. Şahin, W.C. Gruber, and K.U. Jansen, for the C4591001 Clinical Trial Group*

ABSTRACT

BACKGROUND

BNT162b2 is a lipid nanoparticle-formulated, nucleoside-modified RNA vaccine encoding a prefusion-stabilized, membrane-anchored severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) full-length spike protein. BNT162b2 is highly efficacious against coronavirus disease 2019 (Covid-19) and is currently approved, conditionally approved, or authorized for emergency use worldwide. At the time of initial authorization, data beyond 2 months after vaccination were unavailable.

METHODS

In an ongoing, placebo-controlled, observer-blinded, multinational, pivotal efficacy trial, we randomly assigned 44,165 participants 16 years of age or older and 2264 participants 12 to 15 years of age to receive two 30-μg doses, at 21 days apart, of BNT162b2 or placebo. The trial end points were vaccine efficacy against laboratory-confirmed Covid-19 and safety, which were both evaluated through 6 months after vaccination.

RESULTS

BNT162b2 continued to be safe and have an acceptable adverse-event profile. Few participants had adverse events leading to withdrawal from the trial. Vaccine efficacy against Covid-19 was 91.3% (95% confidence interval [CI], 89.0 to 93.2) through 6 months of follow-up among the participants without evidence of previous SARS-CoV-2 infection who could be evaluated. There was a gradual decline in vaccine efficacy. Vaccine efficacy of 80 to 100% was seen across countries and in populations with diverse ages, sexes, race or ethnic groups, and risk factors for Covid-19 among participants without evidence of previous infection with SARS-CoV-2. Vaccine efficacy against severe disease was 96.7% (95% CI, 80.3 to 99.9). In South Africa, where the SARS-CoV-2 variant of concern B.1.351 (or beta) was predominant, a vaccine efficacy of 100% (95% CI, 53.5 to 100) was observed.

CONCLUSIONS

Through 6 months of follow-up and despite a gradual decline in vaccine efficacy, BNT162b2 had a favorable safety profile and was highly efficacious in preventing Covid-19. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Dormitzer can be contacted at philip.dormitzer@pfizer.com or at Pfizer, 401 N. Middletown Rd., Pearl River, NY 10965.

*A list of the investigators in the C4591001 Clinical Trial Group is provided in the Supplementary Appendix, available at NEJM.org.

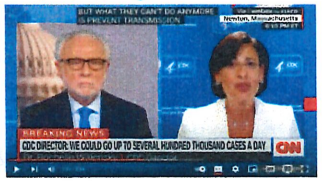
This article was published on September 15, 2021, at NEJM.org.

N Engl J Med 385:1761-1773.
DOI: 10.1056/NEJMoa2110345

CME at NEJM.org

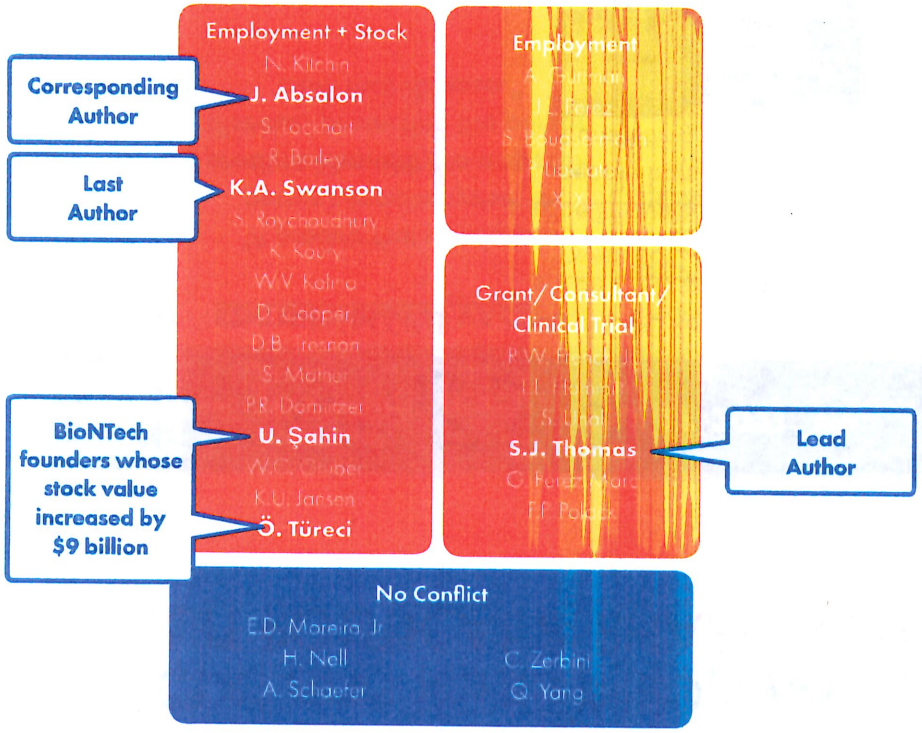
https://www.nejm.org/doi/pdf/10.1056/NEJMoa2110345?articleTools=true

THE CDC HAS REDEFINED "VACCINE" TO SUIT POLITICAL & PHARMACEUTICAL INTERESTS

For many years	Jul 27, 2021	Aug 18, 2021	Starting Sep 2, 2021
CDC Definition of VACCINE *"A product that stimulates a person's immune system **to produce immunity to a specific disease, protecting the person from that disease."***	Head of CDC Rochelle Walensky went on CNN and admitted the COVID-19 vaccines do not provide immunity - they don't stop people from catching or transmitting COVID-19. 	Joe Biden announced booster shots for all Americans. 	**CDC Definition of VACCINE CHANGED** *"A preparation that is used **to stimulate the body's immune response against diseases."*** **This looks like fraud.**

CONFLICTS OF INTEREST AMONG PFIZER REPORT AUTHORS

6 MONTH REPORT AUTHORS



I am a real person. This is my true story. It is with a lot of hesitancy that I share this experience because the few times I have, it resulted in a lot of backlash, uncomfortable silence and or/disbelief from the medical community and even people that I once considered good friends.

I am the CEO of a health care organization and I fear the ramifications of speaking up about my vaccine injuries and the impact on my career. I am one of the lucky ones that has been able to work remotely and through the use of Zoom and using different screen backgrounds have even worked when I was completely bedridden.

I hope one day things will change and I will feel safe enough to come out and share these things in person.

I want to make clear that I am not anti -vaccine, but I am definitely pro informed consent. I do not feel that I had all of the information necessary at the time to make an informed decision.

On April 2, 2021 my life was forever changed by the decision I made to get one dose of the Pfizer COVID vaccine.

It is hard for me to think of who I once was or even look at photos or videos of what I used to be, when to this day I have difficulty walking, due to the post vaccine disability in my feet. Throughout 2021, 2022 and now even into 2023, I have spent many days bedridden or dependent on a wheelchair due to high heart rate and nerve pain in my feet.

Pre-vaccine, I was a fully recovered early stage breast cancer survivor. I started each day with 3 mile walks or hour long cycling classes, and 10-mile outdoor biking was part of my weekly regimen. I rode my bike 15 miles the day before the vaccine.

I had a clean bill of health from my doctor. I had perfect blood work one week prior to receiving the vaccine and I was on no medications. I was advised by my doctor to get the vaccine. It is hard to swallow that I am a breast cancer survivor but got my butt kicked by the COVID vaccine.

My reaction happened within 4 hours of receiving the vaccine and the physical ramifications have been relentless ever since.

The vaccine has impacted multiple systems throughout by body; cardiac, neurological, gastrointestinal, and vascular. I have verified post vaccine autoimmune syndrome and dysautonomia (injury of the autonomic nervous system).

My daily symptoms include brain fog, muscle twitching, loss of muscle mass, internal tremors, poor balance accompanied by a concussed dizzy off balance feeling, extreme nerve pain in both my hands and feet (burning, stabbing, pins and needles, numbness, and itching), vascular insufficiency in my toes verified via ultrasound, and difficulty walking. I can't even sleep with a blanket on my hands and feet due to the nerve pain (which has plagued me daily for the last 2 years). I also suffer from heat, cold, and exercise intolerance, tinnitus, light sensitivity, blurred vision, hair loss, dry eyes, dry mouth, fatigue and nausea, insomnia, shortness of breath, rashes, gastrointestinal issues, and inappropriate sinus tachycardia (suspected dysautonomia) with heart rates as high as 210.

Post vaccine, my menstrual cycles got heavier and heavier and closer and closer together until I eventually hemorrhaged, became severely anemic and was rushed in for emergency surgery in Feb 2022.

During the last two plus years, I have sought medical help starting with primary care. The primary care doctor did not know how to help me and hoped I would improve as time went on. Unfortunately, time is not my friend and I continue to decline.

Out of desperation, I even emailed neurologists at the NIH, who emailed me back saying that they were aware of neuropathy across all the vaccines and to consult with a local neurologist.

I was then shuffled around amongst many specialists, neurologist, 2 cardiologists, rheumatologist, 2 hematologists, gynecologist, podiatrist, vascular surgeon, osteopath, dermatologist, functional medicine doctor, ear nose throat doctor, and a second opinion with the Cleveland Clinic.

Most of them have heard very little about this type of reaction and the rheumatologist told me I am in unchartered waters. The neurologist labeled me with an "anxiety disorder" because I continue to seek answers and treatment and he cannot figure out what is wrong with me.

Since the vaccine, I've had 4 Emergency Department visits, 1 surgery, 2 hospital stays and a variety of tests (multiple vascular and pelvic ultrasounds, lost count of number of ECG's, 2 echocardiograms, 5 halter monitors, lung CT, chest x rays, countless blood tests, tilt table test, neurological exams, etc.)

I've been diagnosed with mixed connective tissue disease (my ANA titer is high and I have symptoms of Lupus, Rheumatoid Arthritis, Reynaud's, vascular and small blood vessel problems etc. but they cannot pinpoint it to one autoimmune disorder).

I've developed autoantibodies for Antiphospholipid Syndrome (a rare autoimmune blood clotting disorder), inappropriate sinus tachycardia from suspected autonomic nervous system injury from the vaccine, erythromelalgia, (a rare condition that causes episodes of burning pain and redness in the feet, hands, arms, legs, and ears) and vascular insufficiency in my toes.

I am still in the process of sorting out whether or not I have small fiber neuropathy and a host of other autoimmune diseases.

My condition is not improving and is poorly controlled by a careful regimen of medications that I cannot function without which was figured out by working with the different specialists, trial and error, many different tests (described above), blood draws, monitoring of symptoms, and countless doctors' appointments (including a second opinion from a Cleveland Clinic hematologist which cost $2,000 out of pocket).

I am still terrified that this is some sort of degenerative process.

I went from taking no medications pre vaccine to 5 medications and a variety of supplements post vaccine to control my symptoms. I am patched together by medications, which do not always work to keep me functional, and I am nowhere near the person I used to be.

I was recently turned away by a local Idaho rheumatology group once they saw that I was vaccine injured after they received all my medical records (my rheumatologist, Dr. Robert Fox at Scripps recently retired). The Idaho rheumatology group cancelled my appointment and told me that they could not help me. I was also turned away by a local Idaho neuro muscular doctor.

In order to receive treatment by a neuromuscular doctor, a neurologist specializing in dysautonomia, and a rheumatologist, my local GP advocated for me with the University of Utah. I am grateful they accepted me as a patient, but I will have to travel 5 hours for care and I've been waiting 6 months for the appointments.

This is a terrifying way to live and the local doctors really do not know how to help as there is very little information available to help those that are experiencing adverse reactions to the vaccine.

So, why am I writing to you today?

My life has been stolen from me by this vaccine. On a daily basis, I battle the fear of what will go wrong next. My husband and I cannot make plans for our future because of my medical condition. At first, I thought that I was alone in what happened to me as so many vaccine injured were made to feel that way. But along this journey, I have met thousands of others like me, and I believe that we should not leave our injured or vulnerable behind.

We need to stop denying that the COVID vaccine injuries exist, the injured should be validated and not gas lighted. I am here to inform others that these injuries are very real and not just fade into the background as collateral damage.

I am advocating for awareness of the injured, for informed consent, for never again legislating mandatory MRNA COVID vaccination, and I am praying that someday others will come along beside the injured and advocate for the necessary research that will pave the way for proper medical care and treatment.

There is currently very little help for those of us that suffer every day with our injuries, not even at long haul clinics. Although, I share many of the same symptoms as those with long haul COVID, I am turned away by long haul clinics because I am vaccine injured and <u>never</u> had a COVID infection (verified by blood tests).

This medical situation has both physical and emotional ramifications. I know of injured that have given up on life and made the choice to no longer continue living with the pain, isolation, and frustration of trying to find viable medical treatments. I understand, as at times I have also plummeted into a dark place emotionally and spiritually. It is only through a supportive family and my faith in God that I find the courage to take on this adversity.

It is a slow daily uphill climb with a lot of setbacks and struggles.

I am very thankful to be alive, but I am still searching for answers, for treatment, for a way back to who I used to be.

Thank you for listening.

DECLARATION BRIANNE DRESSEN

Pursuant to 28 U.S.C. § 1746, Brianne Dressen, of Saragota Springs, Utah, hereby declares:

I am over the age of 18 and fully competent to make this declaration through my education, knowledge, experience and training, of the facts stated in this declaration.

This declaration is submitted in support of: LEGAL ACTIONS TO CONVENE A GRAND JURY AND TO PULL THE COVID-19 "VACCINES" UNDER CONSUMER PRODUCT PROTECTION STATUTES FOR LACK OF SAFETY AND EFFICACY, MISREPRESENTATION, MISBRANDING, ADULTERATION AND DEGRADATION, CAUSES.

I am a clinical trial participant in the AstraZeneca Covid vaccine trial, conducted in the United States in 2020. I am also a clinical trial participant in the NIH trial on Covid vaccine injuries. I am a Co-Chair of React19, a patient advocacy organization consisting of over 20,000 Covid vaccine injured Americans. This advocacy organization is medically-centered, using science to further our understanding of these diseases.

I do herby declare that I freely participated and was injured in the clinical trial for AstraZeneca's Covid vaccine. Because my injury was from the first dose, the trial company advised that I not receive the second dose. I was thus unblinded and confirmed I received the Covid vaccine, and was also dropped from the clinical trial. My injury that consists of debilitating and persisting symptoms to this day is not noted in the clinical trial report that is published in the New England Journal of Medicine. The report does however state that all participants with injuries are followed for at least 730 days. My injury data was only recorded to day 60. This is two years of critical safety data gone. The clinical trial report also states that participants elected to

forego the second dose, which is also inaccurate. The clinical trial company told me to not receive any subsequent doses. When I appealed to the New England Journal of Medicine for a revision to the study, I was approached by Dr. Eric Ruben who is on the FDA's Covid vaccine advisory committee and chief editor at the New England Journal of Medicine. Dr. Ruben told me that they would not be revising the study report, as just one person in a study with tens of thousands would have little effect. He also stated that the drug companies are the only ones in possession of the totality of the data and told me to take up my concerns with the drug company.

I have yet to hear from a real human being at the drug company. My cries for help as I lay in the hospital, at home trapped in my room unable to move or have my small children in the same room as me, AstraZeneca remained silent through it all. I was abandoned, even though I have a contract that states AstraZeneca will help with any expenses incurred as a result of injury.

As it became apparent that the drug company would not do their part, my husband reported my injury to the National Institutes of Health to Dr. Avidnra Nath, at the neuro-infectious disease research under Dr. Anthony Fauci. They responded right away and launched a study to look into adverse events to the Covid vaccines. This NIH study does not have the words "Covid vaccine" anywhere on the protocol/enrollment paperwork that I signed. I was flown out to the National Institutes of Health in June of 2021 to be evaluated and treated. The NIH confirmed and documented that I have post-vaccine neuropathy, tinnitus, severe POTS, and other life-altering diseases after my Covid vaccine. This visit and the treatment I and many other injured received at the NIH changed the trajectory of my recovery, yet the public was not informed of this therapy that helped me and dozens of others.

In March 2021, Dr. Nath, Dr. Safavi (NIH), Dr. Rochelle Wallensky (CDC), Dr. Janet

Woodcock (FDA), Harvard and Stanford researchers all are communicating via email with my fellow injured, Dr. Danice Hertz, promising her they will disclose neurological complications to the Covid vaccines to the public but to give them a couple more weeks, and not publicize this. Furthermore, In June 2021, I was asked in-person at the NIH to NOT discuss the research being conducted at the NIH. I complied in hopes that they would own up to their promises and inform the public.

In addition to the NIH research on Covid vaccine injuries, the NIH secretly cared for Covid vaccine injured Americans. We would send our most critical and desperate cases to this research team at the NIH, under Dr. Antony Fauci at the NIAID, with Dr. Avindra Nath. Dr. Nath and his team would conduct telehealth appointments with the patient and call their home medical teams, providing testing and treatment recommendations. Dr. Nath provided such a consult to a fellow clinical trial participant, Ms. Maddie deGaray, imploring her physicians to take her injury seriously, providing direction on testing, and potential therapeutics to help her. The NIH still has yet to provide clear communication at all about this research to the public or the medical community, leaving the many injured Americans across the country without adequate recognition or help, when they don't have to be.

In the Fall of 2021, Dr. Nath (NIH) subsequently co-authored a paper describing the safety of these vaccines in comparison to Covid-19. In the middle of this paper he is acknowledging neurological complications to vaccines historically, and describes the need for early recognition and early intervention with immunotherapies for Covid vaccines. This small two paragraph summary in a 12 page long paper is not sufficient communication to the public to be able to be aware of the NIH's involvement or knowledge on these new diseases from Covid vaccines. Dr.

Avindra nath also said the same to me regarding early intervention and recognition, in a private email in the summer of 2021, Dr. Janet Woodcock, commissioner of the FDA agreed with early intervention and recognition in a subsequent email with me.

In the Fall of 2021, Because of the government's repeated failures to help the public who are suffering from Covid vaccine injuries, I formed an advocacy organization called React19. React19 began to have meetings with Dr. Peter Marks, head of biologics and the FDA. We also received private acknowledgement of neurological complications from the Covid vaccines from Dr. Janet Woodcock, commissioner of the FDA. Both Dr Marks and Dr. Woodcock repeatedly told us that they are not denying Covid vaccine injuries are occurring. Dr Marks also acknowledged that they have found a safety signal for neuropathy in females age 30-50, that has yet to be disclosed to the public. Neuropathy can be a very debilitating disease that the medical community is failing to recognize post-vaccination because the FDA has not provided this critical communication. We, at React19, were promised follow-up in many areas by both Dr. Woodcock and Dr. Marks including following up on death reports in VAERS, investigating deleted or missing VAERS reports, investigating MIS-V which is a deadly and rapid disease for teens, and failure to acknowledge the NIH research or any of these other conversations with the medical or research communities in any form.

Because of the NIH and FDA's failures to disclose their knowledge to the public, the Covid vaccine injured have suffered irreparable damages to their health with continuing progression of serious disease that has gone untreated, extreme censorship and publicly allowed ostracization from our communities and families. We have been suppressed in the media and kept from sharing our suffering and truth with the world. Medical exemptions are not being granted. We

have been even separated on support forums on social media, preventing us from being able to peaceably assemble to support one another, and share tests and protocols that are helping us heal. We also have experienced the cases of many attempted and completed suicides. I have notified the FDA of all of these issues, with promises to help, but help never came.

Because there is no covid vaccine injury diagnosis code here in the United States, despite the WHO having such a code (U12.9). We are not accurately recognized in our medical records either. We have repeatedly appealed to the US Senate and to the Diagnostics coding department to correct this issue, but our pleas have been ignored. The US diagnostic codes do however include: (unvaccinated with Covid) and (partially vaccinated with Covid); but do NOT include: fully vaccinated with Covid.

In conclusion, I hereby do declare that everything I have stated is accurate to the best of my knowledge and recollection and I have permission to discuss the other injured individuals in this declaration. I wish for only the truth to come out and for those suffering like myself to be made whole. The National Institutes of Health and the Food and Drug Administration certainly know far more about Covid vaccine injuries than they are disclosing to the public or medical communities. The drug companies also have skewed the clinical trial data for the Covid vaccines. These institutions must now do what's right for the American public and adhere to their oath dedicated to truth and transparency to serve Americans, not to serve the drug companies.

I am giving this declaration to: PROVIDE WRITTEN TESTIMONY TO SUPPORT LEGAL ACTIONS TO CONVENE A GRAND JURY AND TO PULL THE COVID-19 "VACCINES" UNDER CONSUMER PRODUCT PROTECTION STATUTES FOR LACK OF SAFETY AND EFFICACY. MISREPRESENTATION, MISBRANDING AND ADULTERATION/DEGRADATION, CAUSES.

I declare under penalty of perjury under the laws of the United Statesof America that the

foregoing is true and correct.

Executed on this the 26th day of February, 2023.

Brianne Dressen
(NAME)

Co-Chair – React19.org
(TITLE)

Experimental, Never before Tested Novel Genetic Therapy Pushed in Pregnancy. The Most Egregious Violation of Ethics in the History of Medicine

James A Thorp, MD. Thursday

November 10, 2022

This IS the greatest disaster in the history of obstetrics and all of medicine. I testify that this unwarranted experimental gene therapy was NEVER indicated in pregnancy and was perpetrated unlawfully and with falsified data. Res ipsi loquitor. The facts speak for themselves. It was known by Schàdlich et al as early as 2012 that lipid nanoparticles (LNP) concentrate in the ovaries of mice and Wistar rats. The FOIA request of the Japanese Pfizer biodistribution studies confirmed that within 48 hours the "vaccine" was immediately absorbed into the bloodstream and concentrated in the ovaries 118-fold by 48 hours and the trajectory would have risen even higher had the animals not been sacrificed at 48 hours. This experimental therapy may have permanently damaging effects on the human genome for multiple generations or perpetuity and makes diethylstilbestrol pale in comparison. It was incumbent upon the stakeholders to have excluded long-term effects prior to rolling this novel experimental gene therapy out. The long-standing golden rule of pregnancy has NEVER allowed unknown substances to EVER be used in pregnancy.

A preborn baby near term-limited (gametes or germ cells) for her entire lifetime - only one million ova (eggs). Men's gametes (sperm) are continuously produced throughout life with estimates of over 20 million per hour. As argued in 2020, COVID-19 inoculations were NEVER necessary for pregnancy because there were ample data demonstrating that alternate therapies were available. Unfortunately, this truthful long-standing evidence was suppressed, altered, buried, and villainized by the medical-industrial complex for the sole purpose of paving the way for a lucrative experimental gene therapy masqueraded as a "vaccine".

The narrative that the vaccine must be pushed in pregnancy is supported by many experts in part because of the long-held belief that pregnant women have diminished immune function to accommodate the fetus and are thus at much greater risk of dying from viral pneumonia. Maternal Fetal Medicine physician Beth Pineles in 2021 documents that pregnancy does not predispose to morbidity and mortality from viral pneumonia but lessens the risk.

Not only do the biodistribution studies document the disastrous concentration of the LNP in the ovaries adjacent to the precious and limited ova – the life of all our future generations - but it also concentrates in the thymus gland in fetal life, potentially rendering permanent harm to the "seed of the immune function for life".

Alexandra Latypova a pharmaceutical whistleblower testifies (here and here) that the industry knowingly and purposely falsified and hid damaging data from the public in their reproductive toxicology studies. She provides internal documents with birth defects including rib abnormalities in animals' fetuses, a condition in humans that could lead to lethal skeletal dysplasia. "*They accepted fraudulent test designs, substitutions of test*

responsible for killing and injuring tens of millions. The most accurate medical database in the world, the military DMED database showed disastrous effects of the "vaccine" in pregnancy as reviewed by Senator Ron Johnson. CDC tried to hide their v-safe (smart phone) data that could be easily manipulated as used in the Shimabukuro NEJM. CDC is attempting to hide v-save data because of the damning data; 7.7% of the 10.1 million participants required a visit to the hospital or medical provider and another 25% loss from work or school or had a vaccine complication. In the ultimate display of irony, the creator of v-safe died suddenly just one month after his second COVID-19 "vaccine".

There are now two recently published articles documenting intact pseudo-uridinated mRNA (pumRNA) from the "vaccine" in human breast milk that has extraordinarily concerning implications, Jia Ming Low et al, and Alisa Kachikis et al. This is a disaster of unparalleled proportions. I have reviewed the frightening drop in birthrates in countries all over the world since the rollout of the "vaccine". COVID-19 and Disaster Capitalism – Part I outlines the playbook of the medical industrial complex to game the system thus producing a new pandemic billionaire on a daily basis since the onset of the pandemic (500+).

The movie-documentary by the Stew Peters Network premiers on November 21, 2022 and its trailer already has almost 1.5 million views on just Rumble (here, here, here and here).

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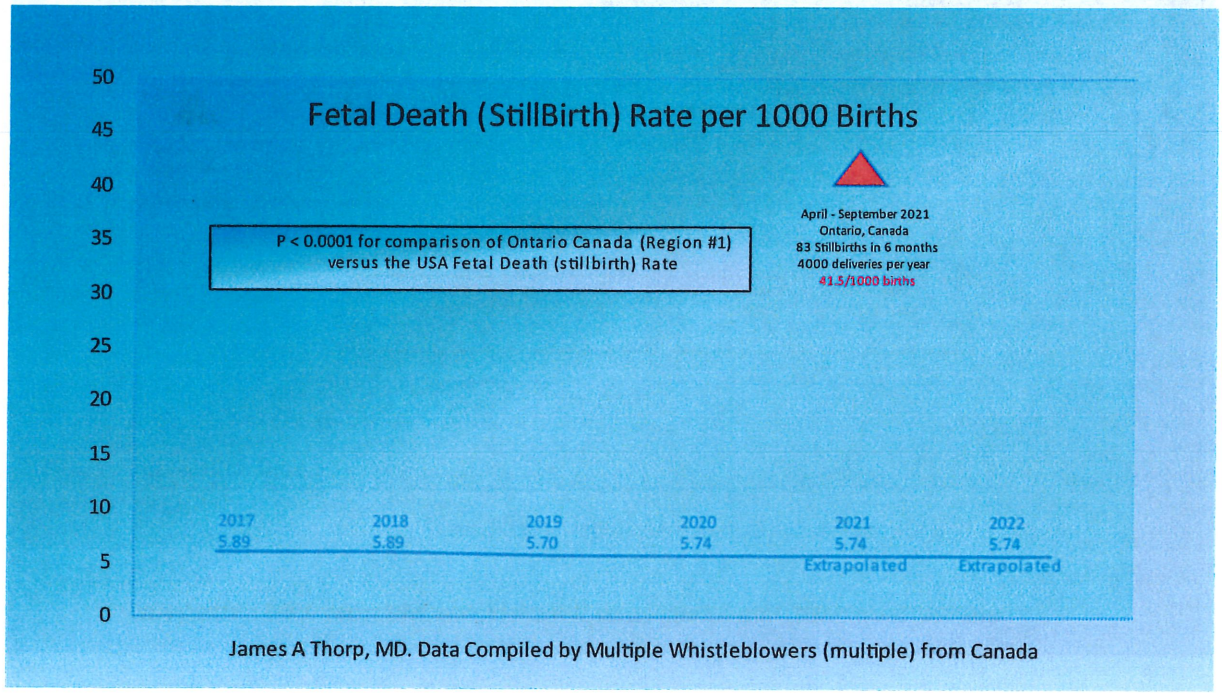
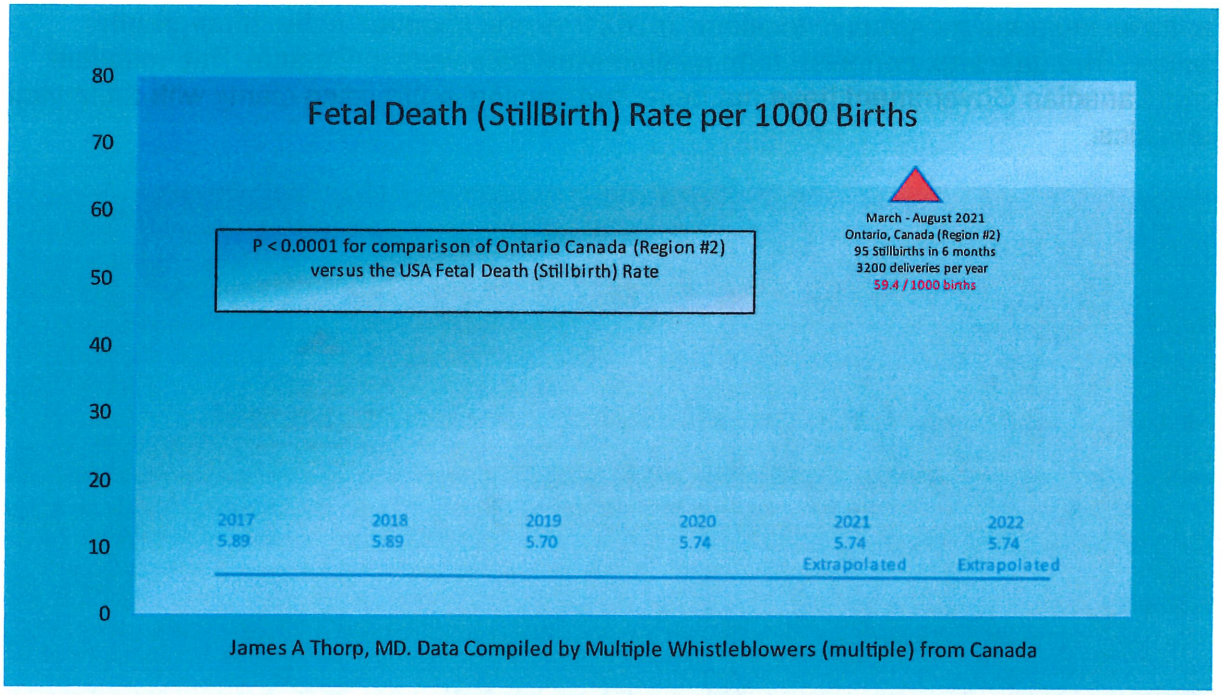
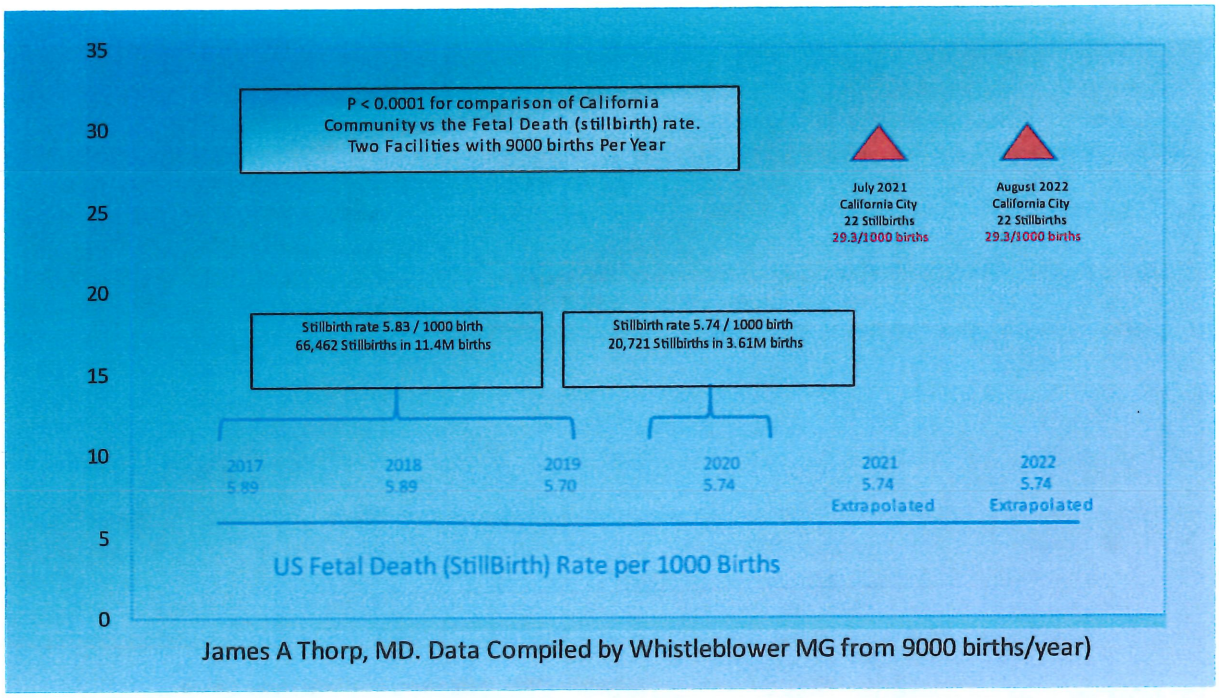
November 10, 2022

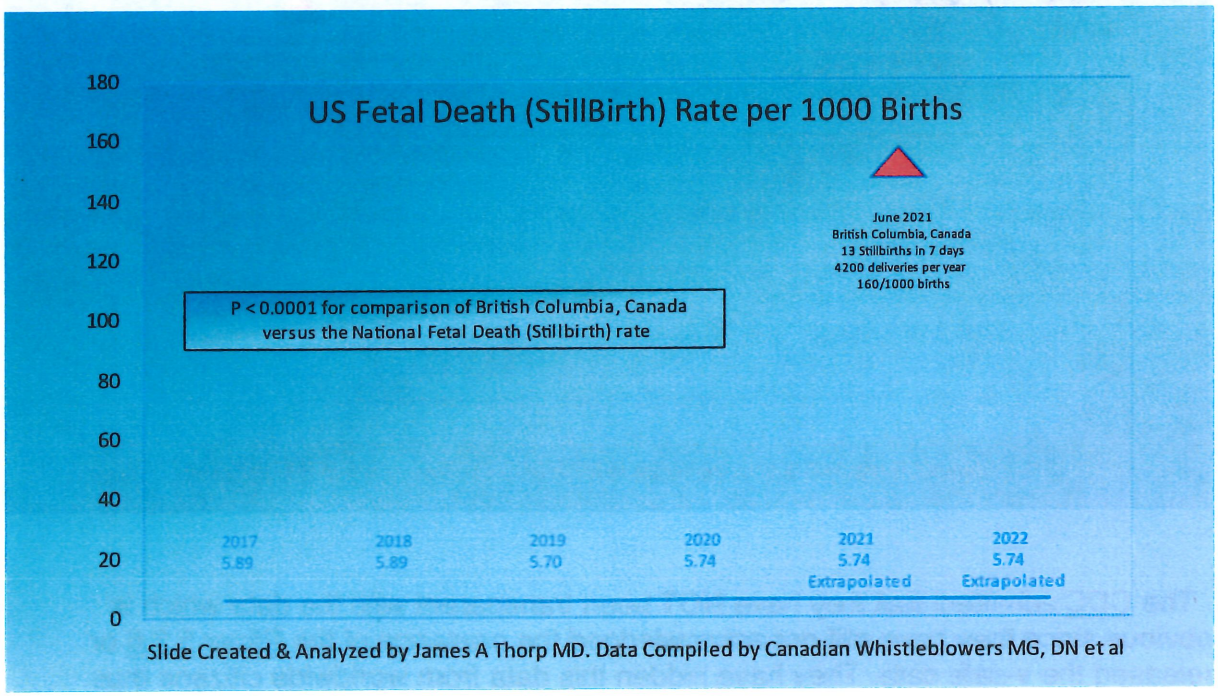




The CDC admitted that they have NOT been transparent with the data which is obvious since they have still not acknowledged the presence of the Pfizer 5.3.6 or released the v-safe data. They have hidden this data from worldwide citizens thus



Three other Canadian whistleblowers document a substantial surge in the stillbirth rates in three separate geographic locations in 2021 as documented in the three graphs below. The data was compiled from multiple whistleblowers in Canada. The hospitals and Canadian Government have not been forthcoming in providing clarity with their vital statistics.



SECTION BREAK

*Big Pharma Tried to hide this document for 75 years.

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

SECTION BREAK

Masking location: under adjustment

Japanese Biodiversity Stud
It goes to the entire body, bre
ovaries, testes, (placenta), sple

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [3H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159 Report Number: 185350

Sample	Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined)							% of Administered Dose (males and females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Lymph (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	-	-	-	-	-	-	-
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	-	-	-	-	-	-	-
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	-	-	-	-	-	-	-
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001	0.009	0.008	0.016	0.025	0.037	0.095
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003	0.007	0.014	0.015	0.015	0.011	0.019
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000	0.001	0.001	0.001	0.000	0.000	0.001
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001	0.001	0.002	0.003	0.003	0.004	0.003
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003	0.007	0.008	0.008	0.005	0.006	0.009
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	-	-	-	-	-	-	-
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024	0.130	0.319	0.543	0.776	0.906	0.835
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001	0.002	0.002	0.003	0.001	0.001	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013	0.093	0.325	0.385	0.982	0.821	1.03
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006	0.019	0.034	0.030	0.040	0.037	0.039
Tests (Males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007	0.010	0.017	0.030	0.034	0.074	0.074
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004	0.007	0.010	0.012	0.008	0.007	0.008
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000	0.001	0.001	0.001	0.001	0.001	0.001
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002	0.011	0.015	0.008	0.016	0.018	0.022
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	-	-	-	-	-	-	-
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	-	-	-	-	-	-	-
Blood: plasma ratio	0.815	0.515	0.550	0.510	0.555	0.530	0.540	-	-	-	-	-	-	-

Japanese Biodiversity Stu
It goes to the entire body, bu
ovaries, testes, (placenta)

2.6.5.5B. PHARMACOKINETICS: ORGAN

DISTRIBUTION CONTINUED

Test Article: [3H]-Labelled LNP-mRNA formulation containing

ALC-0315 and ALC-0159 Report Number: 185350

Sample	Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined)							% of Administered Dose (males and females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Lymph (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	-	-	-	-	-	-	-
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	-	-	-	-	-	-	-
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	-	-	-	-	-	-	-
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001	0.009	0.008	0.016	0.025	0.037	0.095
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003	0.007	0.014	0.015	0.015	0.011	0.019
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000	0.001	0.001	0.001	0.000	0.000	0.001
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001	0.001	0.002	0.003	0.003	0.004	0.003
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003	0.007	0.008	0.008	0.005	0.006	0.009
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	-	-	-	-	-	-	-
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024	0.130	0.319	0.543	0.776	0.906	0.835
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001	0.002	0.002	0.003	0.001	0.001	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013	0.093	0.325	0.385	0.982	0.821	1.03
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006	0.019	0.034	0.030	0.040	0.037	0.039
Tests (Males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007	0.010	0.017	0.030	0.034	0.074	0.074
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004	0.007	0.010	0.012	0.008	0.007	0.008
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000	0.001	0.001	0.001	0.001	0.001	0.001
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002	0.011	0.015	0.008	0.016	0.018	0.022
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	-	-	-	-	-	-	-
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	-	-	-	-	-	-	-
Blood: plasma ratio	0.815	0.515	0.550	0.510	0.555	0.530	0.540	-	-	-	-	-	-	-

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [3H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159

Report Number: 185350

Species (Strain):	Rat (Wistar Han)
Sex/Number of Animals:	Male and female/3 animals/sex/timepoint (21 animals/sex total for the 50 µg dose)
Feeding Condition:	Fed adlibitum
Method of Administration:	Intramuscular injection
Please:	50 µg [3H]-08-A01-C0 (lot # NC-0552-1)
Number of Doses:	1
Detection:	Radioactivity quantitation using liquid scintillation counting
Sampling Time (hour):	0.25, 1, 2, 4, 8, 24, and 48 hours post-injection

Sample	Mean total lipid concentration (µg lipid equivalent/g (or mL) (males and females combined)							% of administered dose (males and females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.057	0.100	0.126	0.128	0.093	0.084	0.181	-	-	-	-	-	-	-
Adrenal glands	0.271	1.48	2.72	2.89	6.80	13.8	18.2	0.001	0.007	0.010	0.015	0.035	0.066	0.106
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365	0.000	0.001	0.001	0.001	0.001	0.002	0.002
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687	-	-	-	-	-	-	-
Bone marrow (femur)	0.479	0.960	1.24	1.24	1.84	2.49	3.77	-	-	-	-	-	-	-
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068	0.007	0.013	0.020	0.016	0.011	0.010	0.009
Eyes	0.010	0.035	0.052	0.067	0.059	0.091	0.112	0.000	0.001	0.001	0.002	0.002	0.002	0.003
Heart	0.282	1.03	1.40	0.987	0.790	0.451	0.546	0.018	0.056	0.084	0.060	0.042	0.027	0.030
Injection site	128	394	311	338	213	195	165	19.9	52.6	31.6	28.4	21.9	29.1	24.6
Kidneys	0.391	1.16	2.05	0.924	0.590	0.426	0.425	0.050	0.124	0.211	0.109	0.075	0.054	0.057
Large intestine	0.013	0.048	0.093	0.287	0.649	1.10	1.34	0.008	0.025	0.065	0.192	0.405	0.692	0.762
Liver	0.737	4.63	11.0	16.5	26.5	19.2	24.3	0.602	2.87	7.33	11.9	18.1	15.4	16.2
Lung	0.492	1.21	1.83	1.50	1.15	1.04	1.09	0.052	0.101	0.178	0.169	0.122	0.101	0.101

Found in body at least 60 days!

Crosses Blood Brain Barrier
Blood - placenta barr

ISSN: 2475-6296

Review Article

Journal of Clinical & Experimental Immunology

COVID-19 vaccines – An Australian Review

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Abstract

After millions of people have been vaccinated as often as four times within a year, the effects of these vaccinations are slowly becoming apparent. This review has been written from an Australian perspective with the main focus on the COVID-19 mRNA vaccines. We will look at the promises/predictions originally made and the actual facts. We will evaluate the safety and efficacy by looking at the literature and the data from government agencies. The literature review will be summed up in a table listing the so far reported side effects of which many are very serious including death, with this data coming from 1011 case reports. Long term side effects will also be covered and the risk benefit ratio will be explored. The review is ending with some very critical question that need further discussion.

Introduction

This review is written from an Australian perspective and will concentrate on the COVID-19 mRNA vaccines. In Australia the COVID vaccination is still heavily promoted. Until April 2022 only the mRNA vaccines Comirnaty (Pfizer) and Spikevax (Moderna), as well as the vector vaccines Vaxzevria (AstraZeneca) and COVID-19 Vaccine Janssen (Janssen) were preliminarily registered for use. Every one of these vaccines forces the vaccinees body to produce the spike protein for which the genetic code is delivered into the cells as mRNA via a nanoparticle or as double stranded DNA via a viral vector. (https://www.tga.gov.au/international-covid-19-vaccines-recognised-australia).

In April 2022 yet another vaccine, Nuvaxovid (Biocelect on behalf of Novavax, based on a new concept) received preliminary approval in Australian. Nuvaxoid contains a modified spike derived from moth cells cultured after transfection using Baculovirus, which express the spike protein on their cell membrane. This spike protein is harvested and assembled onto a synthetic lipid nanoparticle, which displays 14 spike proteins each. (https://www.precisionvaccinations.com/vaccines/novavax-covid-19-vaccine). The vaccine is registered for 18 years of age and older.

The government continues to push particularly the mRNA vaccinations by encouraging a fourth vaccination and recommending the vaccine for pregnant women as well as children 5 to 11 years old. The official public message is that the mRNA vaccines are safe. However, the Therapeutic Goods Administration (TGA), the medicine and therapeutic regulatory agency of the Australian Government, states quite clearly on their website that the large-scale trials are still progressing and no full data package has been received from any company. The TGA is currently getting rolling data and safety and effectiveness are still being assessed (https://www.tga.gov.au/covid-19-vaccines-undergoing-evaluation).

Initial information

The mRNA vaccines were supposed to remain at the injection site and be taken up by the lymphatic system. This assumption proved to be wrong. During an autopsy of a vaccinated person that had died after mRNA vaccination it was found that the vaccine disperses rapidly from the injection site and can be found in nearly all parts of the body [1]. The mRNA is enveloped in liquid nano particles (LNP) containing a mixture of phospholipids, cholesterol, PEGylated lipids and cationic or ionizable lipids [2]. Research has shown that such nanoparticles can cross the blood-brain barrier [3] and the blood-placenta barrier [4], so it came as no surprise that the European Medicines Agency assessment report for the Moderna vaccine on page 47 (https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf) also noted that mRNA could be detected in the brain following intramuscular administration at about 2% of the level found in plasma. In 2021 researchers from Japan reported a disproportionately high mortality due to cerebral venous sinus thrombosis and intracranial haemorrhage. Despite not being able to prove a causal link with vaccines, as no autopsies were performed, they still believed that a link with vaccination is possible and further analysis is warranted [5].

Found in body even at 60 days

It was furthermore stated that the mRNA will degrade quickly. Normally, mRNA breaks down within a few minutes to hours, however, the mRNA in these vaccines is nucleoside-modified to reduce potential innate immune recognition [6, 7] and it has been shown that production of the spike protein in some vaccines is kept up for an extraordinarily long time. A study by Röltgen et al. [8] found that the vaccine mRNA persists in the body up to 60 days, with 60 days being the end point of their study. It is thus unknown and impossible to define how much of the spike protein is actually produced in the vaccinated. It is a standard requirement for vaccine producers to define the amount of antigen in each injection. For a "so called "vaccine that is using the human body as the production facility there is no possible quantification of antigen. This is highly variable and dependant on the amount and stability of nanoparticles in the injection, age and fitness of the vaccinee, their immune status and the injection technique – if a blood vessel is directly injected, the nanoparticles will travel in minutes to all major organs including the brain. It is therefore impossible to assess how much spike protein any individual vaccinee produces following an inoculation. In summary, it is unknown where exactly the vaccine travels once it is injected, and how much spike protein is produced in which (and how many) cells.

Prominent cardiologist Dr Peter McCullough stated that the spike protein - a cytotoxin solely responsible for the severity of the respiratory infection - makes the use of it as immunizing agent dangerous. The spike protein in itself can produce COVID- 19 symptoms as shown in animal experiments. The S1 subunit of the SARS-CoV-2 spike protein when injected into transgenic mice overexpressing human ACE-2 caused a COVID-19 like response (a decline in body weight, dramatically increased white blood cells and protein concentrations in bronchoalveolar lavage fluid (BALF), upregulation of multiple inflammatory cytokines in BALF and serum, histological evidence of lung injury, and activation of signal transducer and activator of transcription 3 (STAT3) and nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) pathways in the lung [9].

It was further shown that the spike protein S1 subunit, when added to red blood cells in vitro, could induce clotting by binding fibrinogen and ACE2 on platelets, thus triggering their aggregation [10]. The S protein also increases human cell syncytium formation, removes lipids from model membranes and interferes with the capacity of high-density lipoprotein to exchange lipids [11, 12]. Another in silico study showed that the spike protein S2 subunit specifically interacts with BRCA-1/2 and 53BP1 [13]. BRCA-1 is frequently mutated in breast cancer in women and prostate cancer in men, while 53BP1 is a well-established tumor suppressor protein.

A paper published by Liu et al. conducted single-cell mRNA sequencing of peripheral blood mononuclear cells (PBMCs) harvested from patients before and 28 days after the first injection of a COVID-19 vaccine [14]. While this vaccine was based on an attenuated virus and not a mRNA vaccine, it also is injected directly into the deltoid muscle, bypassing the mucosal and vascular barriers.

The authors found consistent alteration of gene expression following vaccination in many different immune cell types. One housekeeping gene of high importance is RNA polymerase I (POL I) which transcribes ribosomal DNA into RNA and monitors rDNA integrity in the process. Many of the downregulated genes identified by Liu et al. (2021) were linked to the cell cycle, telomere maintenance, and both promoter opening and transcription of POL I, indicative of impaired DNA repair processes [14].

Seneff et al (2022) describe another mechanism by which the mRNA vaccines could interfere with DNA repair [15]. The microRNA miR-148 has been shown to downregulate homologous recombination in the G1 phase of the cell cycle. MiR-148 is one of two microRNAs found in exosomes released by human cells following SARS-CoV-2 spike protein synthesis in the experiments by Mishra and Banerjea [16].

Natural immunity ignored

It is an amazing fact that natural immunity is completely disregarded by health authorities around the world. We know from SARS-CoV-1 that natural immunity is durable and persists for at least 12-17 years [17]. Immunologists have suggested that immunity to SARS-Cov-2 is no different. The human population has encountered and co-existed with a great number of coronaviruses throughout evolution. Most of us have cross-reacting T-cells, B cells and antibodies derived from encounters with common cold coronaviruses that can recognise SARS-CoV-2 [18-20]. A survey of more than 100 immunologists, infectious-disease researchers and virologists working on the coronavirus, who were asked whether the virus could be eradicated, showed that almost 90% of respondents believe that the coronavirus will become endemic [21]. The four human coronaviruses that cause common colds are also endemic, without there ever having been a vaccine for any of them. The existence of related viruses might explain that approximately 40% to 45% of COVID infected people are asymptomatic and about 80% of COVID cases are mild infections. In some cohorts, the asymptomatic infection figure jumps as high as 96% depending on the age and cross-immunity imparted by other viruses such as beta coronaviruses HCoV-OC43 and HCoV-HKU1, which have been proposed as a mitigating factor in the spread of SARS-CoV-2 [22-23].

The Brownstone institute has established the most updated and comprehensive library list of 150 of the highest-quality, complete, and robust scientific studies and evidence reports/position statements on natural immunity as compared to the COVID-19 vaccine-induced immunity. The consensus of these studies is that immunity induced by COVID infection is robust and long lasting (https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/).

It does change your DNA in 6 hours!

current issues in molecular biology

MDPI

Article

Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line

Markus Aldén [1], Francisko Olofsson Falla [1], Daowei Yang [1], Mohammad Barghouth [1], Cheng Luan [1], Magnus Rasmussen [2] and Yang De Marinis [1,*]

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Abstract: Preclinical studies of COVID-19 mRNA vaccine BNT162b2, developed by Pfizer and BioNTech, showed reversible hepatic effects in animals that received the BNT162b2 injection. Furthermore, a recent study showed that SARS-CoV-2 RNA can be reverse-transcribed and integrated into the genome of human cells. In this study, we investigated the effect of BNT162b2 on the human liver cell line Huh7 in vitro. Huh7 cells were exposed to BNT162b2, and quantitative PCR was performed on RNA extracted from the cells. We detected high levels of BNT162b2 in Huh7 cells and changes in gene expression of long interspersed nuclear element-1 (LINE-1), which is an endogenous reverse transcriptase. Immunohistochemistry using antibody binding to LINE-1 open reading frame-1 RNA-binding protein (ORFp1) on Huh7 cells treated with BNT162b2 indicated increased nucleus distribution of LINE-1. PCR on genomic DNA of Huh7 cells exposed to BNT162b2 amplified the DNA sequence unique to BNT162b2. Our results indicate a fast up-take of BNT162b2 into human liver cell line Huh7, leading to changes in LINE-1 expression and distribution. We also show that BNT162b2 mRNA is reverse transcribed intracellularly into DNA in as fast as 6 h upon BNT162b2 exposure.

Keywords: COVID-19 mRNA vaccine; BNT162b2; liver; reverse transcription; LINE-1; Huh7

Citation: Aldén, M.; Olofsson Falla, F.; Yang, D.; Barghouth, M.; Luan, C.; Rasmussen, M.; De Marinis, Y. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* **2022**, *44*, 1115–1126. https://doi.org/10.3390/cimb44030073

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1. Introduction

Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was announced by the World Health Organization (WHO) as a global pandemic on 11 March 2020, and it emerged as a devasting health crisis. As of February 2022, COVID-19 has led to over 430 million reported infection cases and 5.9 million deaths worldwide [1]. Effective and safe vaccines are urgently needed to reduce the morbidity and mortality rates associated with COVID-19.

Several vaccines for COVID-19 have been developed, with particular focus on mRNA vaccines (by Pfizer-BioNTech and Moderna), replication-defective recombinant adenoviral vector vaccines (by Janssen-Johnson and Johnson, Astra-Zeneca, Sputnik-V, and CanSino), and inactivated vaccines (by Sinopharm, Bharat Biotech and Sinovac). The mRNA vaccine has the advantages of being flexible and efficient in immunogen design and manufacturing, and currently, numerous vaccine candidates are in various stages of development and application. Specifically, COVID-19 mRNA vaccine BNT162b2 developed by Pfizer and BioNTech has been evaluated in successful clinical trials [2–4] and administered in national COVID-19 vaccination campaigns in different regions around the world [5–8].

BNT162b2 is a lipid nanoparticle (LNP)–encapsulated, nucleoside-modified RNA vaccine (modRNA) and encodes the full-length of SARS-CoV-2 spike (S) protein, modified

Causal link to neurodegenerative disease, myocarditis autoimmune disease, impaired immunity & cancer

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PMCID: PMC9012513
PMID: 35436552

Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs

Stephanie Seneff,[a,*] Greg Nigh,[b] Anthony M. Kyriakopoulos,[c] and Peter A. McCullough[d]

Abstract

The mRNA SARS-CoV-2 vaccines were brought to market in response to the public health crises of Covid-19. The utilization of mRNA vaccines in the context of infectious disease has no precedent. The many alterations in the vaccine mRNA hide the mRNA from cellular defenses and promote a longer biological half-life and high production of spike protein. However, the immune response to the vaccine is very different from that to a SARS-CoV-2 infection. In this paper, we present evidence that vaccination induces a profound impairment in type I interferon signaling, which has diverse adverse consequences to human health. Immune cells that have taken up the vaccine nanoparticles release into circulation large numbers of exosomes containing spike protein along with critical microRNAs that induce a signaling response in recipient cells at distant sites. We also identify potential profound disturbances in regulatory control of protein synthesis and cancer surveillance. These disturbances potentially have a causal link to neurodegenerative disease, myocarditis, immune thrombocytopenia, Bell's palsy, liver disease, impaired adaptive immunity, impaired DNA damage response and tumorigenesis. We show evidence from the VAERS database supporting our hypothesis. We believe a comprehensive risk/benefit assessment of the mRNA vaccines questions them as positive contributors to public health.

Keywords: SARS-CoV-2 mRNA vaccines, Type I interferon Response, Exosomes, G-quadruplexes, microRNAs, Cancer

Graphical abstract

Interferes with cancer fighting gene

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S2 Subunit of SARS-nCoV-2 Interacts with Tumor Suppressor Protein p53 and BRCA: an In Silico Study

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ABSTRACT

Novel coronavirus disease 2019 (COVID-19) is the biggest threat to human being globally. The first case was identified in a patient with flu symptoms along with severe acute respiratory syndrome in Wuhan, China in December 2019 and now it has spread in more than 200 countries. COVID-19 is more lethal in the elderly and people with an underlying condition such as asthma, cancer, diabetes. Here we performed bioinformatic analysis to investigate the interaction of S2 subunit protein of SARS-nCoV-2 of novel coronavirus with tumor suppressor proteins p53 and BRCA-1/2. In this short communication we report the interaction between S2 subunit proteins with tumor suppressor proteins for the first time. This preliminary result will open up a new direction to investigate the effect of a novel coronavirus in cancer patients.

In December 2019, an outbreak of pneumonia was reported in Wuhan, China which was caused by a new strain of coronavirus called novel coronavirus (nCoV). The novel coronavirus disease-2019 (COVID-19), which started spreading globally, was latter announced as a pandemic by WHO. Till April 30, 2020, there are 3,090,445 infections and 217,769 deaths worldwide [1]. Previously known SARS-CoV which caused severe acute respiratory syndrome (SARS) has 79.5% sequence similarity with SARS-nCoV-2 (nCoV). The pernicious nCoV has been causing severe flu-like symptoms along with pneumonia specially in the elderly and people with ailments like hypertension, asthma, cancer, diabetes, etc. [2,3] but detail understanding of infection is still lacking.

Coronaviruses (CoVs) belong to coronaviridae family and are the largest RNA viruses identified till date. SARS-nCoV-2 contains a spike (S) protein which consists of two subunits S1 and S2. S1 aids the virus to infect human cells by binding to human angiotensin-converting enzyme 2 (hACE2) and S2 mediates the membrane fusion process. S2 subunit is further divided (N-terminal to C-terminal) into fusion peptide (FP), hepted repeat 1 (HR-1), hepted repeat 2 (HR-2), transmembrane domain (TM), and cytoplasmic domain (CP). After infection to host receptor, the HR-1 and HR-2 domain of S2 subunit interact with each other to form six-helix bundle (6-HB) fusion core, bringing viral and cellular membrane into close proximity for fusion and infection [4]. That is why it is very important to study the interaction of S2 subunit with other proteins, to gain insight in to its function and interaction with other potential proteins which have a central role in human diseases. This would unravel the possible mechanism of COVID-19 infection and severity in humans who are already suffering from an ailment.

Here, we have investigated the interaction of S2 subunit to tumor suppressor and cell cycle-related proteins. HADDOCK 2.2 software [5,6] was used to analyze the interaction and found that S2 subunit of SARS-nCov-2 strongly interacts with p53 and BRCA-1/2 proteins (Figure 1). p53 and BRCA are the well-known tumor suppressor proteins, that regulate downstream genes in response to numerous cellular stress and are frequently mutated in human cancer [5,6]. Interestingly we found p53, BRCA-1 and BRCA-2 interact with heptic repeat-2 region of S2 subunit through C- terminal domain. PDB ID of these proteins was extracted from RCSB Protein Data Base (PDB) and details of crystal structure IDs and interacted amino acid residues are mentioned in the figure legend. This short bioinformatic analysis is a first time report and significant since COVID-19 is more fatal in people with underlying conditions specially lung diseases, diabetes and cancer. Therefore, further research is needed to understand COVID-19 effect in cancer patients and the detailed role of these interactions.

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Author Statement

Nishant Singh: Conceptualization, Methodology, Software, correspondence; **Anuradha Bharara Singh:** Writing - Reviewing and Editing,

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Causes Turbo Cancer

frontiers in Medicine

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PMID: 34901098

Rapid Progression of Angioimmunoblastic T Cell Lymphoma Following BNT162b2 mRNA Vaccine Booster Shot: A Case Report

Serge Goldman, [1] Dominique Bron, [2] Thomas Tousseyn, [3] Irina Vierasu, [1] Laurent Dewispelaere, [4] Pierre Heimann, [4] Elie Cogan, [5] and Michel Goldman [6,*]

Abstract

Since nucleoside-modified mRNA vaccines strongly activate T follicular helper cells, it is important to explore the possible impact of approved SARS-CoV-2 mRNA vaccines on neoplasms affecting this cell type. Herein, we report and discuss unexpected rapid progression of lymphomatous lesions after administration of a BNT162b2 mRNA vaccine booster in a man recently diagnosed with AITL.

Keywords: mRNA vaccine, T cell, lymphoma, COVID-19, angioimmunoblastic, follicular

Introduction

The remarkable efficiency of nucleoside-modified SARS-CoV-2 mRNA vaccines has been related to their ability to induce a potent stimulation of T follicular helper (TFH) cells, resulting in persistent germinal center B cell responses (1, 2). Clinically, this might translate into reactive lymphoadenopathy which sometimes may raise a differential diagnosis with a lymphoproliferative disorder (3, 4). At the same time, the possible impact of SARS-CoV-2 mRNA vaccination on pre-existing peripheral T cell lymphoma is still to be determined.

Case Report

pathologies, shedding, transgeneration

International Journal of Vaccine Theory, Practice, and Research

IJVTPR

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

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ABSTRACT

Operation Warp Speed brought to market in the United States two mRNA vaccines, produced by Pfizer and Moderna. Interim data suggested high efficacy for both of these vaccines, which helped legitimize Emergency Use Authorization (EUA) by the FDA. However, the exceptionally rapid movement of these vaccines through controlled trials and into mass deployment raises multiple safety concerns. In this review we first describe the technology underlying these vaccines in detail. We then review both components of and the intended biological response to these vaccines, including production of the spike protein itself, and their potential relationship to a wide range of both acute and long-term induced pathologies, such as blood disorders, neurodegenerative diseases and autoimmune diseases. Among these potential induced pathologies, we discuss the relevance of prion-protein-related amino acid sequences within the spike protein. We also present a brief review of studies supporting the potential for spike protein "shedding", transmission of the protein from a vaccinated to an unvaccinated person, resulting in symptoms induced in the latter. We finish by addressing a common point of debate, namely, whether or not these vaccines could modify the DNA of those receiving the vaccination. While there are no studies demonstrating definitively that this is happening, we provide a plausible scenario, supported by previously established pathways for transformation and transport of genetic material, whereby injected mRNA could ultimately be incorporated into germ cell DNA for transgenerational transmission. We conclude with our recommendations regarding surveillance that will help to clarify the long-term effects of these experimental drugs and allow us to better assess the true risk/benefit ratio of these novel technologies.

Alden et al

Keywords: *antibody dependent enhancement, autoimmune diseases, gene editing, lipid nanoparticles, messenger RNA, prion diseases, reverse transcription, SARS-CoV-2 vaccines*

Introduction

Unprecedented. This word has defined so much about 2020 and the pandemic related to SARS-CoV-2. In addition to an unprecedented disease and its global response, COVID-19 also initiated an unprecedented process of vaccine research, production, testing, and public distribution (Shaw,

It is gene therapy. It sheds, it transfects

TMR

HYPOTHESIS

Infectious Diseases Research 2022;3(4):22. https://doi.org/10.53388/IDR20221125022

Current state of knowledge on the excretion of mRNA and spike produced by anti-COVID-19 mRNA vaccines; possibility of contamination of the entourage of those vaccinated by these products

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Competing interests
The author declares no conflicts of interest.

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Abbreviations
LNPs, lipid nanoparticles; MMR, measles/mumps/rubella; EVs, extracellular vesicles; VEGF, vascular endothelial growth factor; pDNA, plasmid DNA; IM, intramuscular; VLP, virus like particles; RBD, receptor binding domain (spike).

Citation
Banoun H. Current state of knowledge on the excretion of mRNA and spike produced by anti-COVID-19 mRNA vaccines; possibility of contamination of the entourage of those vaccinated by these products. *Infect Dis Res*. 2022;3(4):22. doi: 10.53388/IDR20221125022.

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Abstract
The massive COVID-19 vaccination campaign is the first time that mRNA vaccines have been used on a global scale. The mRNA vaccines correspond exactly to the definition of gene therapy of the American and European regulatory agencies. The regulations require excretion studies of these drugs and their products (the translated proteins). These studies have not been done for mRNA vaccines (nor for adenovirus vaccines). There are numerous reports of symptoms and pathologies identical to the adverse effects of mRNA vaccines in unvaccinated persons in contact with freshly vaccinated persons. It is therefore important to review the state of knowledge on the possible excretion of vaccine nanoparticles as well as mRNA and its product, the spike protein.

Vaccine mRNA-carrying lipid nanoparticles spread after injection throughout the body according to available animal studies and vaccine mRNA (naked or in nanoparticles or in natural exosomes) is found in the bloodstream as well as vaccine spike in free form or encapsulated in exosomes (shown in human studies). Lipid nanoparticles (or their natural equivalent, exosomes or extracellular vesicles (EVs)) have been shown to be able to be excreted through body fluids (sweat, sputum, breast milk) and to pass the transplacental barrier. These EVs are also able to penetrate by inhalation and through the skin (healthy or injured) as well as orally through breast milk (and why not during sexual intercourse through semen, as this has not been studied). It is urgent to enforce the legislation on gene therapy that applies to mRNA vaccines and to carry out studies on this subject while the generalization of mRNA vaccines is being considered.

Keywords: COVID-19 vaccine; vaccine shedding; COVID vaccine adverse effects; Lipid nanoparticles; LNPs; mRNA vaccine; exosome; exosome excretion route; gene therapy; spike protein; LNPs excretion routes; exosomes penetration

Infectious Diseases Research 2022;3(4):22. https://doi.org/10.53388/IDR20221125022

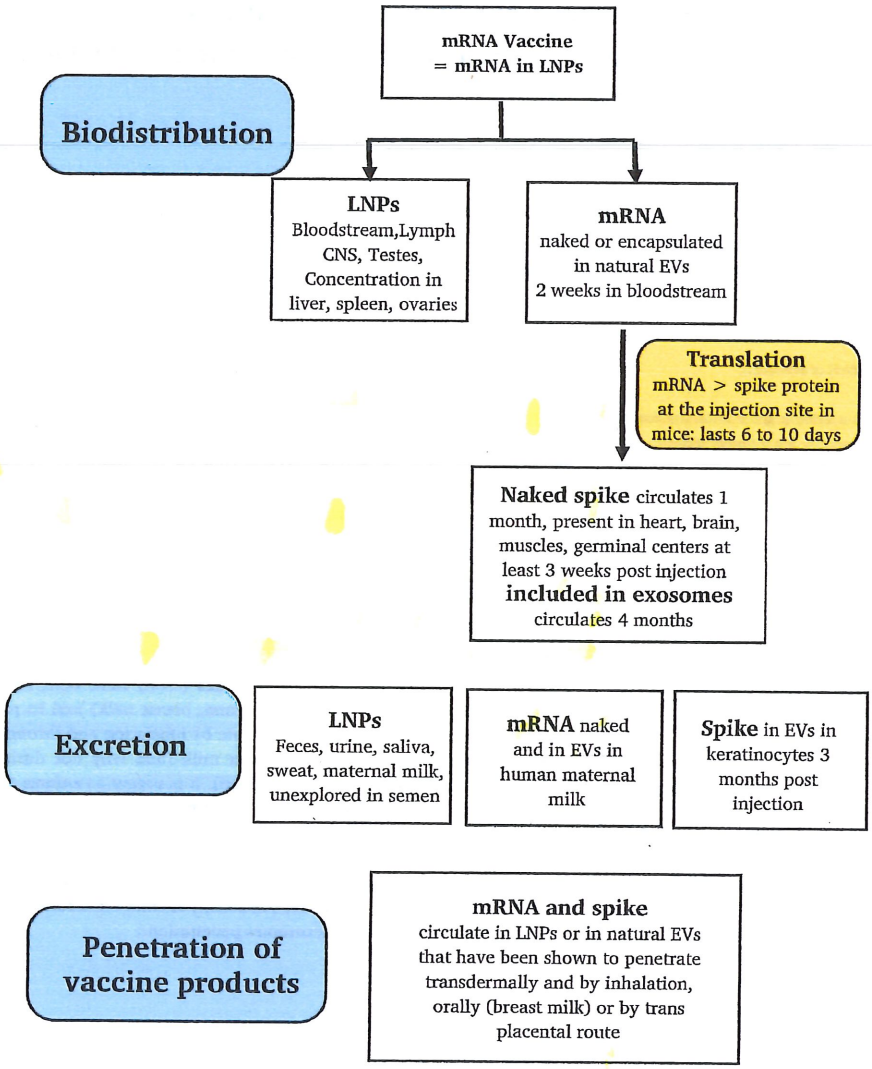


Figure 1 State of knowledge on excretion of mRNA vaccines

Fate of spike protein after mRNA translation

A CDC-sponsored news site accessed on July 21, 2021 notes that the lifespan of spike in the bloodstream is "unknown and may be a few weeks." [57]. Injection of LNPs containing pseudouridine-modified mRNA by IM, subcutaneously and intradermally results in protein production at the site of injection, the duration of active translation is 6 to 10 days in mice. Intradermal injection produces a lower initial amount of protein but over a longer period of time than the IM route. By the intradermal route, the half-life of protein production is the longest compared with other injection routes (IM, subcutaneous, IV, Iperitoneal, intra-tracheal). By IM delivery, the majority of translation ceased in the liver at day 2 post-injection but lasted for up to 8 days in muscles [58].

In humans, the spike protein could persist for a long time in vaccinees, monitoring of vaccine adverse effects should therefore be extended [59]. Comparison of spike concentrations achieved during disease and after vaccination shows that during severe COVID-19 the median concentration observed is 50 pg/mL with maximums at 1 ng/mL. During severe Covid infection, levels of up to 135 pg/mL of S1 spike can be detected, most commonly between 6 and 50 pg/mL. After vaccination with mRNA vaccine concentrations up to 150 pg/mL are commonly observed but may reach 10 ng/mL in individuals with vaccine-induced thrombocytopenia [60].

The same team [61] also shows that spike protein persists for a long time in free form: vaccine-induced spike mRNA circulates in plasma as early as D1 after vaccination and up to 14 days, with the peak occurring at D5 with 68 pg/mL of S1 sub-unity detected; full-length spike is detected up to D15, with a peak at 62 pg/mL. After the 2nd dose, free spike is no longer detected as it would be bound to antibodies; the study does not detect antibody-spike immune complexes.

Another team also showed that, after vaccination with mRNA, spike protein enters the bloodstream, persists for more than a week and is completely eliminated within 1 month. The increase in blood spike concentration after vaccination is rapid (1 to 3 days) [62].

According to an autopsy, vaccine spike is found up to three weeks after injection in different organs (heart, brain, muscles, germinal centers, etc.) and particularly in the endothelium of capillaries [63].

Circulating spike-containing exosomes

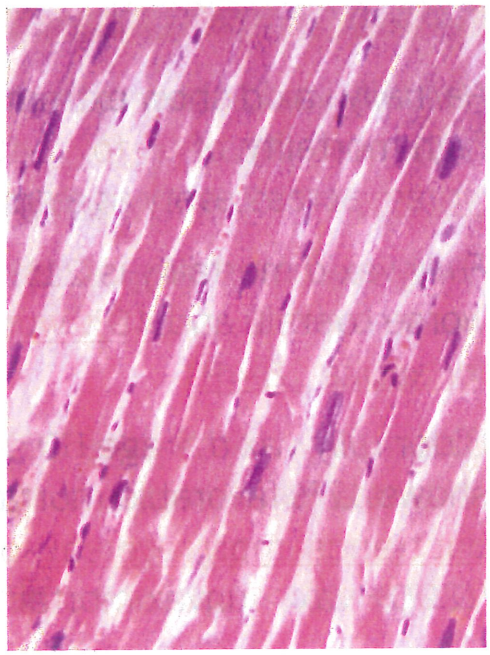
After COVID-19 infection, spike circulates as exosomes. Exosomes are released from cells into the extracellular environment under normal and pathological conditions. Exosomes are an important tool for intercellular communication, as they serve as shuttles for the transfer of biologically active proteins, lipids, and RNA. EVs can incorporate pathogenic proteins and/or viral RNA fragments from infected cells to

SECTION BREAK

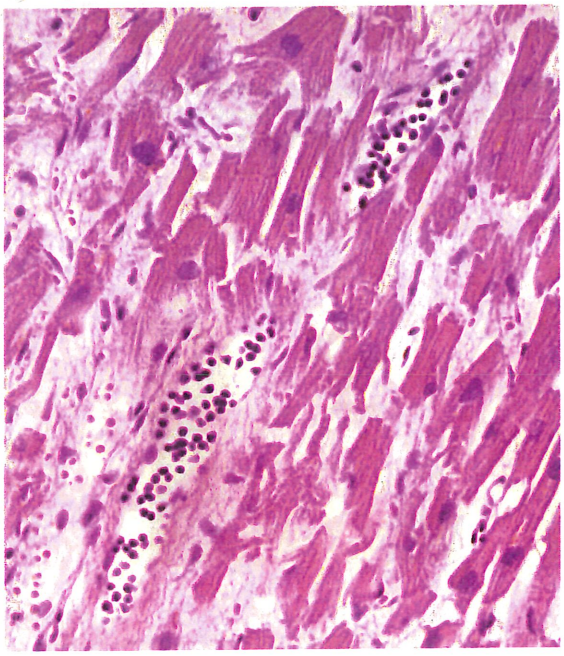
This is happening to childr
It's breaking our childrens heart s literally!

Vaccine induced Myocarditis

normal heart muscle



lymphocytes invading heart muscle

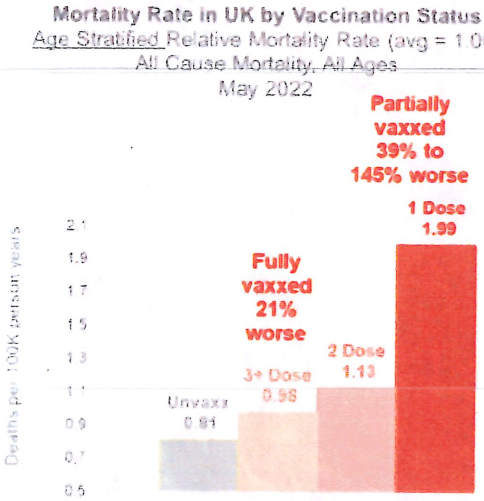


Complications/ injuries caused by COVID injections.

Over 3,000 peer-reviewed articles have been published on COVID vaccine injuries. Find links to these studies at COVID Vaccine Injuries, REACT19, and on Substack. A selection of symptoms is listed below:

- Myocarditis, pericarditis, stress cardiomyopathy (contraction band necrosis)
- Takotsubo cardiomyopathy
- Acute coronary syndrome
- Hypertension
- MIS-V, Multisystem Inflammatory Syndrome
- Thrombosis, including pulmonary emboli and stroke (prothrombotic state)
- Cerebral venous thrombosis
- Thrombocytopenia
- Thrombotic thrombocytopenic purpura
- Idiopathic thrombocytopenic purpura
- Henoch Schönlein Purpura
- Immune-mediated hemolysis
- Reactivation and exacerbation of chronic underlying diseases/disorders
- Immune dysregulation
- Metabolic dysregulation (diabetes)
- Menstrual irregularities
- Menorrhagia
- Amenorrhea
- Spontaneous abortion
- Vulval and vaginal ulcers
- Vasculitis, including Leukocytoclastic vasculitis, Granulomatous vasculitis, microscopic polyangiitis.
- Guillain-Barre Syndrome
- Acute Myelitis
- Systemic lupus erythematosus
- Bell's Palsy
- Stills disease.
- Sweets syndrome
- Facial nerve palsy
- Multiple sclerosis
- Polyarthralgia/polyarthritis
- Cryoglobulinemia
- Lymphadenopathy, local and generalized.
- Anaphylaxis
- Allergic reactions
- Intracerebral hemorrhage
- Strokes (thrombotic strokes)
- Generalized neurological symptoms including "brain fog", cognitive decline, memory loss.
- Alzheimer's Disease like syndrome
- Acute hyperactive encephalopathy
- Acute disseminated encephalomyelitis
- Neuromyelitis Optica
- Ageusia and anosmia
- Aphasia
- Depression
- New onset panic disorders
- New onset psychosis and delirium
- Small fiber neuropathy
- Autonomic neuropathy
- POTS syndrome (postural Orthostatic Tachycardia syndrome)
- Mononeuritis multiplex, polyneuropathy
- Acute inflammatory neuropathies
- Tinnitus (severe and persistent)
- Sensorineural hearing loss
- Vestibulitis
- Severe headaches and migraines
- Seizures and status epilepticus
- Prion disease i.e., Mad Cow Disease
- Acute macular retinopathy
- Uveitis
- Acute Optic Neuropathy
- Rhabdomyolysis
- Keratolysis
- Herpes Keratitis
- Inflammatory myositis
- Immune mediate hepatitis
- Pancreatitis
- Acute kidney injury
- Nephrotic syndrome
- ANCA glomerulonephritis

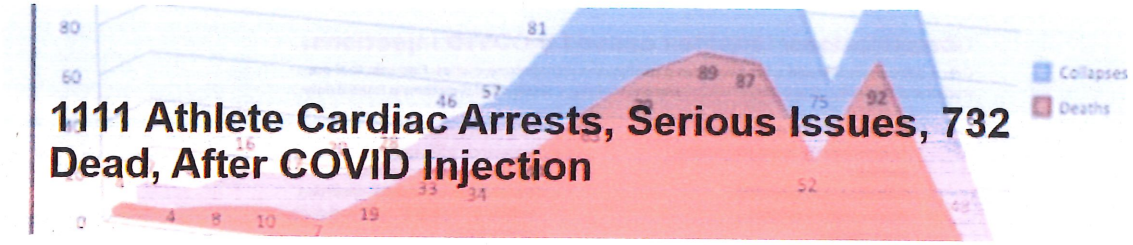
Mortality in UK is now +26% worse for vax'd than unvax'd

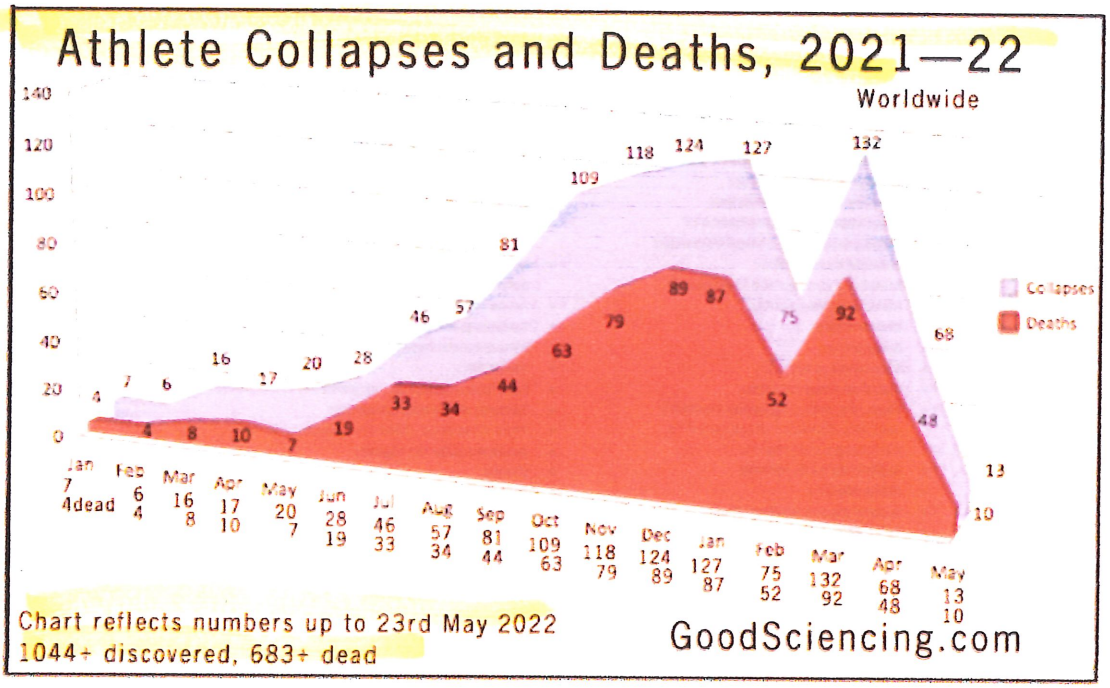


https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland

Adverse impact is greatest for partially vax'd and younger ages

- *Partially vax'd* show extremely high mortality, **of up to +145% worse**, across every age group.
- *Fully vax'd* mortality is 21% worse overall, and **49% worse for adults 18-49**
- Older *fully vax'd* > age 50 still shows 17% favorable mortality, **but trends imply reversal soon** (& 90+ vax > unvax mortality)





Athlete collapses and deaths chart from 1st January 2021 to 23rd May 2022 Good Sciencing.

VigiAccess™ Uppsala Monitoring Centre | WHO Collaborating Centre for International Drug Monitoring

Medicine	Year started reporting	Deaths	Adverse events
Ivermectin	1992	25	6 558
Remdesivir	2020	579	7 798
Tocilizumab	2005	786	47 345
COVID-19 vaccines	2021	**23 018***	**4 804 663**
Tetanus vaccine	1968	32	15 647
Measles vaccine	1992	35	6 445
Acetaminophen (Tylenol)	1968	3 865	> 146 000

* Underreporting by a factor of a least 30x

World Health Organization FDA Pfizer MERCK

News

Life Insurance Payouts Jumped 163% During First Year Of Vaccine Rollout

June 19, 2022 NEWS

Authored by Margaret Menge via Crossroads Report,

Five months after breaking the story of the CEO of One America insurance company saying **deaths among working people ages 18-64 were up 40% in the third quarter of 2021**, I can report that **a much larger life insurance company, Lincoln National, reported a 163% increase in death benefits paid out under its group life insurance policies in 2021.**

This is according to the annual statements filed with state insurance departments — statements that were provided exclusively to Crossroads Report in response to public records requests.

The reports show a more extreme situation than the 40% increase in deaths in the third quarter of 2021 that was cited in late December by One America CEO Scott Davison — an increase that he said was industry-wide and that he described at the time as "unheard of" and "huge, huge numbers" and the highest death rates that have *ever been seen in the history of the life insurance business.*

The annual statements for Lincoln National Life Insurance Company show that the company paid out in death benefits under group life insurance polices a little over **$500 million** in 2019, about **$548 million** in 2020, and a stunning **$1.4 billion** in 2021.

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 8 August 2022 doi:10.20944/preprints202208.0151.v1

29.4% of these children had cardiac issues!

Article

Cardiovascular Effects of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents

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Abstract: This study focuses on cardiovascular effects, particularly myocarditis and pericarditis events, after BNT162b2 mRNA COVID-19 vaccine injection in Thai adolescents. This prospective cohort study enrolled students from two schools aged 13–18 years who received the second dose of the BNT162b2 mRNA COVID-19 vaccine. Data including demographics, symptoms, vital signs, ECG, echocardiography and cardiac enzymes were collected at baseline, Day 3, Day 7, and Day 14 (optional) using case record forms.We enrolled 314 participants; of these, 13 participants were lost to follow up, leaving 301 participants for analysis. The most common cardiovascular effects were tachycardia (7.64%), shortness of breath (6.64%), palpitation (4.32%), chest pain (4.32%), and hypertension (3.99%). Seven participants (2.33%) exhibited at least one elevated cardiac biomarker or positive lab assessments. Cardiovascular effects were found in 29.24% of patients, ranging from tachycardia, palpitation, and myopericarditis. Myopericarditis was confirmed in one patient after vaccination. Two patients had suspected pericarditis and four patients had suspected subclinical myocarditis.
Conclusion: Cardiovascular effects in adolescents after BNT162b2 mRNA COVID-19 vaccination included tachycardia, palpitation, and myocarditis. The clinical presentation of myopericarditis after vaccination was usually mild, with all cases fully recovering within 14 days. Hence, adolescents receiving mRNA vaccines should be monitored for side effects.

Clinical Trial Registration: NCT05288231

Keywords: BNT162b2 mRNA COVID-19 vaccine; COVID-19 vaccine; cardiovascular effects; myocarditis; adolescents; Thailand

1. Introduction

In December 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech mRNA vaccine (BNT162b2) for the prevention of COVID-19 disease. Clinical trials have revealed that the vaccine's efficacy is 95% and its safety profile is good, similar to that of other vaccines [1-4]. Systemic reactions to the vaccine, which were usually mild and transient, have been reported more commonly among the younger population and more often after the second dose [1-2,5].

Historically, postvaccination myocarditis has been reported as a rare adverse event after vaccinations, especially smallpox vaccination [4], influenza and hepatitis B, among others. In the general population, myocarditis is diagnosed in approximately 10–20 individuals per 100,000 per year [6], and occurs more commonly and at younger ages in males than females [7]. The highest

FDA knew as of February 2021 that the mRNA vaccine crosses the placenta, passes into milk, and causes adverse events in breastfed infants

Preprint · April 2023

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FDA knew as of February 2021 that the mRNA vaccine crosses the placenta, passes into milk, and causes adverse events in breastfed infants

FDA Report: spontaneously collected adverse events for Pfizer BNT162b2 vaccine between December 11, 2020, and February 28, 2021[1]

This is the report of adverse event reports from Pfizer's safety database until February 28, 2021: this database includes cases reported spontaneously by health authorities, in the medical literature, collected by Pfizer-funded programs, by non-interventional studies. This collection therefore concerns only a little more than two and a half months of vaccine administration (between December 11, 2020, the date of authorization, and February 28, 2021).

The report notes that the rate of spontaneous underreporting of adverse events is unknown.

458 cases of adverse events following BNT162b2 vaccine received during pregnancy were identified and 215 during breastfeeding.

210 cases following vaccine received during pregnancy were excluded as having no associated adverse event or an AE related to off-label use or use of the product, either for the mother or the child. This is confusing: why would there be people who would fill out an ADR file without mentioning an ADR? Similarly, what does exclusion for off-label compliance mean? Would the exclusion include people who could not provide the lot number of the vaccine?
Whatever the answer, these results are likely to be underestimated because of these undocumented exclusions.

Vaccine exposure during pregnancy

Of the 248 cases retained, 53 miscarriages and 6 premature deliveries were reported

Miscarriages: most were reported within 3 weeks of vaccination (it can be assumed that miscarriages occurring within a longer period were not reported).

Preterm deliveries

One premature baby developed tachycardia 7 days after the mother received the second dose of vaccine, the fate of the child is unknown.

One baby is described as having received the vaccine transplacentally by the FDA. The injection at 13 to 28 weeks' gestation resulted in early delivery and the baby did not survive, having experienced severe respiratory distress and a pneumothorax.

Another preterm delivery (vaccine received in the second trimester of pregnancy) resulted in a baby with sequelae who was treated with aspirin and heparin: did he show signs of thrombosis?

Another premature baby of a mother vaccinated in the second trimester died of severe respiratory distress and pneumothorax.

Another premature baby had been exposed to the vaccine even transplacentally, according to the FDA.

Exposure during breastfeeding

Of the 215 cases reported in 174 cases, no adverse events were reported: see note above!
On the 41 remaining cases, various adverse effects are reported, the most frequent of which are: fever, irritability, headache, rash, diarrhea, sickness, insomnia, milk drying, milk discoloration, vomiting of the baby, lethargy, pain, hypothermia, urticaria, ...
10 AEs concerning babies were reported. They all occurred within 7 days after the mother's vaccination: skin peeling and irritability of the infant, rash and urticaria, angioedema, unspecified

illness (with or without hospitalization).

Data from the April 30, 2021 full adverse event document

It should also be noted that in the full document [2] regarding all signals received as of February 28, 2021, 270 pregnancies were exposed to the vaccine and for only 32 of these pregnancies is the pregnancy outcome known. Of these 32 pregnancies, Pfizer's report shows 23 spontaneous abortions (miscarriages), two premature births with neonatal death, two spontaneous abortions with intrauterine death, one spontaneous abortion with neonatal death, and one pregnancy with "normal outcome." This means that out of 32 pregnancies with known outcomes, 28 resulted in fetal death. Pfizer's report indicates that there were five pregnancies with "pending" outcomes, as well as the 238 pregnancies with unknown outcomes. But 32 minus 28 equals four, not five.

Discussion

It should be noted that this document concerns only the first 2.5 months of the vaccination campaign: these notifications are already numerous and could therefore be a strong signal of safety not taken into account by the FDA concerning vaccination during pregnancy or breastfeeding
The FDA approved the vaccine for pregnant women on April 23, 2021, thus after this first alarming report [3].
Those who received the vaccine prior to the approval for pregnant women were mostly caregivers: caregivers were the first group of young people to receive the vaccine. Pregnant women were excluded from the clinical trials.
This document therefore confirms that the vaccine (or its product spike) can cross the placental barrier [4].
It was already known from 4 publications that the vaccine mRNA could pass into the milk during the first week after the injection [4,5]. The adverse events reported here all concern this first week and therefore confirm these publications. The pathologies described for premature babies could be due to the toxic effect of the spike protein which could have passed from the mother to the fetus or even be produced directly by the fetus after transfection of the cells. In fact, it seems to be thrombosis and heart problems which are the effects most often described in people who have directly received the vaccine.

Can we continue to recommend mRNA vaccines to pregnant and breastfeeding women?

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April 2023

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Birth Rates Plunge in Heavily Vaccinated Countries

In many countries, births drop sharply nine months after peak COVID vaccine uptake. Let's look at how this happens. And will these populations recover?

COLLEEN HUBER NMD
FEB 16, 2023

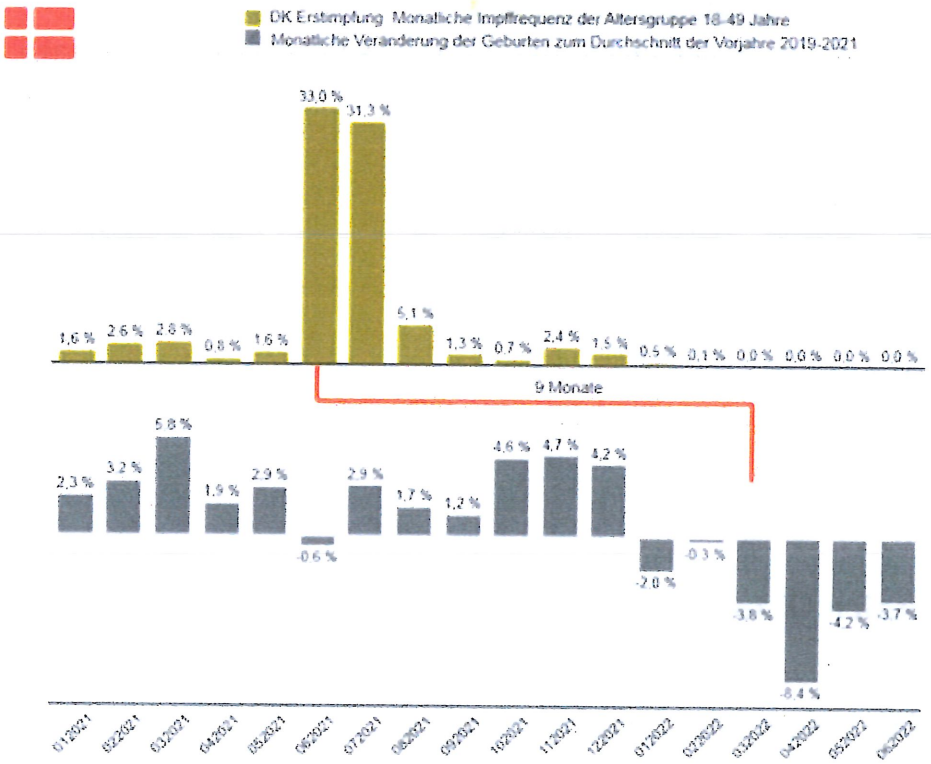
Vital Statistics – Hidden Data

Since the beginning of COVID, vital statistics as reported by governments around the world are hard to come by. Spotty availability hinders analysis and understanding

For example, even today in the United States, Massachusetts and New York, Illinois and Washington are four of the states that, at this writing, have not updated births data since 2019 [1] and 2020. [2] [3] [4]

Nineteen European Countries

By August 2022, Raimond Hagemann, Ulf Lorré and Dr. Hans-Joachim Kremer had compiled data on birth rate changes in 19 European countries and produced an extremely important paper. [5] In country after country, the inflection point of reduced births is consistently at the end of the year 2021. This was nine months after the spring zeitgeist to take the COVID vaccines. Germany, Austria, Switzerland, France, Belgium, Netherlands, Denmark, Estonia, Finland, Latvia, Lithuania, Sweden, Portugal, Spain, Czech Republic, Hungary, Poland, Romania and Slovenia, as well as Iceland, Northern Ireland, Montenegro, Serbia, all show this pattern. Nine months after peak vaccine uptake, the births decline. From Hagemann, et al. Danish data:



The corresponding graph for each of the 19 countries has a similar pattern: peak uptake of COVID vaccines in spring of 2021, followed by precipitous birthrate declines beginning nine months later. All of the nineteen countries studied saw accelerating declines in births in 2022, beginning at nine months after peak COVID vaccine uptake. Note the small p values in the following table, favoring temporal association of the two events. This in turn, supports the Bradford Hill temporality criterion regarding causation of infertility, rather than highly coincidental correlation between peak vaccination in spring of 2021 and sharply declining birth rates nine months later.

Toxicology Reports 8 (2021) 1665–1684

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Toxicology Reports

journal homepage: www.elsevier.com/locate/toxrep

Why are we vaccinating children against COVID-19?

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Adverse events
Vaccine safety

ABSTRACT

This article examines issues related to COVID-19 inoculations for children. The bulk of the official COVID-19-attributed deaths per capita occur in the elderly with high comorbidities, and the COVID-19 attributed deaths per capita are negligible in children. The bulk of the normalized post-inoculation deaths also occur in the elderly with high comorbidities, while the normalized post-inoculation deaths are small, but not negligible, in children. Clinical trials for these inoculations were very short-term (a few months), had samples not representative of the total population, and for adolescents/children, had poor predictive power because of their small size. Further, the clinical trials did not address changes in biomarkers that could serve as early warning indicators of elevated predisposition to serious diseases. Most importantly, the clinical trials did not address long-term effects that, if serious, would be borne by children/adolescents for potentially decades.

A novel *best-case scenario* cost-benefit analysis showed *very conservatively* that there are five times the number of deaths attributable to each inoculation vs those attributable to COVID-19 in the most vulnerable 65+ demographic. The risk of death from COVID-19 decreases drastically as age decreases, and the longer-term effects of the inoculations on lower age groups will increase their risk-benefit ratio, perhaps substantially.

1. Introduction

Currently, we are in the fifteenth month of the WHO-declared global COVID-19 pandemic. Restrictions of different severity are still in effect throughout the world [1]. The global COVID-19 mass inoculation is in its eighth month. As of this writing in mid-June 2021, over 800,000,000 people globally have received at least one dose of the inoculation and roughly half that number have been fully inoculated [2]. In the USA, about 170,000,000 people have received at least one dose and roughly 80 % of that number have been fully inoculated [2].

Also, in the USA, nearly 600,000 deaths have been officially attributed to COVID-19. Almost 5,000 deaths following inoculation have been reported to VAERS by late May 2021; specifically, "Over 285 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through May 24, 2021. During this time, VAERS received 4,863 reports of death (0.0017 %) among people who received a COVID-19 vaccine." [3] (the Vaccine Adverse Events Reporting System (VAERS) is a passive surveillance system managed jointly by the CDC and FDA [3]. Historically, VAERS has been shown to report about 1% of actual vaccine/inoculation adverse events [4]. See Appendix 1 for a first-principles confirmation of that result). By mid-June, deaths following COVID-19 inoculations had reached the ~6000 levels.

A vaccine is legally defined as any substance designed to be administered to a human being for the prevention of one or more diseases [5]. For example, a January 2000 patent application that defined vaccines as "compositions or mixtures that when introduced into the circulatory system of an animal will evoke a protective response to a pathogen." was rejected by the U.S. Patent Office because "The immune response produced by a vaccine must be more than merely some immune response but must be protective. As noted in the previous Office Action, the art recognizes the term "vaccine" to be a compound which prevents infection" [6]. In the remainder of this article, we use the term

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COVID-19 Vaccines: The Impact on Pregnancy Outcomes and Menstrual Function

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ABSTRACT

This population-based retrospective cohort study assesses rates of adverse events (AE) after COVID-19 vaccines experienced by women of reproductive age, focusing on pregnancy and menstruation, using data collected by the Vaccine Adverse Events Reporting System (VAERS) database from Jan 1, 1998, to Jun 30, 2022.

The proportional reporting ratio comparing AEs reported after COVID-19 vaccines with those reported after influenza vaccines is significantly increased (≥ 2.0) for COVID-19 vaccine for menstrual abnormality, miscarriage, fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal cardiac arrest, fetal arrhythmias, fetal vascular malperfusion, fetal growth abnormalities, fetal abnormal surveillance, placental thrombosis, fetal death/stillbirth, low amniotic fluid, preeclampsia, premature delivery, preterm premature rupture of membrane, and premature baby death.

When normalized by time-available, doses-given, or number of persons vaccinated, all COVID-19 vaccine AEs far exceed the safety signal on all recognized thresholds.

These results necessitate a worldwide moratorium on the use of COVID-19 vaccines in pregnancy.

Introduction

Historically, a vaccine is subjected to an average of 10-12 years in clinical trials before it is authorized to be administered to the general population. The response to the COVID-19 pandemic, organized under Operation Warp Speed, rolled out novel SARS-CoV-2 vaccines in record time. Under an Emergency Use Authorization (EUA), these vaccines were available to the public as early as 10 months after development. The sentiment at the onset of the pandemic was that early treatment strategies for COVID-19 were ineffective, and these novel vaccines were promoted as the sole solution to the pandemic.

The rapid rollout of the COVID-19 vaccines meant that long-term safety studies had not been conducted by the time the vaccines were made available to the general population. COVID-19 vaccines were immediately authorized for use in pregnant women, which is unprecedented in the history of medicine. The influenza vaccine underwent continuous development and testing for nearly 60 years before being authorized in 1997 for use during pregnancy. The rapid development of COVID-19 vaccines, very limited safety data, and subsequent clinical observations prompt urgent inquiry into the safety of the COVID-19 vaccines in pregnancy.

Methods

A retrospective analysis was conducted of the adverse event (AE) reports post-COVID-19 vaccines and post-influenza vaccines in the U.S. Centers for Disease Control and Prevention (CDC) Vaccine Adverse Events Reporting System (VAERS) database between Jan 1, 1998, and Jun 30, 2022. Influenza vaccines were chosen as the control group because the CDC first approved influenza vaccines for pregnant women in 1997. Reports in VAERS after Jan 1, 1998, would count AEs due to on-label use of the vaccines. The study period ending on Jun 30, 2022, provides 282 months of data for the Influenza vaccine and 18 months of data for the COVID-19 vaccines.

AE Report Counts

Based on a high-volume obstetrical practice over 43 years, a board-certified obstetrician-gynecologist and maternal-fetal medicine physician (JAT) chose AEs of interest from the VAERS database that are most relevant to fertility and reproductive physiology. A query of the VAERS database was made for each AE: menstrual abnormality, miscarriage (spontaneous abortion), fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal cardiac arrest, fetal arrhythmia, fetal vascular malperfusion, fetal growth abnormalities, fetal abnormal surveillance, placental thrombosis, fetal death (stillbirth), low amniotic fluid, preeclampsia, preterm premature rupture of membranes (PPROM), premature delivery/baby (PTD), and premature baby death. AE reports were counted globally and within the U.S. for both the COVID-19 and the influenza vaccines. The global counts for these events, which include U.S. counts, are listed in Table 1. U.S. counts only are in Table 1 Supplement, available at https://jpands.org/vol28no1/thorpsupplement.pdf.

Doses Given

The AE report count data is normalized by doses of each vaccine administered during the study period. Using Our World in Data,[1] we estimate that 12.07 billion doses of the COVID-19 vaccine were given globally. Using CDC data, we estimate that 66 billion doses of the influenza vaccine were given globally, and 3.3 billion doses were given in the U.S.[2-6]

Estimating the Number of People Vaccinated

Additionally, the AE report counts are normalized by the number of people vaccinated during the study period. CDC data estimates that 5.23 billion people received at least one dose of a COVID-19 vaccine globally, including 260 million in the U.S. The influenza vaccines were administered to 7.71 billion people globally, including 313 million in the U.S. [2-6] Determining the number of people vaccinated with the COVID-19 vaccine is straightforward; however, the influenza vaccine doses are difficult to count because there is no widespread tracking system and there are yearly seasons in which an individual may or may not choose to receive subsequent vaccinations. To estimate the number of people who received at least one dose of the influenza vaccine since 1998, we used a Monte Carlo simulation.

The simulation started in 1980 with a sample of an eligible population of 100,000,000 people, with 50% of them pre-vaccinated from previous years. From 1980 to 1997 the population grows by f_e, shrinks by f_d, and individuals are vaccinated using

HHS-CDC Completely Captured ACOG and 'Fait Accompli' Rollout of Jab in Pregnancy was Planned Despite Knowledge that it was THE MOST LETHAL Med/Vax/Drug EVER Rolled Out (Pfizer 5.3.6)

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Gulf Breeze, FL April 30, 2023
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Pfizer 5.3.6 Post-Marketing Dec 1, 2020 to Feb 28, 2021 (Page 7)

- The deadliest vaccine–medicine–drug EVER rolled out in the history of medicine
- 1,223 deaths in the first 90 days
- > 100 deaths per week

BNT162b2
5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

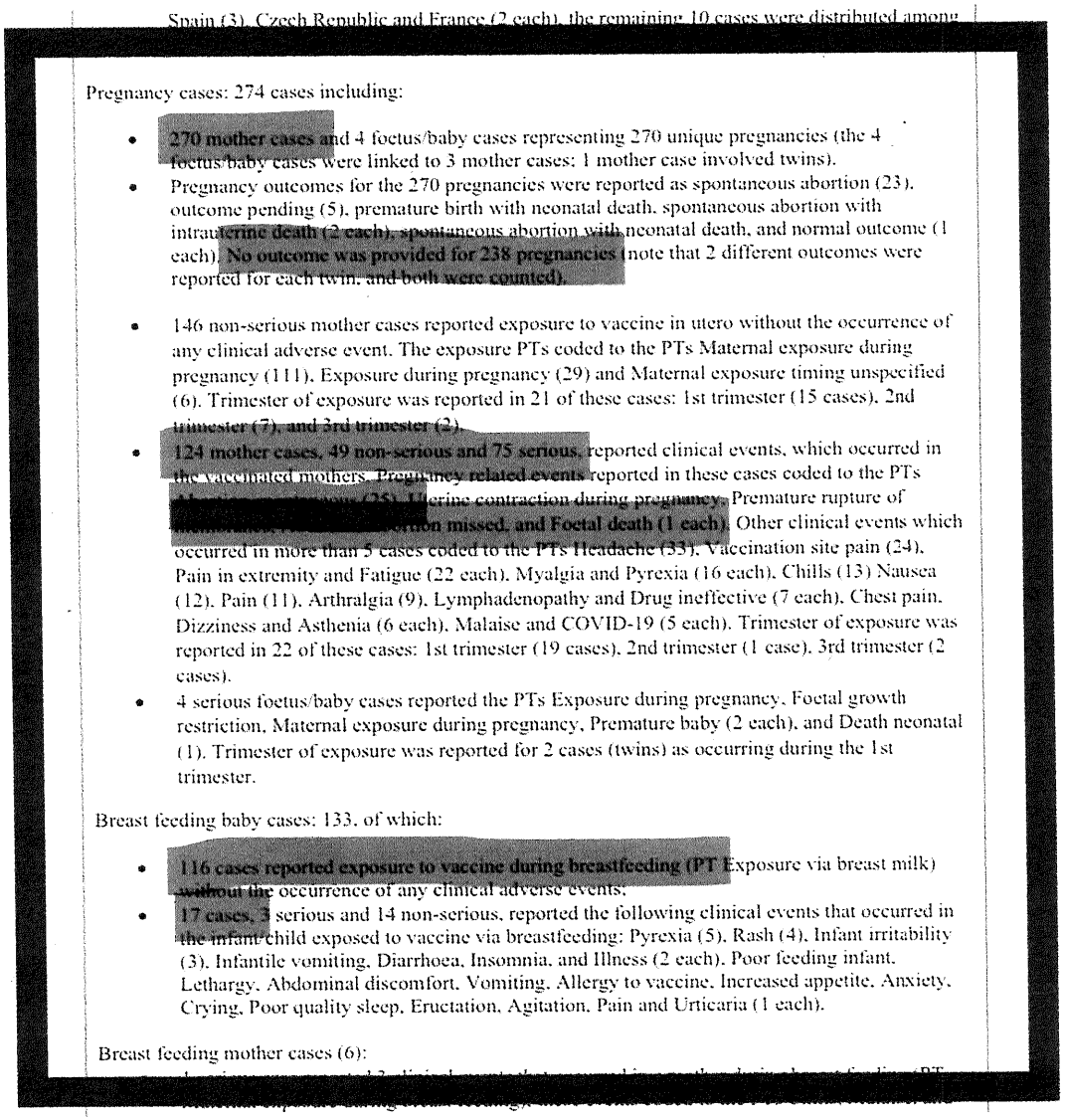
Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17	175[a]
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3098
	≥ 75	5214
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Pfizer 5.3.6 Post-Marketing Dec 1, 2020 to Feb 28, 2021 Page 12

- 270 pregnant moms
- 238/270 had NO follow-up
- Only 32 of 270 were followed up to term
- 124/270 (46%) with jab complications
- 25/32 with miscarriage aka spont abortion
- 1/32 "missed abortion" aka miscarriage
- 26/32 or 81% miscarriage rate
- 1/32 fetal death equates to stillbirth rate of 31/1000 with expected rate of 5.8/1000
- Breastfeeding complications in 17/116 or 14.7% of babies



Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among

Pregnancy cases: 274 cases including:

- 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins).
- Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted).
- 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2).
- 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs [redacted] were (25), Uterine contraction during pregnancy, Premature rupture of [redacted] abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases).
- 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester.

Breast feeding baby cases: 133, of which:

- 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events.
- 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each).

Breast feeding mother cases (6):

The Largest 5th Generational Psy Ops Campaign in the History of the World

- DOD DARPA BARDA HHS CDC FDA
- $13,000,000,000 (Billion with a B)
- Qualifies as textbook definition of a BRIBE
- 275 (298) Sectors of our entire society
- Launched ***only after*** they knew 2.28.2021 that Pfizer 3.5.6 internal documents proved it to be the most dangerous and deadly drug/medicine/vaccine ever rolled out 122.3 deaths/week in just 10 weeks. Why?
- "5 Eyes" USA, Canada, UK, Australia & New Zealand most captured by globalists and most fascist on mandates. Why?

← **Tweet**

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James Thorp MD
@jathorpmfm

"He who PAYS THE PIPER CALLS THE TUNES". The $13 BILLION in bribes from HHS & CDC to 270 sectors of our society to push the DEADLIEST ☠ EVER medicine / drug / vaccine was an unprecedented 5th Generation Psychological Operations on not only the USA 🇺🇸 but the entire world. CRIMINAL PROSECUTIONS NOW. #ABOG #ACOG #SMFM @unbridledmd @DOCBISS @drmcdyer1

COVID-19 Community Corps
$13 Billion to 298 Sectors in 12 Categories

1. Public health & medical organizations: 25/298 (8.5%)
2. Sports & entertainment: 12/298 (4.4%)
3. Rural leaders: 25/298 (9.1%)
4. Unions/organized labor leaders: 25/298 (8.4%)
5. LatinX leaders: 6/298 (2.0%)
6. Black leaders: 21/298 (7.0%)
7. Asian/Pacific Islanders: 15/298 (5.0%)
8. Native/Tribal leaders: 9/298 (3.0%)
9. Veterans: 10/298 (3.4%)
10. Business leaders: 10/298 (3.4%)
11. Faith leaders: 87/298 (29.2%)
12. Community leaders: 53/298 (17.8%)

Public Health & Medical Organizations

- [redacted]
- American Association of Nurse Practitioners (AANP)
- American Academy of Pediatrics
- American Association of Pediatrics
- American Academy of Family Physicians
- American College of Physicians
- American Lung Association
- American Medical Association
- American Medical Student Association
- American Medical Women's Association
- [redacted]
- American College of Obstetricians and Gynecologists
- [redacted]
- Chickasaw Vaccine Corps Partnership
- COVID Collaborative
- Infectious Disease Society Association
- Medical Healthcare Association
- National Association of Community Health Centers
- National Council of Urban Indian Health

- [redacted]
- [redacted]
- Protect Our Care*
- Vaccinate Your Family
- [redacted]

Sports & Entertainment

- MLB
- MLS
- National Association of Broadcasters
- NASCAR
- NFL
- Anthony Bright*
- Charles Pitts*
- Orlando Perez*
- PGA Tour
- WWE
- Ana Navarro*
- Geonia Lopez*

Rural Leaders

- [redacted]
- Agents of Food Production Federation
- American Indian Higher Education Consortium
- American Red Cross
- Association of Public and Land Grant Universities
- California Fresh Fruit Association
- Center for Rural Strategies
- Farm Bureau
- Food Council
- National 4-H Council
- National Association of State Departments of Agriculture
- National Association of Wheat Growers
- National Corn Growers Association
- National Farmers Union
- National Milk Producers Federation
- National Rural Education Association
- National Rural Health
- National Rural Health Association
- North American Meat Institute
- North American Meat Institute

- NTCA-The Rural Broadband Association
- Rebuild Rural Coalition
- Rural Coalition
- The National Grange
- [redacted]

Union & Organized Labor Leaders

- Actors Equity
- AFL-CIO
- AFL-CIO
- AFSCME
- AFT
- [redacted]
- International Brotherhood of Electricians
- International Brotherhood of Electrical Workers
- International Brotherhood of Teamsters
- International Federation of Professional and Technical Engineers
- International Longshoremen's Association
- International Organization of Masters, Mates & Pilots
- International Union of Bricklayers and Allied Craftworkers
- Iron Workers

- IUPAT
- National Association of Manufacturers
- National Education Association
- RWDSU
- SEIU
- Stage Directors and Choreographers Society
- Transport Workers Union
- UFCW
- United Brotherhood of Carpenters
- United Farm Workers
- [redacted]

Latinx Leaders

- Clinica Puente Rio
- Hispanic National Bar Association
- NALEO
- Poder Labor
- UNIDOS
- [redacted]

Black Leaders

- Bennett College

- Benedict College
- Bennett College
- Black Coalition Against COVID
- Black Women's Roundtable
- Cheyney University (PA)
- Delaware State University
- Morgan State University
- NAACP
- National Action Network
- National Coalition on Black Civic Participation
- National Council of Negro Women
- National Urban League
- Prairie View A&M University
- Stillman College
- Texas Southern University
- Thurgood Marshall College Fund
- Tougaloo College
- United Negro College Fund
- University of the Virgin Islands
- Wiley College

AAPI Leaders

- [redacted]
- AAPCHO
- APAICS
- APALA
- APIAHT
- APIAVote
- LPAC
- Esther Cope
- Hudson Yang
- IMPACT
- Michael Kwan
- NAAAPA
- NCAPA
- NCAPIA
- [redacted]

Native/Tribal Leaders

- [redacted]
- Center for Native American Youth
- [redacted]
- Mid-Atlantic Alliance of Sovereign Tribes

- National Congress of American Indians
- National Indian Health Board
- Native Peoples Action
- United South and Eastern Tribes (USET)
- UNITY

Veterans

- [redacted]
- Blinded Veterans of America
- Disabled American Veterans
- Iraq and Afghanistan Veterans Association
- Modern Military Association of America
- Student Veterans of America
- The Mission Continues
- VetsFirst: United Spinal Association
- Vietnam Veterans of America
- [redacted]

Business Leaders

- Asian Pacific Islander American Chamber (ACE)
- Black Economic Alliance
- Business Roundtable

- Mundo Business RoundTable
- NAM
- Public Private Strategies
- US Black Chambers
- US Chamber
- US Hispanic Chambers
- US Women's Chambers

Faith Leaders

- [redacted]
- AME Church
- AME Zion Church
- America Indivisible
- American Baptist Church
- American Muslim Public Health Professionals
- Archbishop Vicken Aykazian*
- Asian American Christian Collaborative
- Association of Catholic Colleges and Universities
- Association of Neighbors Concerned for Latino Advancement (ANCLA)
- BAPS
- Barbara Cutler

- Bend the Arc: Jewish Action
- Bishop Joseph Walker*
- Bishop Lawrence Reddick*
- Bishop Leah Daughtry
- Bishop Michael Mitchell*
- Bishop Salley Dyck*
- Bishop Teresa Jefferson-Snowden*
- Bishop William Barber II*
- Bridging Cultures in State
- Catholic Charities USA
- Catholic Health Association
- Center for Public Justice
- Christian Churches Together
- Christian Methodist Episcopal Church
- Church of the Brethren, Office of Peacebuilding and Policy
- City Gate Network
- Community of Christ
- Community Resource Network
- Cooperative Baptist Fellowship
- Council for Christian Colleges and Universities

- Disciples of Christ
- Ecumenical Catholic Communion
- Emgage
- Eugene Cho*
- Evangelical Lutheran Church in America
- Faith and Community Empowerment
- Faith in Action
- Faith4Vaccines
- Fr. Sr. Rob Nemkovich*
- Franciscan Action Network
- Hard Dave*
- Friends United Meeting
- Greek Orthodox Archdiocese of America
- Interfaith Alliance
- Interfaith Center of New York
- Interfaith Youth Core
- International Council of Community Churches
- Jeannette Salgado*
- Jo Anne Lyon*
- Joshua Dubois*

- Know Your Neighbor
- Leadership Conference of Women Religious
- Malankara Orthodox Syrian Church
- Mark Hamsen*
- Metropolitan Zachariah Mar Nicholovos*
- Multifaith Neighbor Network
- NAICA Inspired Schools Network
- National African American Clergy Network
- National Association of Evangelicals
- National Council Jewish of Women
- National Latino Evangelical Coalition
- NETWORK
- New York Jewish Agenda
- Rabbi David Saperstein*
- Religious Action Center of Reform Judaism
- Rev. Carlos Malave*
- Rev. Dr. Amos Brown*
- Rev. Eddy Alemar*
- Rev. Jim Winkler*
- Rev. Luis Cortes*

- Rev. Stephen Green*
- Rev. Tom Herd Owens*
- Rev. Tyrone Pitts*
- Salam Al Marayati*
- Salvation Army
- Sojourners
- Syriac Orthodox Church
- T. David Smith*
- The Episcopal Church
- The Episcopal Diocese of Washington
- The Methodist Church Northern Province
- The Sikh Coalition
- United Church of Christ
- [redacted]

Community Leaders

- AARP
- America Indivisible
- Americans United for the Separation of Church of State
- Blue Future
- DSP Research

- Care in Action
- Center for American Progress
- Center for Popular Democracy
- Center for Science in the Public Interest
- Center for Wellness and Nutrition
- Civic Nation
- CLASP/New Deal Youth
- Data for Progress
- Democracy Partners
- Feeding America
- GLAAD
- Greater Good Initiative
- Hunger Free America
- Indivisible
- Islamic Networks Group & Affiliates
- Know Your Neighbor
- Meals on Wheels America
- Military Emergency Preparedness Task Force
- Movement Labs
- National Association of Chemine

- National Bar Association
- National Black Justice Coalition (NBJC)
- National Center for Lesbian Rights (NCLR)
- National League of Cities (NLC)
- National WIC Association
- National America
- Opportunity Youth
- Parents Together
- People's Action
- People's Action Institute
- PFLAG
- School Nutrition Association
- Sierra Club
- Stand Up Republic Foundation
- Stop the Spread
- Students Learn. Students Vote Coalition
- The Leadership Conference on Civil and Human Rights
- Think of Us
- Trans Latin@
- Trevor Project
- UltraViolet

- Trans Latin@
- Trevor Project
- UltraViolet
- United We Dream
- Uniting Garden Homes Inc
- Wholesome Wave
- Young Invincibles

ORIGINAL ARTICLE

Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons

Tom T. Shimabukuro, M.D., Shin Y. Kim, M.P.H., Tanya R. Myers, Ph.D., Pedro L. Moro, M.D., Titilope Oduyebo, M.D., Lakshmi Panagiotakopoulos, M.D., Paige L. Marquez, M.S.P.H., Christine K. Olson, M.D., Ruiling Liu, Ph.D., Karen T. Chang, Ph.D., Sascha R. Ellington, Ph.D., Veronica K. Burkel, M.P.H., et al., for the CDC v-safe COVID-19 Pregnancy Registry Team*

June 17, 2021
N Engl J Med 2021; 384:2273-2282
DOI: 10.1056/NEJMoa2104983
Chinese Translation 中文翻译

32 References 349 Citing Articles Letters

Abstract

BACKGROUND

Many pregnant persons in the United States are receiving messenger RNA (mRNA) coronavirus disease 2019 (Covid-19) vaccines, but data are limited on their safety in pregnancy.

METHODS

From December 14, 2020, to February 28, 2021, we used data from the "v-safe after vaccination health checker" surveillance system, the v-safe pregnancy registry, and the Vaccine Adverse Event Reporting System (VAERS) to characterize the initial safety of mRNA Covid-19 vaccines in pregnant persons.

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Medical Ethics | Review

COVID-19 & Disaster Capitalism – Part I

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In a study intended to evaluate vaccine safety during pregnancy, Shimabukuro et al. followed outcomes in 3958 vaccinated pregnant women between mid-December 2020 and the end of February 2021. During the two-and-a-half-month period 827 women completed their pregnancy of which 712 (86.1%) were live births and 115 (13.9%) pregnancy losses. Of the pregnancy losses, 104 were spontaneous abortions the vast majority of which (92.3%) occurred before 13 weeks of gestation. Upon review of the data, however, 700 (84.6%) of women weren't vaccinated until the third trimester, long after the spontaneous abortions would have occurred. Nonetheless, authors included these 700 third-trimester vaccinations in the denominator when they calculated the spontaneous abortion rate. Based on their statistical sleight-of-hand, authors pegged the spontaneous abortion rate at 12.6% (104/827) when, in fact, it was actually 82% (104/127). This astonishing miscarriage rate is equivalent to the efficacy of the so-called abortion pill, RU486, which carries an FDA black box warning to alert consumers to major drug risks. And yet Shimabukuro et al. concluded there were no obvious safety concerns.

The ABOG EMAIL Sent to ALL Constituents September 2021

ABOG
American Board of Obstetrics & Gynecology
First in Women's Health

Statement Regarding Dissemination of COVID-19 Misinformation

The American Board of Obstetrics and Gynecology (ABOG) fully supports the statement published by the Federation of State Medical Boards (FSMB) that asserts that providing misinformation about the COVID-19 vaccine contradicts physicians' ethical and professional responsibilities, and therefore may subject a physician to disciplinary actions, including suspension or revocation of their medical license. Additionally, ABOG supports a recent American Board of Medical Specialties (ABMS) statement, which expresses concern regarding the serious public health effects of the persistent spread of misinformation regarding the COVID-19 virus.

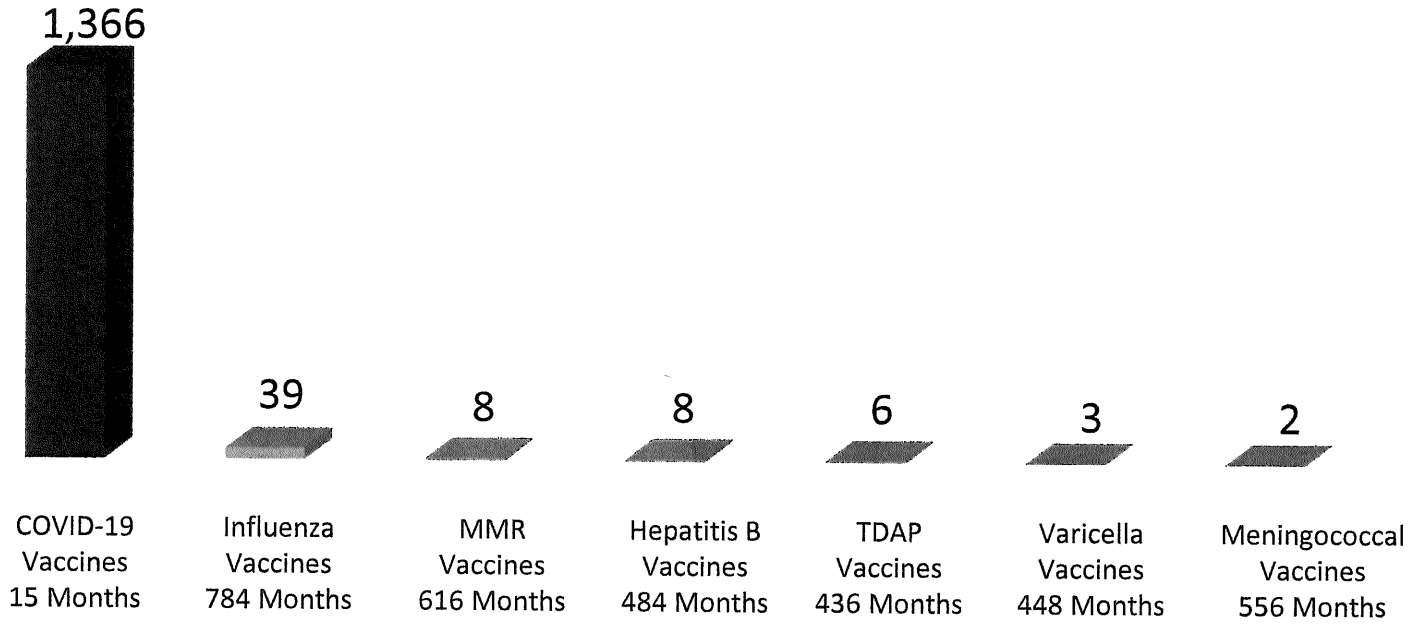
Patients rely on physicians to practice evidence-based medicine based on facts and scientific data. The FSMB and ABMS statements align with the ABOG standards and policies for certification and maintenance of certification that involve medical professionalism and professional standing. These standards include:

- acting in your patients' best interests
- behaving professionally with patients, families, and colleagues across health professions
- taking appropriate care of yourself
- representing your Board certification and MOC status in a professional manner

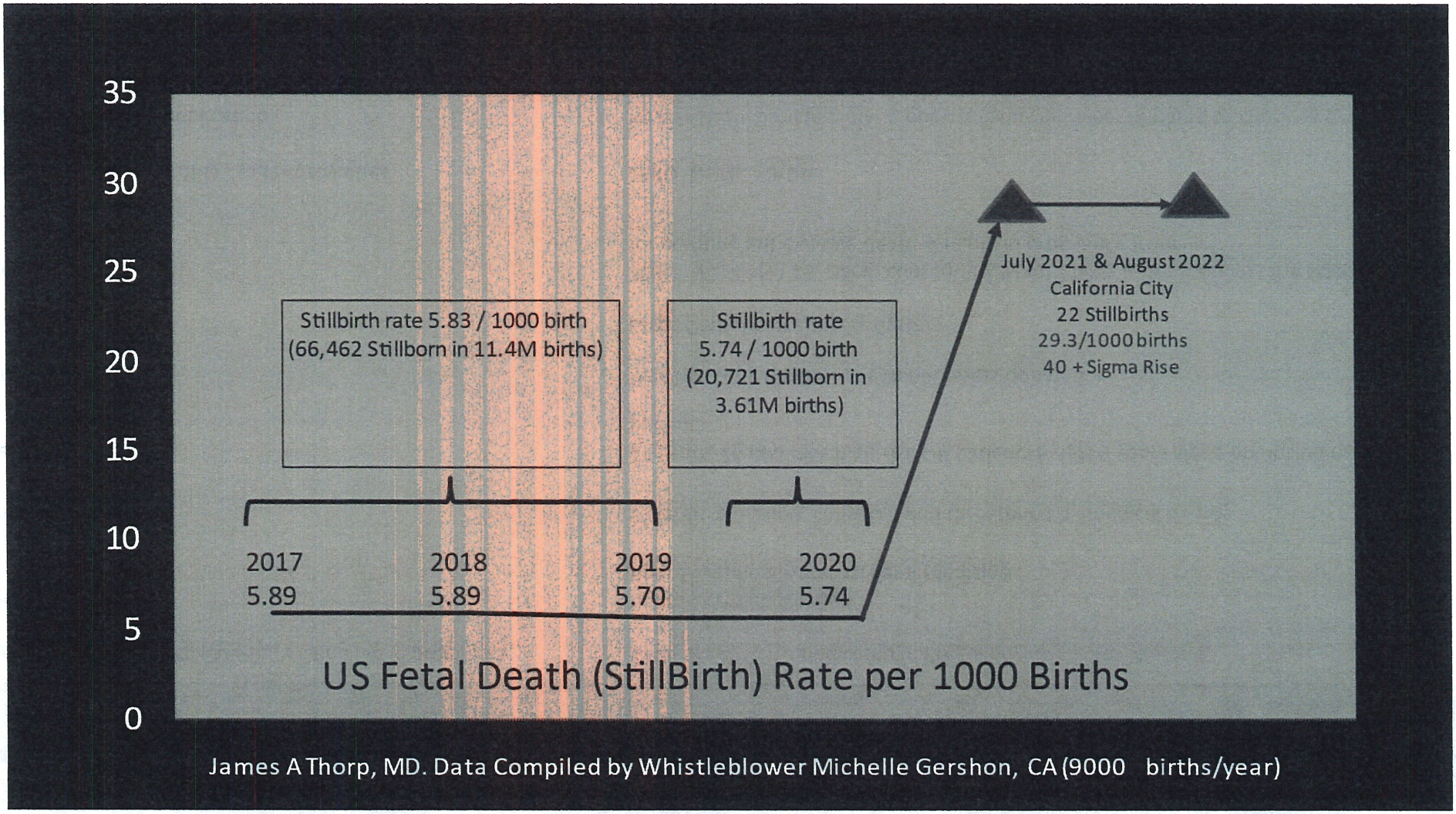
A recent article highlights the risks posed to pregnant people by COVID-19 and the reports of increasing numbers of unvaccinated pregnant individuals in ICUs in several states with severe infection. The CDC has reported that the deaths in August are the highest number of deaths reported in any month since the start of the pandemic, citing that about 97% of pregnant people treated in the hospital for COVID-19 have been unvaccinated. The ACOG, SMFM, and CDC recommend the COVID-19 vaccine for all people over the age of 12, including pregnant people. ABOG supports these recommendations and has incorporated this information in our Maintenance of Certification (MOC) learning and self-assessment offerings to help diplomates provide evidence-based care to the people and families that we serve.

abog.org

Peer-Reviewed Medical Journal Publications Documenting Severe Injury or Death after Vaccination: COVID-19 Vaccines (15 months) versus Other Vaccines



Thorp KE, Thorp JA, Thorp EM. COVID-19 and the Unraveling of Experimental Medicine - Part III. G Med Sci. 2022; 3(1):118-158. https://www.doi.org/10.46766/thegms.pubheal.22042302


35
30
25
20
15
10
5
0
Stillbirth rate 5.83 / 1000 birth
(66,462 Stillborn in 11.4M births)
Stillbirth rate
5.74 / 1000 birth
(20,721 Stillborn in
3.61M births)
July 2021 & August 2022
California City
22 Stillbirths
29.3/1000 births
40 + Sigma Rise
2017
5.89
2018
5.89
2019
5.70
2020
5.74
US Fetal Death (StillBirth) Rate per 1000 Births
James A Thorp, MD. Data Compiled by Whistleblower Michelle Gershon, CA (9000 births/year)

	James A Thorp MD 
Recommendations for Exp COVID-19 Gene jab in pregnancy	Category X, Contraindicated in Pregnancy, Black Box Warning
Specialty	Board Certified Ob/Gyn Board Certified Maternal Fetal Medicine
Cui Bono?	Severely punished, censored and threatened by medical boards
Clinical OB Experience	44 years, 26,000 plus high-risk OB patients in last 4 years alone not including pro bono patients
Funding Source	Personal time donated; Personal assets donated.
Employer	Large Catholic Healthcare System
Conflicts of Interest (COI)	ZERO. NONE. NADA. Harsh consequences for taking a stand against the state narrative and for pointing out massive death & injury in pregnancy from vax
Benefits from Vaccine profits / patent royalties	ZERO. NONE. NADA.
Royalties from books / publications	NONE; 100% Donated; 10+ X book royalties per year donated to charities over career
Major Pertinent Publication	Journal of American Physicians & Surgeons extensively peer-reviewed. No journal COI. Journal independent of Pharma industrial complex. Article written by authors
Availability	Answers to all. Willing to debate anyone in the world over the last two years.

SECTION BREAK

We the People 50-Recall the Shots Initiative

A Former Feds Group Initiative

We the people 50, are a group of doctors, scientists, healthcare workers, COVID vaccine-injured, attorneys, activists, and pharma regulatory specialists who have gathered together to demand that the COVID genetic vaccines be pulled. These shots must be recalled and investigated due to the egregious number of adverse events and deaths, as well as clear evidence of contamination and degradation of the genetic mRNA sequence.

The Pfizer and Moderna COVID Shots are Contaminated and Degraded

Recent scientific evidence by two different labs show that both the Pfizer and Moderna shots are heavily contaminated and degraded. Contamination and adulteration of consumer products violates Consumer Product Protection statutes and informed consent as well as multiple other laws that regulate pharmaceutical safety.

1. **The Pfizer shots are adulterated with over a thousand times the allowable level of DNA from the DNA plasmids used to make the shots in E.Coli bacteria. They represent up to 35% of the shot genetic material.**

2. **These plasmids carry a non-disclosed SV40 sequence that allows them to infect human cells and go to the cell nucleus. SV40 is an oncogenic promoter and contamination of the Polio shots with this virus, historically, has been postulated to have caused millions of cancers.**

3. **The plasmids are also designed to infect E.Coli, such as E.Coli in the human gut. The functional consequence of this is that the gut could become a permanent spike factory through the E.Coli that are naturally present there.**

4. **The plasmids carry two antibiotic resistance genes to kanamycin and neomycin, which could confer antibiotic resistance to two major classes of antibiotics used in medicine today, to the billions that have been injected.**

5. **There is the possibility of contamination with E. Coli bacterial proteins and "endotoxin", LPS. These, if present, would cause massive immune reactions and sepsis in the recipients. It is plausible that this contamination exists given the shoddy manufacturing practices, the presence of the DNA plasmids and the fact that these shots were grown in E. Coli.**

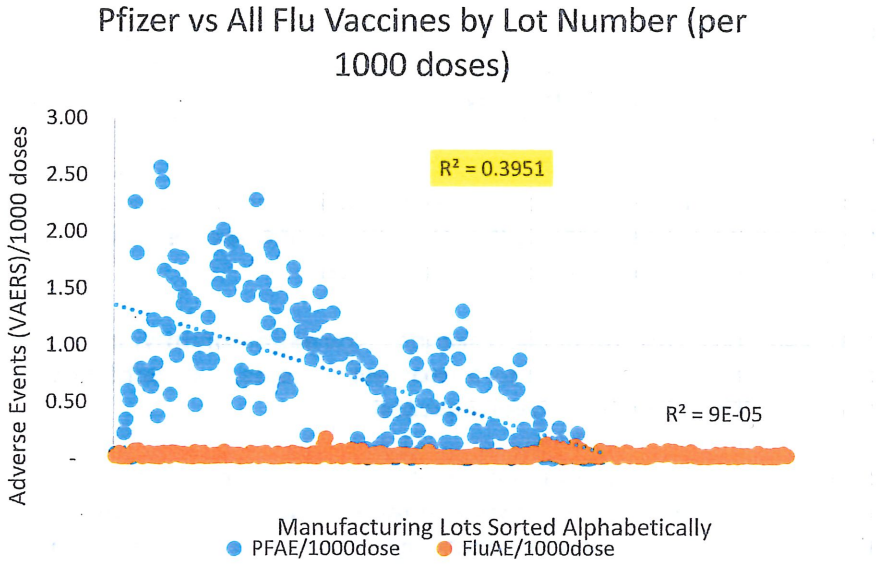
6. **The mRNA in the shots is also broken and degraded. Contamination and degradation of the mRNA genetic sequence, can lead to genetic integration, gene silencing and severe adverse auto-immune events, anaphylaxis, cancers and death as well as be passed on to next generations.**

There is Regulatory Failure by Both the FDA and CDC to Oversee and Enforce the Purity and Safety of these Genetic Vaccines

1. **Pharma specialists, have exposed a global failure of the secondary contracted manufacturers to adhere to Good Manufacturing Practice (cGMP) and multiple FDA violations, which were never remediated or followed up on by the FDA.**

2. **There is a clear lot-to-lot variability in adverse events and deaths that support the findings of contamination and degradation (see chart below).**

The FDA and CDC have failed to seize the COVID vaccines and investigate these findings despite being made aware of them, several months (contamination) to years ago (degradation). The clearly compromised financial relationship between these regulatory agencies and the COVID vaccine manufacturers and beneficiaries, makes their lack of action highly suspect. There has been zero response from either on these findings of batch variability, contamination and degradation, prompting this action by We the People 50-Recall the Shots, to go to the states directly and demand their removal and an immediate investigation into these issues, for the safety of the citizens involved. This is a graphic representation of the lot to lot variability in adverse events for the COVID shots as compared to the flu shots.



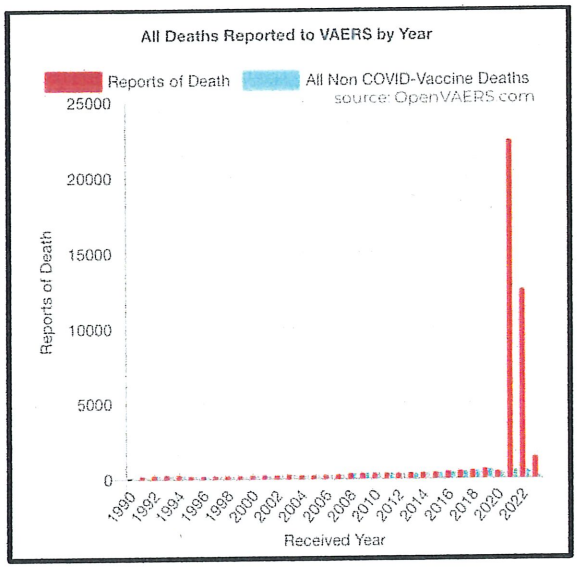
FDA,CDC Not Adhering to Past Vaccine Safety and Recall Practice with COVID Shots

We have been highly alarmed at the lack of CDC or FDA action to pull the COVID genetic vaccines based upon the large number of adverse events and deaths reported,

1. **In the past, just 26 deaths prompted the recall of the swine flu vaccine. We are now in excess of 35,000 deaths in the CDC Vaccine Adverse Event Reporting System (VAERS) as of April 7, 2023.**

2. **Pfizer's own documents show that even they recorded 1223 deaths the first 90 days following the vaccine rollout, but there has been no recall.**

This is very unusual and questions regarding this inconsistency have been met with no logical response from either entity. The number of deaths alone reported into the VAERS system for the COVID shots dwarf all other traditional vaccines given for the past 30 years, *combined* and supports the lack of safety of these products. The recent findings of contamination may provide some explanation for these adverse events and deaths ***(See VAERS Chart Below through April 7. 2023)***. www.openvaers.com



Had these contaminations and adulterations been noted in infant formula or even dog food, these products would have been immediately seized and recalled. These are products that we are allowing, in some cases even mandating, be injected into our infants and children where we are recording heart attacks, strokes and "sudden deaths" in previously healthy children and no one has demanded their recall. This is a travesty.

We hope that these materials (A full report is also enclosed with references), help inform of our concerns and for the undeniable necessity to recall these dangerous genetic vaccines. We seek to use the Consumer Product Protection laws of most states to remove these products from the commerce stream and to prosecute the manufactures for the egregious neglect of cGMP of their products which were mandated to many and encouraged for all, despite the knowledge of their un-safe, contaminated and degraded nature. We hope to also bring federal pressure to reform the FDA and CDC for failure to enforce the regulations they are bound to enforce for the health and safety of the American people, as well as prohibit conflicts of interest within these institutions.

We the People 50 Committee— April, 2023

Dr. Janci Lindsay, PhD., Director, We the People 50-Recall the Shots (832) 646-1378
www.wethepeople50.com jlindsay@toxicologysupport.com

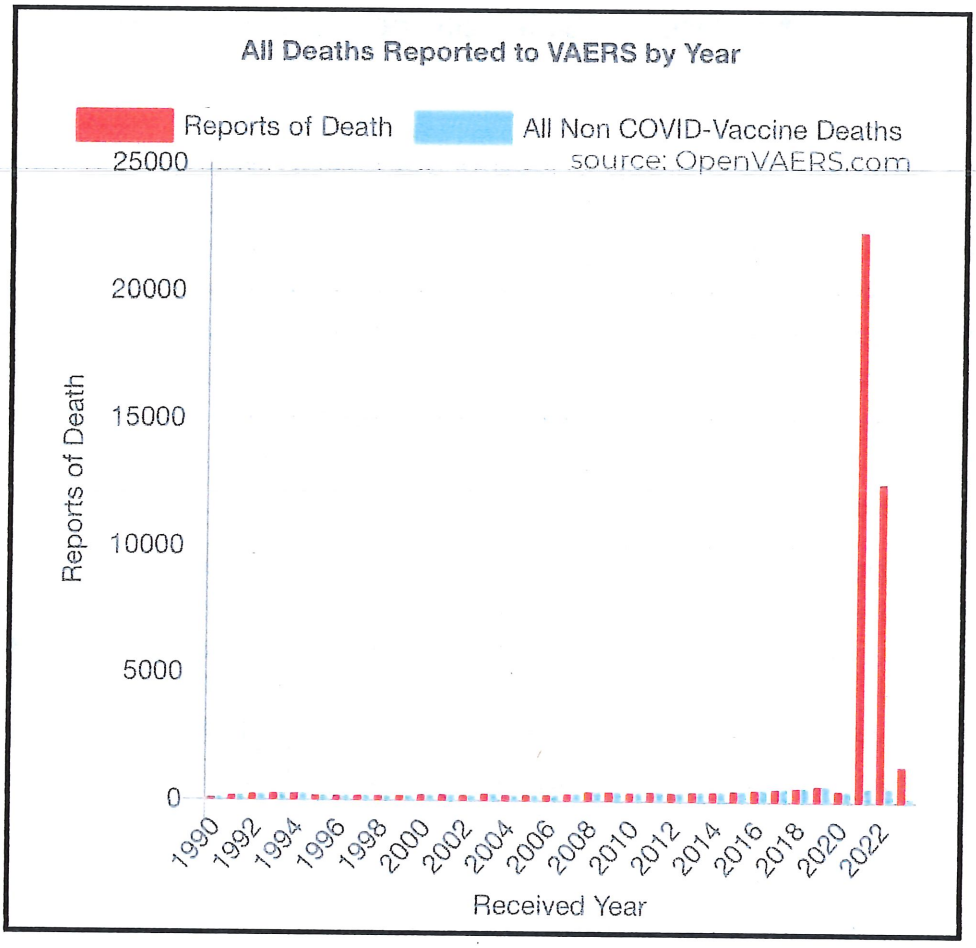
We the People 50-Recall the Shots Initiative

We the people 50, are a group of doctors, scientists, healthcare workers, COVID vaccine-injured, attorneys, activists, and pharma regulatory specialists who have gathered together to demand that the COVID genetic vaccines be pulled. These genetic therapies must be investigated due to egregious numbers of adverse events and deaths and clear evidence of contamination and degradation of the genetic sequence. Recent scientific evidence by two different labs show that the shots are both contaminated and degraded. Contamination and adulteration of consumer products violates most states' Consumer Product Protection statutes.

Further investigations by pharma process engineers and pharma regulatory specialists, have revealed poor manufacturing practices and failure to adhere to cGMP coupled with a lack of proper regulatory oversight by the FDA and the manufacturers, of lot-to-lot purity and consistency in the manufacturing processes. DNA plasmid contamination from the **E. Coli** plasmid system, used to make the shots on a large scale, and degradation of the mRNA genetic sequence, can lead to severe adverse immune events, anaphylaxis, cancers and death.

The lot-to-lot variability in adverse events and deaths supports the findings of contamination and degradation. The FDA has failed to seize the COVID vaccines and investigate these findings despite being made aware of them, several months to years ago. There has been zero response from either the FDA or CDC on these findings of batch variability, contamination and degradation, prompting this action by We the People 50-Recall the Shots, to go to the states and demand their removal and an immediate investigation into these issues, for the safety of the citizens involved.

We have been highly alarmed at the lack of CDC or FDA action to pull the COVID genetic vaccines based upon the large number of adverse events and deaths reported, temporally associated with these shots, throughout their administration. In the past, just 26 deaths prompted the recall of the swine flu vaccine. We are now in excess of 35,000 deaths in the CDC Vaccine Adverse Event Reporting System (VAERS) and Pfizer's own documents show that even they recorded 1223 deaths the first 90 days following the vaccine rollout, but there has been no recall. This is very unusual and questions regarding this inconsistency have been met with no logical response from either entity. The number of deaths alone reported into the VAERS system for the COVID shots dwarf all other traditional vaccines given for the past 30 years, *combined* ***(See VAERS Chart Below through April 7. 2023)***.



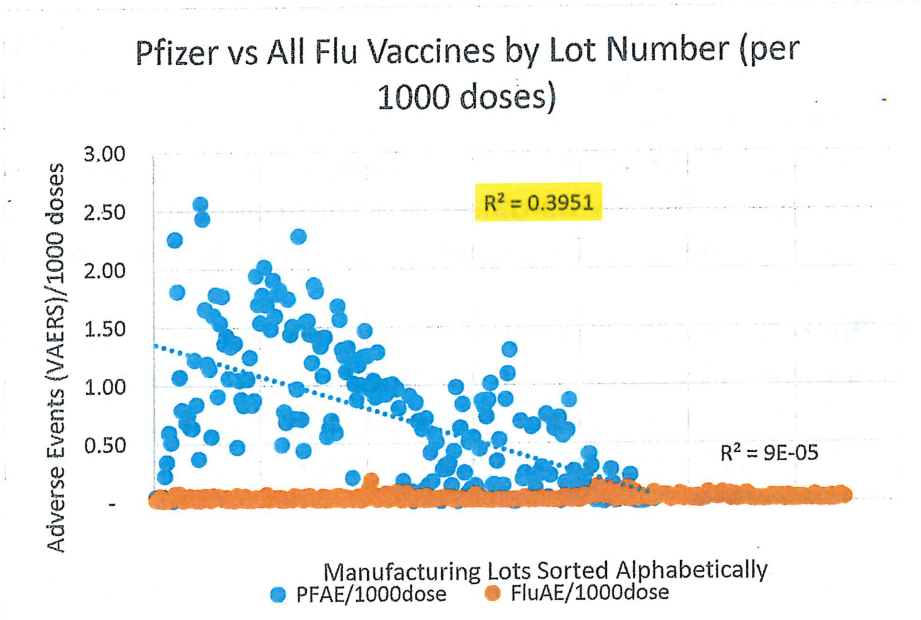
1. The genetic vaccines are what has traditionally been termed "gene therapy" for regulatory purposes or "genetic biologics"—the administration of a genetic sequence that encodes the protein one wishes the body to produce. In the early days gene therapy was used in "right to try" cases in order to correct lethal genetic defects in essential proteins. In more recent times the technology has been explored as a way to make internal "vaccines" as well as augment human physiology with desired traits.

2. This technology, gene therapy, has been researched over the past 3 decades, but was never brought to market due to the severe adverse events that were seen in the early trials, which included lethal auto-immune reactions and latent cancers, that emerged consistently several years after the administration of the gene product. The cancers were thought to be due to the given gene integrating into the genome and causing the expression of mutated proteins. The lethal autoimmune reactions were thought to be due to the attempt to express a foreign or modified protein

on "self" cells. Twenty to thirty years ago the greatest concerns surrounding the large-scale use of gene therapies, were cancers and "accidental" gene transfer, should the therapies make it to the testes or ovaries and contamination of the gene pool. Recipients were often sterilized prior to receiving the technology to avoid inadvertently passing on the administered gene.[1] Therefore it was quite surprising that this technology was rolled out en-masse recently without close monitoring of any of these conditions. Since their rollout we have learned that the vaccines in the lipid nanoparticles make it to both the testes and the ovaries where they are directing the expression of the spike protein.

3. There has been a wide variability to the deaths and disability of the COVID vaccines by lots, which was very different than the typical lot to lot consistency of AE's that you might see with flu lots (***see chart below included in attached witness statement of pharma regulatory specialist Sasha Latypova Attachment A)***. This prompted much concern amongst scientists and regulatory experts, early on, who knew that with typical regulatory oversight, these lots should have been flagged right away and examined for contamination or degradation. Degradation of the mRNA in the shots was noted by Europe's equivalent to the FDA, the EMA, in early license applications by the manufacturers in 2020 and 2021.

Pfizer COVID Genetic Vaccine Adverse Events by Lot Compared to Flu Vaccine



[1] Nancy M. P. King. "Accident & Desire: Inadvertent Germline Effects in Clinical Research." *The Hastings Center Report*, vol. 33, no. 2, 2003, pp. 23–30. *JSTOR*, https://doi.org/10.2307/3528151.

4. Further investigations showed the continued presence of mRNA degradation of the COVID shots. Degradation of the mRNA could cause the production of mutated proteins or silence protein expression. This is also very dangerous. There was apparently no oversight to ensure that this problem was corrected before administering these shots to the public and vulnerable infants and children as well as pregnant women.

5. These are the statements from an affidavit by Pharma specialist Sasha Latypova which speak to this evidence of degraded and contaminated COVID vaccine product. ***(See attached full witness statement by Sasha Latypova)***:

    a. **"The modified RNA (mRNA) which is the active substance of Pfizer's vaccine BNT162b2 is allowed to vary in its integrity by up to 50% in the finished product.**

    b. **Product impurities in the form of truncated mRNA, untranslated DNA and other unknown nucleic acid constructs have been allowed in the finished product in unspecified quantities.**

    c. **As a result of the reckless widening of quality acceptance criteria for the integrity of active ingredient in manufacturing batches, there is a great variation in resulting formulations of final product as dispensed in vials. Furthermore, the contents of the vials are cut by hand into multiple doses by untrained and unsupervised vaccinators who are working outside of the Good Manufacturing Practice compliance.**

    d. **There is an excessive variation in the rates of adverse events and deaths observed post-vaccination for different manufacturing batches which far exceeds expected batch-to-batch variations for compendia pharmaceutical products, such as for example seasonal flu vaccines."**

6. Given the past experience with this technology, and its first time use in massive amounts of the population, you would expect that the regulatory oversight for these shots, would be all that more stringent to ensure the safety of the new technology. Unfortunately, this did not happen. Both

Pfizer and Moderna contracted out the manufacture of these shots to other companies including Lonza, Renschler and Cataland. These companies received FDA 483 forms citing their multiple violations of good manufacturing practice at their facilities, cGMP. There is no indication that these deficits were corrected, and there are no follow up to the original citations issued, but they were all allowed to continue to produce the shots that were administered without pause to the world. To our knowledge, not a single lot has been pulled from the market, despite a strong and variable lot-to-lot association with AE's and death (***See attached declaration of Pharma Process and Regulatory Specialist, Hedley Reese, Attachment B, and links below***).

Catalent's Belgium operations get a second FDA scolding within 1-year span
Catalent cuts 2023 sales expectations as productivity issues and costs pile up at 3 plants
Rentschler slapped with FDA Form 483 citing lax manufacturing procedures
Moderna's new booster launch tripped up by production issues at Catalent plant
BioNTech gets rolling with mRNA production at former Novartis site in Marburg

7. Recently it has been found by two separate laboratories that both the Pfizer and Moderna mRNA monovalent and bivalent (booster) vaccines are contaminated with the DNA plasmids that are used to create the shots on a large scale (***See attached publication by scientist and genomics specialist, Kevin McKernan*** ***https://osf.io/b9t7m/*** ***Attachment C***) The plasmid DNA is supposed to be purified away from the mRNA final product before administration, as residual DNA in significant amounts or any kind is carefully regulated in vaccines due to the dangers of its presence and potential consequences. In the case of plasmid DNA, no amount of residual plasmid DNA is acceptable especially in its transfective form, as it can replicate in the body in gut **E. Coli** once administered. Once of the dangers of the plasmids in the shots is the potential for these plasmids to infect (transfect) the **E.Coli** in the gut of the recipient, making them a continual spike protein factory. This may explain the detection of the spike protein in the brain up to 9 months out from injection (**Morz et al. 2023**) as well as the phenomenon of "Long Covid" in the vaccinated, as well as explain the excess deaths and adverse events, in part.

8. The plasmids contain antibiotic resistance genes for Kanamycin and Neomycin, which are antibiotic classes widely used in medicine to treat bacterial and fungal infections. Recipients of these shots could become resistant to treatment with these classes of antibiotics creating a public health emergency of unimaginable consequence. The presence of these

plasmids in significant amounts in every vial tested, is a grave concern which demands immediate seizure and recall of these products!

- **McKernan, K., Helbert, Y., Kane, L. T., & McLaughlin, S. (2023, April 10). Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose. https://doi.org/10.31219/osf.io/b9t7m. https://osf.io/b9t7m/**

- **Schmeling, M, Manniche, V, Hansen, PR. Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine. Eur J Clin Invest. 2023; 00:e13998. doi:10.1111/eci.13998. https://onlinelibrary.wiley.com/doi/10.1111/eci.13998**

- **COVID-19 mRNA vaccines contain excessive quantities of bacterial DNA: evidence and implications. https://doctors4covidethics.org/covid-19-mrna-vaccines-contain-excessive-quantities-of-bacterial-dna-evidence-and-implications/**

9. The spike protein was not meant to be continually produced. Moreover, the continued production of the DNA encoding for the spike in the body will increase the chance of genomic integration and cancers. These could also be passed on more easily through the gametes, though intercourse, breast milk and contact with others through the well-known mechanism of "shedding". Shedding studies of all gene therapies is recommended by the FDA, but was never conducted by the manufacturers on these genetic vaccines. Nor, was shedding monitored in the public after the COVID vaccines' large scale release, despite thousands of reports of adverse events including vaginal bleeding, miscarriage and even stroke following the unvaccinated being in close proximity to the recently vaccinated.

10. Additional concerns regarding the DNA plasmid contamination is the possibility of the concurrent contamination with **E. Coli** bacterial proteins and "endotoxin", LPS. These, if present, would cause massive immune reactions and sepsis in the recipients. It is plausible that this contamination exists given the shoddy manufacturing practices, the presence of the DNA plasmids and the fact that these shots were grown in **E. Coli**.

Had these contaminations and adulterations been noted in infant formula or even dog food, these products would have been immediately seized and recalled without even a single death, none the less over 35,000 deaths, many in previously healthy children.[2] These are products that we are allowing, in fact even

[2] www.openvaers.com/covid-data/child-summaries

mandating be injected into our infants and children where we are recording heart attacks, strokes and "sudden deaths" during their sleep and no one has demanded their recall. This is a travesty.

We hope that these materials help inform of our concerns and for the undeniable necessity to recall these dangerous genetic vaccines. We seek to use the Consumer Product Protection laws of most states to remove these products from the commerce stream and to prosecute the manufactures for the egregious neglect of cGMP of their products which were mandated to many and encouraged for all, despite the knowledge of their un-safe, contaminated and degraded nature.

We the People 50 Committee— April, 2023

We the People 50-Recall the Shots Initiative

A Former Feds Initiative

www.wethepeople50.com

www.formerfedsgroup.org

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Attachment A

Declaration of Pharma Specialist, Sasha Latypova

required a resolution prior to the product approval. The discussions around this issue are recorded in numerous documents that were released from EMA, at the end of November 2020, including email exchanges between EMA staff and management (see Emails in Attachment). For example, a PowerPoint document from the meeting on November 26, 2020 between EMA and Pfizer/BioNTech describes the issue of mRNA integrity (see 20201126_BNT162b2_EMAmeeting14.pdf in Attachment).

In this meeting it was discussed that the batches manufactured with Process 2 had a much lower range of % intact mRNA and higher % of impurities – fragmented nucleic acid chains of various length and type (DNA and RNA). Specifically, p. 20 lists final product batches manufactured with both processes, ranging in mRNA integrity from 55% to 85% with the remaining % of volume occupied by uncharacterized fragments.

EMA regulatory concern with lack of mRNA integrity in Pfizer's product was evident. Specifically, on p. 4 the document states that:

"Significant differences between batches manufactured by DS Process 1 and 2 are observed for the CQA *[critical quality attribute]* mRNA integrity. In addition, the characterisation of BNT162b2 DS *[drug substance]* is currently not found acceptable in relation to this quality attribute. This is especially important considering that the current DS and DP *[drug product]* acceptance criteria allows (sic) for up to 50% fragmented species."

Further, on p. 5 the reviewers discussed the presence of uncharacterized fragmented nucleic chains, some long enough to translate into unknown proteins, and deemed them product impurities that required further characterization:

"Truncated and modified RNA species should be regarded as product-related impurities. Even though two methods, namely agarose gel electrophoresis and capillary gel electrophoresis (CGE), have been applied to determine RNA integrity of BNT162b2 DS *[drug substance]*, no characterisation (sic) data on truncated forms is presented. "

As a result of the manufacturing inconsistency, the clinical trial data collected using the Process 1 material was not deemed applicable to the material manufactured in Process 2. Several EMA reviewers wanted to understand the potential impact on safety and efficacy via bridging clinical studies (see Emails in Attachment). No such comparisons were done. Pfizer provided comparison of some chemical analyses from various batches, but no further characterization of the fragments of RNA and DNA or study of impact of these impurities on safety and efficacy of patients was provided.

EMA reviewers and Pfizer "resolved" this Major Objection by arbitrarily lowering the acceptance criteria for %mRNA integrity (see p.4):

"In addition, we are revising the RNA integrity specification for drug substance to >=60%, drug product release to >=55%, and drug product shelf life to >=50%. "

An extremely wide variation of the integrity of the active substance in bulk material (batch) of the product and abundant presence of uncharacterized impurities means that batches of different formulation - and thus different potency and safety profiles - are being produced. This variation is further amplified when the bulk material is filled in small quantities into vials. Each batch of Pfizer product contains approximately 300,000 vials filled with 0.45ml of drug product which may get varying quantities of intact and broken mRNA molecules. In addition, at the final step of administration, this variability is further exacerbated by dose preparation in a non-GMP environment by untrained and unsupervised staff at the vaccination centers.

Both the regulators and Pfizer to date have not disclosed the acceptable ranges for the key ingredients of the vaccine product, neither in bulk product nor in a vial (as dispensed), and claim "commercial secrets" that prevent them from doing so.

Evidence from adverse event reports (in VAERS database) analyzed by manufacturing lot number.

Manufacturing of pharmaceutical products is regulated by laws that are established to control within tight ranges acceptable criteria for the identity, quantity, quality, purity, potency and other characteristics of the product ingredients to ensure safety and conformity to the approved product labeling. It is expected that the product lot-to-lot, or batch-to-batch, is essentially the same. Therefore, when outcomes data such as rates of adverse events reported for each manufacturing lot is examined, it is expected that only minor variations from lot-to-lot may be observed. This is true for conventional pharmaceutical products and for traditional vaccines such as seasonal flu vaccines.

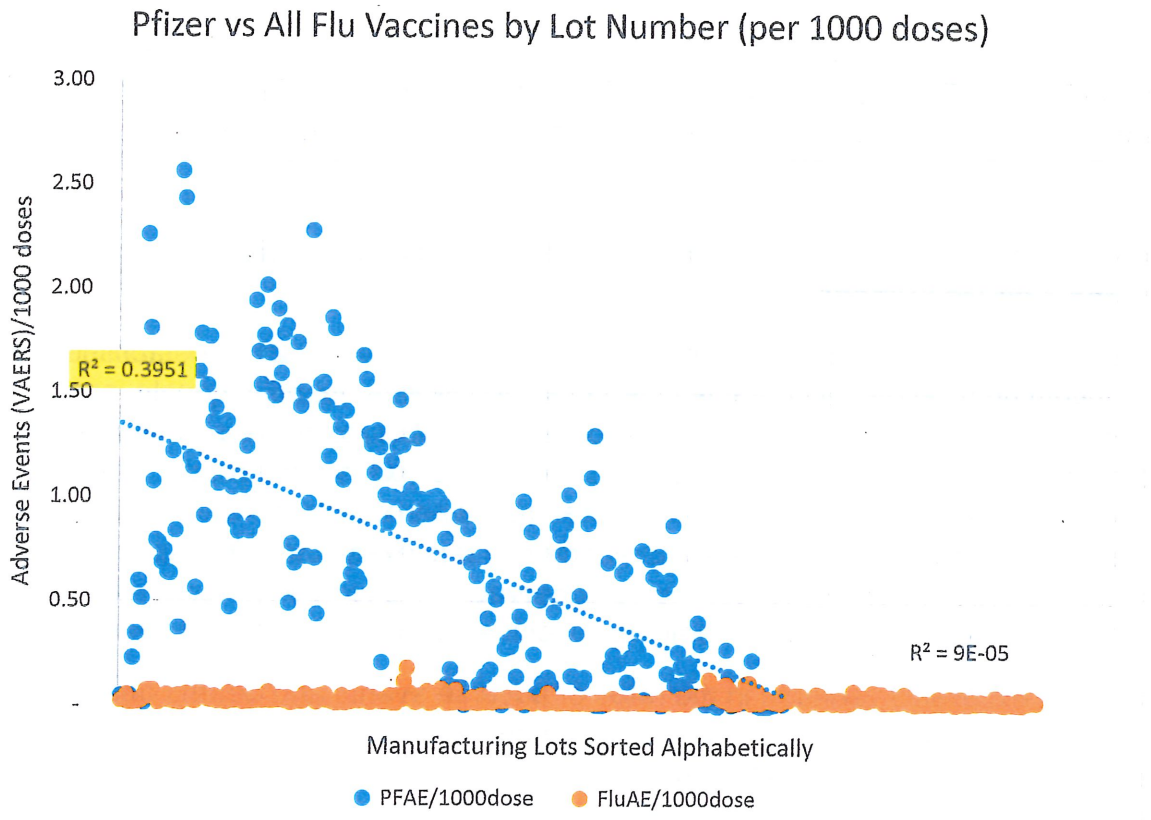
There is an excessive variation in the rates of adverse events and deaths observed post-vaccination for different manufacturing batches which far exceeds expected batch-to-batch variations for compendial pharmaceutical products, such as for example seasonal flu vaccines.

The graph below shows a comparison between the manufacturing lots of Pfizer's BNT162b2 product and manufacturing lots of all seasonal flu vaccines released in 2019-2020. The lot numbers for Pfizer were verified with CDC and dates of manufacture and expiration were obtained. The flu vaccine lot numbers were obtained by downloading data from VAERS. Rates of adverse events reported for each lot are plotted against the lot number (not shown on X-axis for clarity), sorted alphabetically. Finally, the adverse event rates are expressed in "per 1000 doses" to normalize for the lot size.

As evident from this analysis, there is an excessive variability in the toxicity (rates of adverse events) for Pfizer product. The flu vaccine lots in comparison look very similar to each other and have overall a very low rate of adverse events. There is a large correlation between the adverse even rates for Pfizer lots with the lot number (R^2=0.4). This should not happen. There should be no difference in the safety (toxicity) of a

product depending on how its manufacturing lot is numbered. This does not exist for the flu vaccine lot numbers. Overall, the rate of adverse events per lot/dose adjusted is extremely high as can be visualized on the graph below.

The difference between the two sets of products is stark and cannot be explained by normal demographic variations such as age or underlying health status of the recipient. Flu vaccines are administered to approximately 50% of population, including to old and frail people with compromised health status as well.



In conclusion, the evidence presented in my statement shows that Pfizer's manufacturing quality acceptance criteria permit for an extremely large variation of the key ingredient (up to 50%) and allow for a substantial presence of uncharacterized impurities. This can be deemed as product adulteration with de-facto different formulations produced in different batches. This leads to overall large rates of toxicities, reported adverse events and to extreme variations of product safety (toxicity) parameters in different manufactured lots.

Alexandra (Sasha) Latypova

PO Box 2981

Stateline, NV, 89449, USA

latypova@hotmail.com

Attachment B

Declaration of Pharma Specialist Hedley Rees

Attachment B

Declaration of Pharma Specialist Hedley Rees

DECLARATION: HEDLEY REES, B. ENG., HONS., EXECUTIVE MBA.

Pursuant to 28 U.S.C. § 1746, Hedley Rees, Bridgend, United Kingdom, hereby declares:

I am over the age of 18 and fully competent to make this declaration through my education, knowledge, experience, and training, of the facts stated in this declaration.

This declaration is submitted in support of: LEGAL ACTIONS TO CONVENE A GRAND JURY AND TO PULL THE COVID-19 "VACCINES" UNDER CONSUMER PRODUCT PROTECTION STATUTES FOR LACK OF SAFETY AND EFFICACY, MISREPRESENTATION, MISBRANDING, ADULTERATION AND DEGRADATION, CAUSES.

Based on my experience, knowledge, and training as a pharmaceutical and biologics supply chain management and regulatory specialist (CV here)[i], I explain below key aspects of the control of product and material contamination, and the potential impact of contamination on the identity, strength, quality, and purity of the SARS-CoV-2 injections:

1. Any company involved in the manufacture of prescription drugs (drugs) must adhere to CGMP regulations as defined in the US Code of Federal Regulations, Title 21.[ii]
2. The relevant sections applicable to drugs manufactured by chemical synthesis (small molecule) are *21 CFR PART 210 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL*[iii] and *PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS*[iv]
3. The SARS-CoV-2 injections are categorized as biological products, and in addition to 21 CFR PART 210/211, are also governed by 21 CFR PART 600 - BIOLOGICAL PRODUCTS: GENERAL[v] where biological products are defined as:

"Biological product means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."

4. Biological products are far more susceptible to quality issues than small molecule drugs. This is because they are made from living organisms such as animal and human cells, which can suddenly change character depending on the physical environment (eg temperature or humidity), methods of preparation and processing procedures.
5. Microbial, particulate and pyrogen contamination are ever present, critical risks in the manufacture of sterile injectables such as the SARS-coV-2 injections.
6. Adherence to PART 210/211/600 is essential to assure material and product quality.
7. § 211.113 *Control of microbiological contamination* states [vi]:

   "Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation [proof they work as intended] of all aseptic and sterilization processes."

8. Contamination is classed as a quality deviation, and must recorded and justified, as per § 211.100 Written procedures; deviations.[vii]

   "(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this

subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified."

9. The quality control unit, under § 211.22 "Responsibilities of quality control unit," [viii] must determine what measures are required. See below:

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

9. The initial response must be to contain the outbreak. Production must be ceased immediately, and all production batches suspected of being contaminated must be placed in a quality status that prevent use, such as 'in bond' or 'quarantined'. The bonded production must be physically labelled clearly stating the inventory is not available for use. There should also be a review of batch manufacturing records (BMRs) of products that have already left the facility, to determine if there could be a need to alert downstream supply chain actors of any potential issues.

10. In parallel with containment activities, a deviation investigation must be instigated. The aim of the investigation is to establish the root cause of the contamination problem. This will involve much interchange of scientific, technical and supply chain information, review and approval by the appropriate organizational units, to be finally reviewed and approved by the quality control unit. Often, it takes weeks, or even months, to arrive at a decision on the root cause of a deviation.

11. Once root cause has been identified, a corrective and preventative action plan (CAPA) must be established and implemented via the organization's quality management system (QMS). This again can take weeks or months, even for the more straight forward small molecule drugs, as corrective standard operating procedures (SOPs) must be written, reviewed, and approved. Operators must then be trained in the new SOPs, sign that they have read and understood, and their training records updated.

12. A contamination finding for a biological product is an order of magnitude more complex

FORM 483.

I am giving this declaration to: PROVIDE WRITTEN TESTIMONY TO SUPPORT LEGAL ACTIONS TO CONVENE A GRAND JURY AND TO PULL THE COVID-19 "VACCINES" UNDER CONSUMER PRODUCT PROTECTION STATUTES FOR LACK OF SAFETY AND EFFICACY. MISREPRESENTATION, MISBRANDING AND ADULTERATION/DEGRADATION, CAUSES.

I declare under penalty of perjury under the laws of the United Statesof America that the foregoing is true and correct.

Executed on this the 6 th day of April, 2023.

Hedley Rees

Director, PharmaFlow Limited

[i] https://www.dropbox.com/s/v3yks45fubbgbls/CV_HR_JULY_2022.pdf?dl=0

[ii] https://www.ecfr.gov/current/title-21

[iii] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210

[iv] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211

[v] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-600

[vi] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-F/section-211.113

[vii] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-F/section-211.100

[viii] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-B/section-211.22

[ix] https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations

Attachment C

Publication by Kevin McKernan et al. 2023

Attachment C

Publication by Kevin McKernan et al. 2023

Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose

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Several methods were deployed to assess the nucleic acid composition of four expired vials of the Moderna and Pfizer bivalent mRNA vaccines. Two vials from each vendor were evaluated with Illumina sequencing, qPCR, RT-qPCR, Qubit™ 3 fluorometry and Agilent Tape Station™ electrophoresis. Multiple assays support DNA contamination that exceeds the European Medicines Agency (EMA) 330ng/mg requirement and the FDAs 10ng/dose requirements. These data may impact the surveillance of vaccine mRNA in breast milk or plasma as RT-qPCR assays targeting the vaccine mRNA cannot discern DNA from RNA without RNase or DNase nuclease treatments. Likewise, studies evaluating the reverse transcriptase activity of LINE-1 and vaccine mRNA will need to account for the high levels of DNA contamination in the vaccines. The exact ratio of linear fragmented DNA versus intact circular plasmid DNA is still being investigated. Quantitative PCR assays used to track the DNA contamination are described.

Introduction

Several studies have made note of prolonged presence of vaccine mRNA in breast milk and plasma (Bansal et al. 2021; Hanna et al. 2022; Castruita et al. 2023). This could be the result of the stability of N1-methylpseudouridine (m1Ψ) in the mRNA of the vaccine. Nance *et al.* depict a vaccine mRNA synthesis method that utilizes a dsDNA plasmid that is first amplified in *E.coli* prior to an *in-vitro* T7 polymerase synthesis of vaccine mRNA (Nance and Meier 2021). Failure to remove this DNA could result in the injection of spike encoded nucleic acids more stable than the modified RNA. The EMA has stated limits at 330ng/mg of DNA to RNA (Josephson 2020-11-19). The FDA has issued guidance for under 10ng/dose in vaccines (Sheng-Fowler et al. 2009). Residual injected DNA can result in type I interferon responses and can increase the potential for DNA integration(Ulrich-Lewis et al. 2022).

Results

To assess the nucleic acid composition of the vaccines, vaccine DNA was deeply sequenced using two different methods. The first method used a commercially available New England Biolabs RNA-seq method that favored the sequencing of the RNA but still presented over 500X coverage for the unanticipated DNA vectors (Figure 1 and 2). The RNA-seq assemblies had truncated poly A tracts compared to the constructs described by Nance *et al.* The second method eliminated the RNA with RNase A treatment and sequenced only the DNA using a Watchmaker Genomics fragment library kit. The DNA focused assemblies delivered vector assemblies with more intact poly A tracts (Figure 3).

These assemblies were utilized to design multiplex qPCR and RT-qPCR assays that target the spike sequence present in both the vaccine mRNA and the DNA vector while also targeting the origin of replication sequence present only in the DNA vector (Figure 3). The assembly of Pfizer vial 1 contains a 72bp insertion not present in the assembly of Pfizer vial 2. This indel is known

for its enhancement to the SV40 promoter and its nuclear localization signal (Dean et al. 1999) (Moreau et al. 1981).

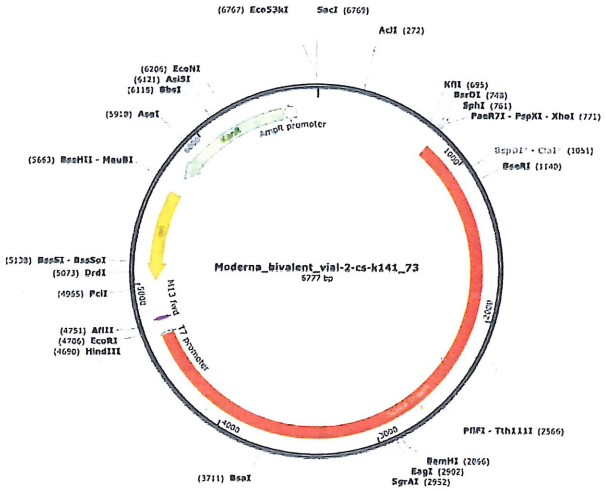


Figure 1. A Moderna vector assembly of an RNA-seq library with a spike insert (red), Kanamycin resistance gene (green) driven by an AmpR promoter and a high copy bacterial origin of replication (yellow).

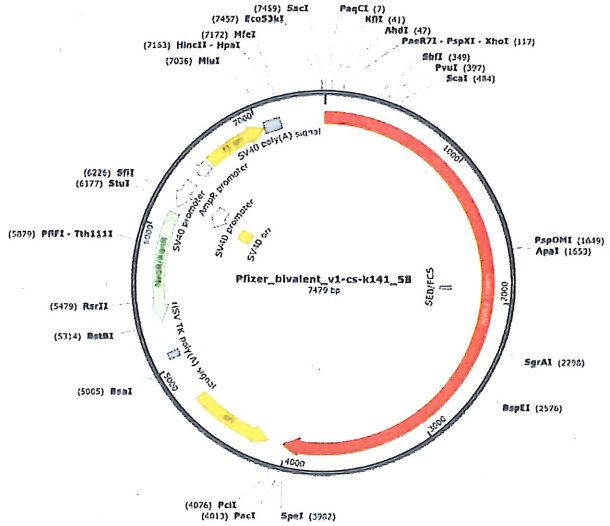


Figure 2. Pfizer bivalent vaccine assembly of the RNA-seq library. Annotated with SEB/FCS, spike insert (red), bacterial origin of replication (yellow), Neo/Kan resistance gene(green), F1 origin (yellow) and an SV40 promoter (yellow and white).

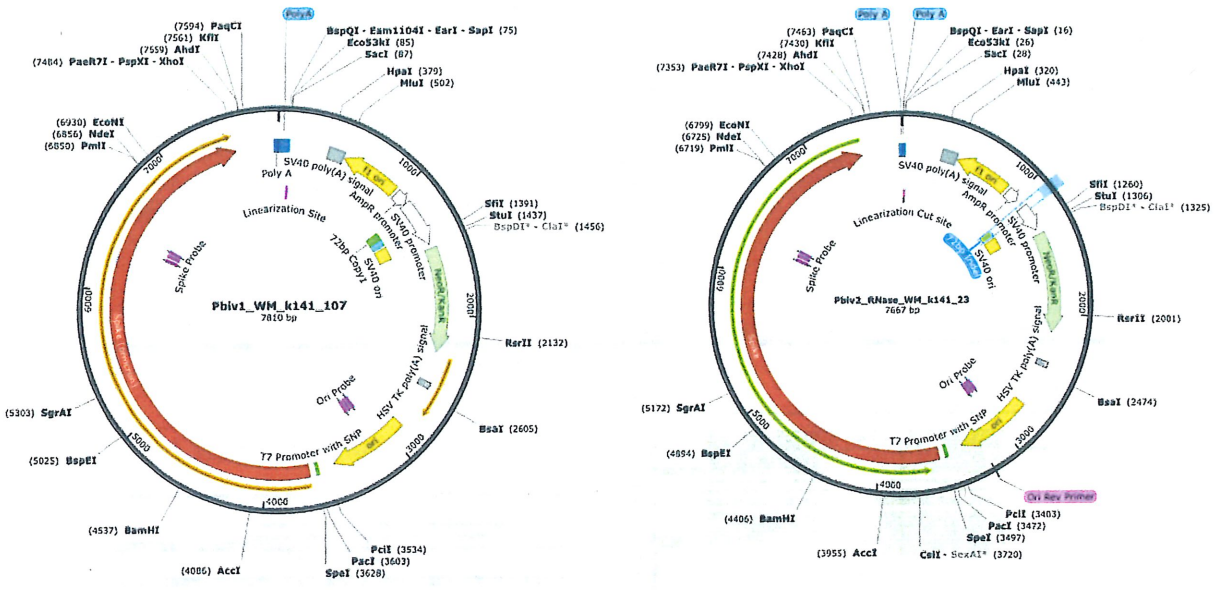


Figure 3. RNase treated vaccines were shotgun sequenced with Illumina (RNase-Seq not RNA-seq). Pfizer vectors from vial 1 (left) and vial 2 (right) contain a 72bp difference in the SV40 promoter (green and light blue annotation). qPCR assays are depicted in pink as Spike probe and Ori probe. The RNase sequencing provided better resolution over the Eam1104i linearization site and the Poly adenylation sequence. The vectors differ in the length of the polyA tail (likely sequencing artifact) and the 72bp indel.

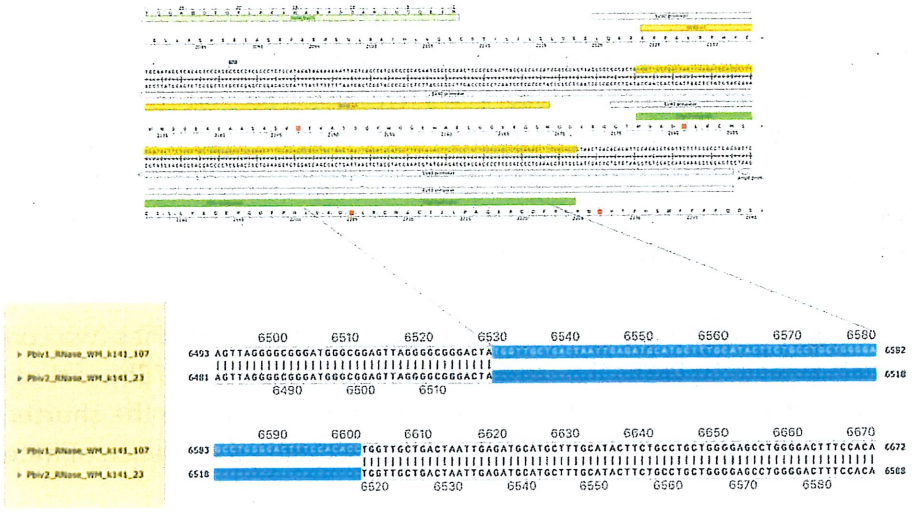


Figure 4. Local alignment of Pfizer vial 1 to Pfizer vial 2 vectors highlights the 72bp tandem duplication in blue.

Figure 5A. Close inspection of the Integrative Genome Viewer (IGV) demonstrates the appearance of a 72bp insertion that is heteroplasmic in Pfizer vial 2. The upper left IGV view is a zoomed-out view where the colored marks depict the indel. The lower Left IGV view shows inverted paired reads as the 72bp insertion is a tandem repeat and paired reads shorter than 72bp can be mapped two different ways. Upper Right IGV view demonstrates a read coverage pile up or 'Plateau'. This occurs when the reference has one copy of the 72bp repeat and the sample has 2 copies. Note- In the upper right IGV depiction, the sequence in Vial 1 is in the opposite orientation in IGV as Vial 2. Lower right IGV view is a zoomed view of the upper right IGV screen.

Since the two Pfizer vials share the same lot number, finding a heterozygous copy number change between the two vials is unexpected. It was hypothesized that the appearance of a heteroplasmic copy number change is instead the result of the Megahit assembler collapsing what is actually two copies of the 72bp sequence into a single copy due to the insert sizes in the sequencing libraries being too short (105bp). It is noteworthy that the longer paired-end reads in the library resolve the 72bp tandem repeat.

When references have a single copy of the 72bp repeat and the sample has two copies of the repeat, reads should pile up to twice the coverage over the single copy 72bp loci as seen in Figure 5A. To test this hypothesis, we added a second 72bp sequence to the shorter plasmid assembly and observed that the reads map without artifact and no evidence of heteroplasmy (Figure 5B).

Figure 5B. IGV view of the read coverage over Pbiv2_k141_23 shows a discrete 72bp plateau in coverage (red rectangle). Editing the Pbiv2_k141_23 reference to include 2 copies of the 72bp sequence, and remapping the sequence data to this corrected sequence shows that the coverage over both vectors is more normal with no coverage plateau in Pfizer vial 2.

These data conclude that all Pfizer vectors contain a homoplastic 2 copy 72bp SV40 Enhancer associated with more robust expression and nuclear localization. The initial heteroplastic indel was an artifact of the Megahit assembler and short insert libraries.

To estimate the size of the DNA, the purified vaccines were evaluated on an Agilent Tape Station™ using DNA (genomic DNA screen tapes) and RNA based (high sensitivity RNA tapes) electrophoresis tapes.

Agilent Tape Station™ electrophoresis reveal 7.5 - 11.3 ng/µl of dsDNA compared to the 23.7 - 55.9ng/µl of mRNA detected in each 300µl sample. Qubit™ 3 fluorometry estimated 1-2.8ng/µl of DNA and 21.8ng - 52.8ng/µl of RNA. There is higher fragmentation seen in the DNA electrophoresis. The total RNA levels are less than the anticipated 30ug (100ng/µl) and 100ug (200ng/µl) doses suggesting a loss of yield in DNA and RNA isolation, manufacturing variance or RNA decay with expired lots.

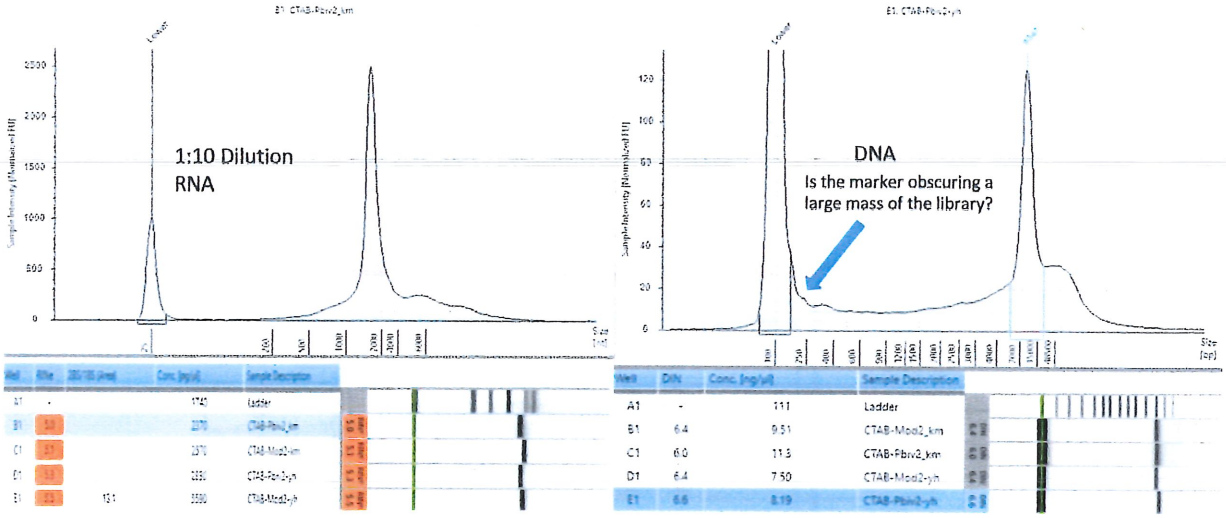


Figure 6. Agilent Tape Station™ electrophoresis demonstrates 23.7ng/µl – 55.9ng/µl of RNA (left). 7.5ng-11.3ng/µl are observed on DNA based Tape Station™. While the DNA electropherogram shows a peak suggestive of a full-length plasmid, this sample is known to have high amounts of N1-methylpseudouridine RNA present. DNA hybrids with N1-methylpseudouridine mRNA may provide enough intercalating dye cross talk to produce a peak. The sizing of the peak on the RNA tape on the left is shorter than expected. This may be the results of N1 methylpseudouridine changing the secondary structure or the mass to charge ratio of the DNA.

Quantitative PCR assays were designed using IDTs Primer Quest software targeting a region in the spike protein that was identical between Moderna and Pfizer spike sequences and a shared sequence in the vectors' origin of replication. This allowed the qPCR and RT-qPCR assessment of the vaccines. qPCR only amplifies DNA while RT-qPCR amplifies both DNA and RNA. Gradient qPCR was utilized to explore conditions where both targets would perform under the same cycling conditions for both RT-qPCR and PCR (gradient PCR data not shown).

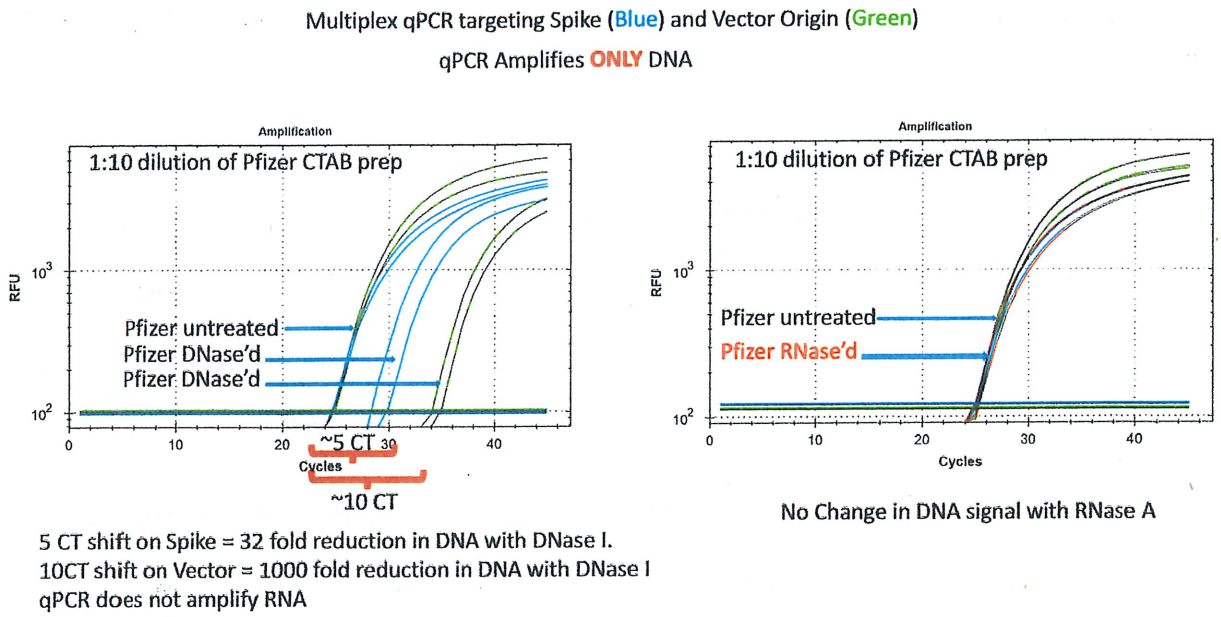


Figure 7. qPCR of Pfizer's bivalent vaccine with and without DNase I (left) and RNase A (right). Untreated mRNA demonstrates equal CTs for Spike and Vector assays as expected. Vector is more DNase I sensitive than the Spike suggesting the modRNA may inhibit nuclease activity of DNase I against complementary DNA targets. RNase A treatment doesn't alter the qPCR signal.

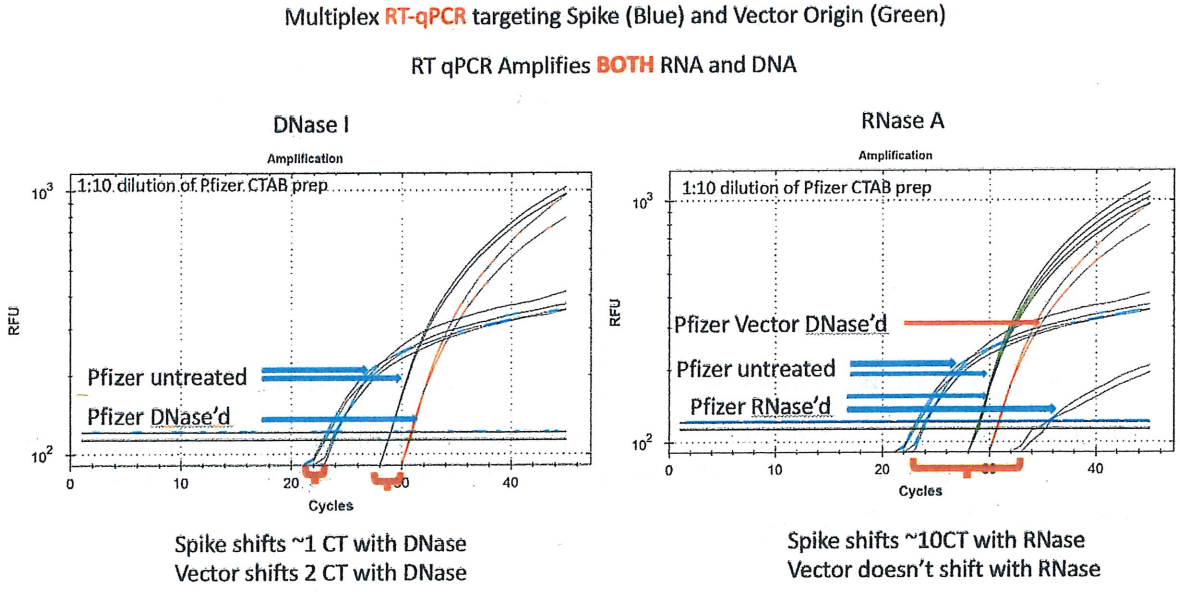


Figure 8. RT-qPCR amplifies both DNA and RNA. The untreated samples show a large CT offset with Pfizer Spike and Vector assays (Left Blue versus Green). This is anticipated as the T7 polymerization should create more mRNA over spike than over the vector. Small 1-2 CT shifts are seen with DNase I treatment. This is expected if the DNA is less than equal concentration of

nucleic acid in RT-PCR. RNase treatment (Right) shows a 10 CT offset but doesn't alter the DNA vector CT.

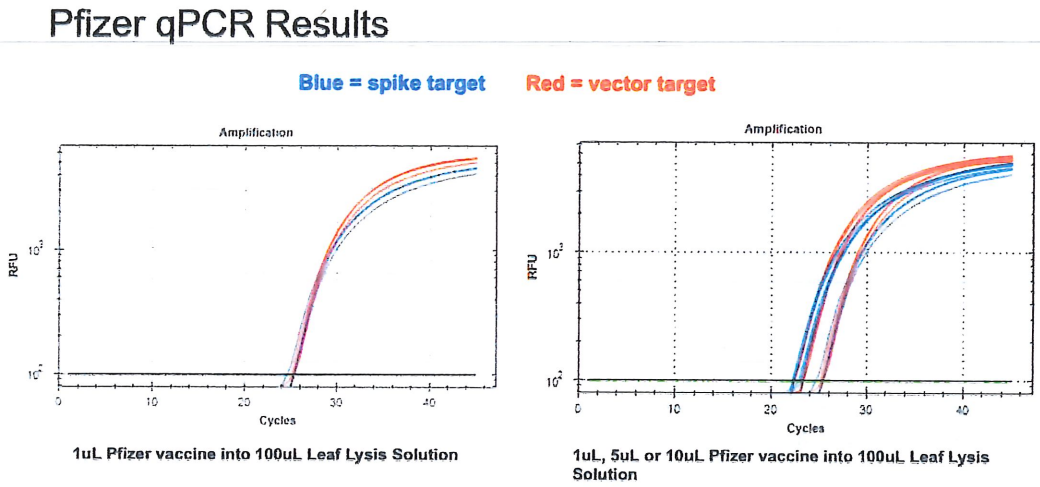


Figure 9. 1µl of the Pfizer bivalent vaccine placed in 100µl Leaf Lysis buffer for an 8 minute boil step delivers a CT of 24 for both Vector and Spike targets in qPCR (Left). Assay is responsive to 1,5,10µl of input (Right).

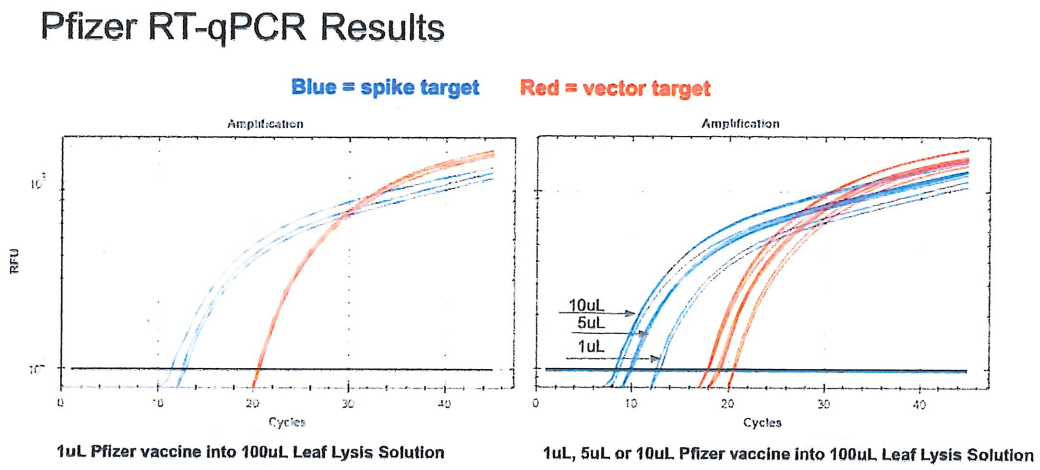


Figure 10. 1µl of the Pfizer bivalent vaccine placed in 100µl Leaf Lysis buffer for an 8 minute boil step delivers a CT of 20 and 12 for both Vector and Spike targets in RT-qPCR (Left). Assay is responsive to 1,5,10µl of input (Right).

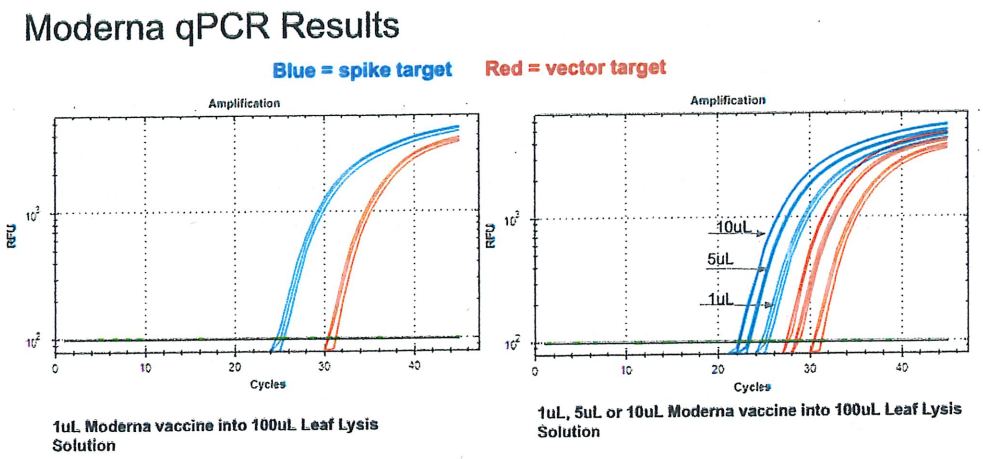


Figure 11. 1µl of the Moderna bivalent vaccine exhibits different CTs values for the spike and the vector targets (Left) with qPCR. This needs to be explored further as the assays provide equal CT scores on Pfizers' vaccines and the sequence of the amplicon is identical between the two vector origins. There are 2 mismatches in the spike amplicons between Moderna and Pfizer but none of the mismatches are under a primer or probe. The assay is responsive to 1,5,10µl of direct boil mRNA (Right).

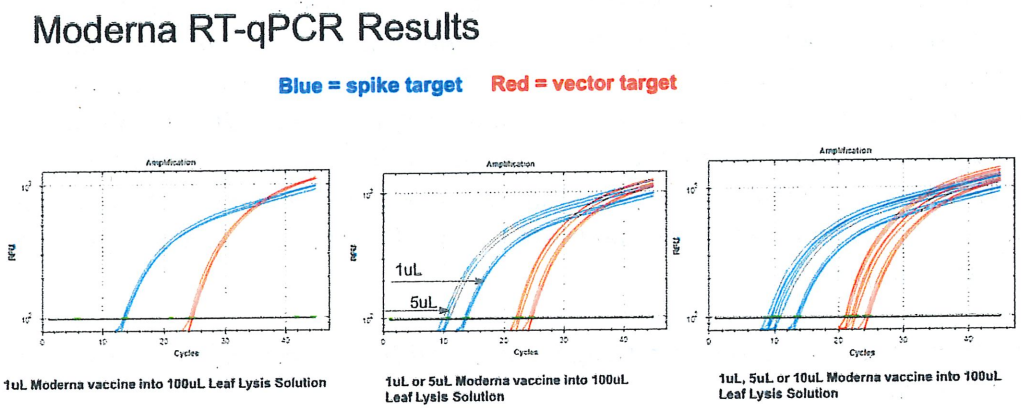


Figure 12. 1µl of the Moderna bivalent vaccine exhibits different CTs values for the spike and the vector targets (Left) with RT-qPCR. The large 10 CT shift between Spike and Vector needs to take into consideration that qPCR control shows a 5 CT offset. The boil preps can tolerate 1-10µl of vaccine (Middle and Right).

	Qubit DNA ng/µl	Qubit RNA ng/µl
Pbiv1	2.81	30.0
Pbiv2	1.47	52.8
Mod1	2.67	21.8
Mod2	1.04	49.0

Table 1. Qubit™ 3 Fluorometry estimates 1.04-2.8 ng/µl of dsDNA in the vaccines and 21.8ng-52.8ng/µl of RNA.

Synthetic templates were synthesized with IDT to build RT-qPCR standard curves to benchmark CTs to the mass of DNA in the reaction. This method uses ideal templates and fails to quantitate DNA molecules smaller than the amplicon size. As expected, this method delivers lower DNA concentration estimates than Qubit™ 3 fluorometry or Agilent Tape Station™. It also represents an ideal environment which doesn't capture the inhibition or primer depletion that can occur when large quantities of mRNA with identical sequence to your DNA target are co-present in a qPCR assay.

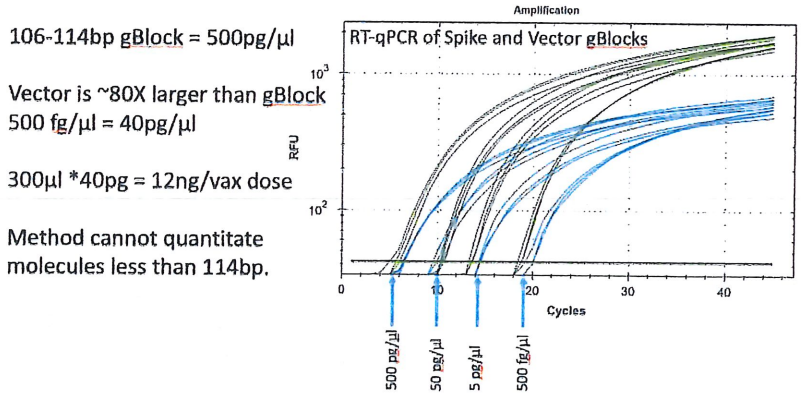


Figure 13. Two gBlocks were synthesized at IDT for Spike and Ori positive control templates used in an RT-qPCR assays. 10-fold serial dilutions were run in triplicate to correlate CT scores with picograms of DNA. The threshold is lowered from 10^2 for review of the background. CT of ~20 = 500fg/RT-qPCR reaction. Since 100bp targets only represent 1/80th of the vector DNA present as a potential contaminant, 500 fg/µl manifests in 40pg/µl of vector DNA. Any DNA that is DNase I treated and is smaller than the amplicon size cannot amplify or be quantitated with this method. This method will under quantitate DNase I treated samples compared to Qubit™ 3 or Agilent Tape Station™.

This work was further validated by testing 8 unopened Pfizer monovalent vaccines with both qPCR and RT-qPCR.

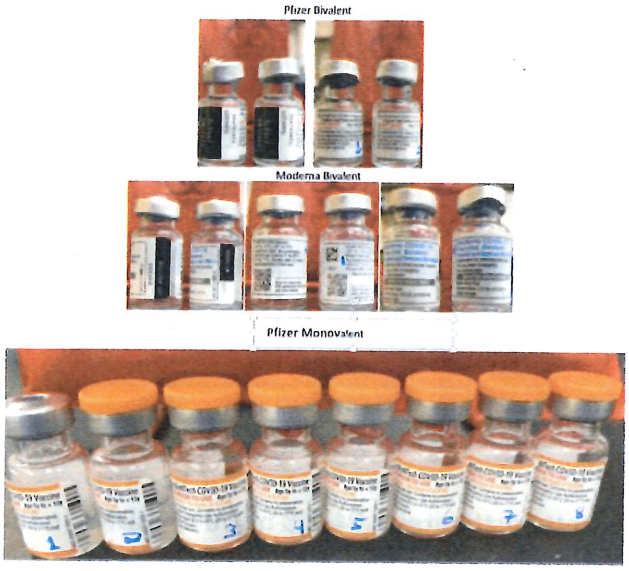


Figure 14. Moderna and Pfizer Bivalent vaccines (Top). 8 Monovalent Pfizer mRNA vaccines. These were unopened but past expiration (Bottom).

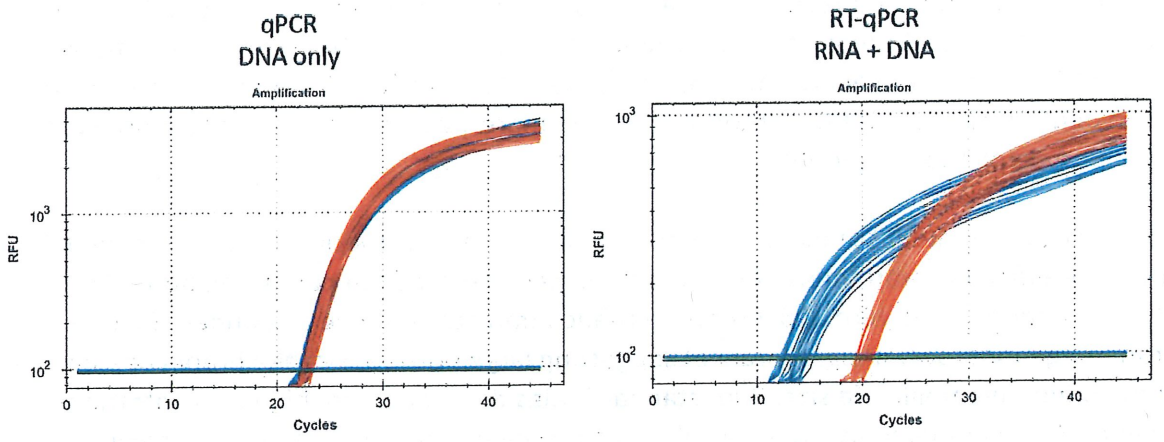


Figure 15. 1µl of vaccine boiled in 100µl of Leaf Lysis buffer was subjected to qPCR (left) and RT-qPCR (right) for Vector (red) and Spike (blue). 8 samples were tested in triplicate.

qPCR-Spike	Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	STDEV
Replicate 1	23.12	22.98	22.58	22.33	22.36	22.08	22.20	22.06	0.401
Replicate 2	23.16	22.90	22.70	22.36	22.20	22.16	22.29	22.22	0.373
Replicate 3	23.22	22.84	22.59	22.29	22.44	22.26	22.29	22.11	0.366
STDEV	0.05	0.07	0.07	0.03	0.12	0.09	0.05	0.08	

qPCR: (Vector-Spike)	Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	STDEV
Replicate 1	0.20	0.08	0.27	(0.00)	0.18	0.18	0.10	0.24	0.090
Replicate 2	0.16	0.22	0.29	0.11	0.18	0.12	0.03	0.13	0.079
Replicate 3	0.14	0.31	0.20	0.17	0.31	0.19	0.20	0.13	0.069
STDEV	0.03	0.11	0.05	0.09	0.08	0.04	0.08	0.06	

qPCR-Vector	Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	STDEV
Replicate 1	23.33	23.06	22.85	22.32	22.54	22.26	22.30	22.30	0.411
Replicate 2	23.32	23.12	23.00	22.47	22.38	22.28	22.32	22.35	0.419
Replicate 3	23.36	23.15	22.79	22.46	22.75	22.46	22.49	22.23	0.383
STDEV	0.02	0.04	0.11	0.08	0.19	0.11	0.11	0.06	

RATIO RNA/DNA	Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	STDEV
Replicate 1	1	1	1	1	1	1	1	1	0.068
Replicate 2	1	1	1	1	1	1	1	1	0.062
Replicate 3	1	1	1	1	1	1	1	1	0.056
STDEV	0.0	0.1	0.0	0.1	0.1	0.0	0.1	0.1	

Table 2. CT values for Spike and Vector during qPCR (DNA only). Standard deviation for the triplicate measurements run horizontally in black font. Standard deviation for vial to vial run vertically in Red. Delta CT or (Vector CT minus Spike CT) represents the ratio of Spike to Vector DNA and should = 1.

RT-Spike	Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	STDEV
Replicate 1	14.05	14.77	13.18	13.77	13.79	12.52	12.62	13.53	0.749
Replicate 2	14.29	14.74	14.38	14.82	13.78	13.82	12.57	12.38	0.925
Replicate 3	14.49	14.91	15.43	13.84	13.74	13.55	12.36	12.19	1.141
STDEV	0.22	0.09	1.12	0.59	0.02	0.69	0.14	0.72	

RT: (Vector-Spike)	Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	STDEV
Replicate 1	6.74	5.93	7.20	6.40	6.51	7.31	7.33	5.97	0.570
Replicate 2	6.33	6.06	5.92	5.67	6.34	6.13	6.92	7.06	0.478
Replicate 3	6.33	6.07	5.43	6.39	6.13	6.38	7.09	7.18	0.562
STDEV	0.24	0.07	0.91	0.42	0.19	0.62	0.21	0.67	

RT-Vector	Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	STDEV
Replicate 1	20.80	20.71	20.39	20.16	20.30	19.83	19.95	19.50	0.439
Replicate 2	20.62	20.80	20.30	20.49	20.12	19.96	19.49	19.45	0.499
Replicate 3	20.81	20.98	20.86	20.23	19.88	19.93	19.45	19.37	0.638
STDEV	0.11	0.14	0.30	0.17	0.21	0.07	0.28	0.07	

RATIO RNA/DNA	Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	STDEV
Replicate 1	107	61	147	84	91	159	161	63	41.54
Replicate 2	80	67	61	51	81	70	121	134	29.25
Replicate 3	80	67	43	84	70	83	136	145	34.79
STDEV	15.5	3.3	55.8	19.2	10.4	47.9	20.3	44.6	

Table 3. CT values for Spike and Vector during RT-qPCR (RNA+DNA). Ratio of RNA:DNA ranges from 43:1 To 161:1. EMA allowable limit is 3030:1. This is 18-70 fold over the EMA limit.

Discussion

Multiple methods highlight high levels of DNA contamination in the both the monovalent and bivalent vaccines. While the Qubit™ 3 and Agilent Tape Station™ differ on their absolute quantification, both methods demonstrate it is orders of magnitude higher than the EMAs limit of 330ng DNA/ 1mg RNA. qPCR and RT-qPCR confirms the relative RNA to DNA ratio. An 11-12 CT offset should be seen between Spike and Vector RT-qPCR signals to represent a 1:3030

contamination limit (2^11.6 = 3100). Instead, we observe much smaller CT offsets (5-7 CTs) when looking at qPCR and RT-qPCR data with these vaccines. It should be noted that Qubit™ 3 and Agilent methods stain all DNA in solution while qPCR measures only amplifiable molecules without DNase I cut sites between the primers. The further apart you space the qPCR primers, the fewer Qubit™ 3 and Agilent detectable molecules will amplify. The primers used in this study are 106bp and 114bp apart, thus any molecules that are DNase I cut below this length will be undercounted with the qPCR methods relative to more general dsDNA measurements from Qubit™ 3 or Agilent Tape Station™.

This also implies that qPCR standard curves using 100% intact synthetic DNA standards will amplify more efficiently and thus undercount the total digested DNA contamination. For example, standard curves with 106-114bp synthetic templates provide CTs under 20 in the picogram range (not low nanogram range) suggesting large portions of the library are smaller than the minimum amplifiable size. Pure standards also do not contain high concentrations of modified mRNA with identical sequence which could serve as a competitive primer sink or inhibitor to qPCR methods.

Alternatively, the Qubit™ 3 and the Agilent Tape Station™ could be inflating the DNA quantification due to intercalating dye cross talk with N1-methylpseudouridine RNA. For this reason, we believe the ratio we observed when these molecules are more scrupulously interrogated with polymerases specific for each template type in qPCR and RT-qPCR is a more relevant metric. The EMA metric is also stated as such a ratio.

This also brings into focus if these EMA limits took into consideration the nature of the DNA contaminants. Replication competent DNA should arguably have a more stringent limit. DNA with mammalian promoters or antibiotic resistance genes may also be of more concern than just random background *E.coli* genomic DNA from a plasmid preparation (Sheng-Fowler et al. 2009). Background *E.coli* DNA was measured with qPCR and had CT over 35.

There has been a healthy debate about the capacity for SARs-CoV-2 to integrate into the human genome(Zhang et al. 2021). This work has inspired questions regarding the capacity for the mRNA vaccines to also genome integrate. Such an event would require LINE-1 driven reverse transcription of the mRNA into DNA as described by Alden *et al.* (Alden et al. 2022). dsDNA contamination of sequence encoding the spike protein wouldn't require LINE-1 for Reverse Transcription and the presence of an SV40 nuclear localization signal in Pfizer's vaccine vector would further increase the odds of integration. This work does not present evidence of genome integration but does underscore that LINE-1 activity is not required given the dsDNA levels in these vaccines. The nuclear localization of these vectors should also be verified.

Prior sequencing of the monovalent vaccines from Jeong *et al.* only published the consensus sequence (Dae-Eun Jeong 2021). The raw reads for this project are not available and should be scrutinized for the presence of vector sequence.

Given these vaccines exceed the EMA limits (330ng/mg DNA/RNA) with the Qubit™ 3 and Agilent data and these data also exceed the FDA limit (10ng/dose) with the more conservative qPCR standard curves, we should revisit the lipopolysaccharide (LPS) levels. Plasmid contamination from *E.coli* preps are often co-contaminated with LPS. Endotoxins contamination can lead to anaphylaxis upon injection (Zheng et al. 2021).

A limitation of this study is the unknown provenance of the vaccine vials under study. These vials were sent to us anonymously in the mail without cold packs. RNA is known to degrade faster than DNA and it is possible poor storage could result in faster degradation of RNA than DNA. RNA as a molecule is very stable but in the presence of metals and heat or background ubiquitous RNases, it can degrade very quickly. All of the vaccines in this study are past the expiration date listed on the vial suggesting more work is required to understand the DNA to RNA ratios in fresh lots. The publication of these qPCR primers may assist in surveying additional lots with more controlled supply chains. Studies evaluating vaccine longevity in breast milk or plasma may benefit from vector DNA surveillance as this sequence is unique to the vaccine and may persist longer than mRNA.

While the sequencing delivered full coverage of the plasmid backbones, it is customary to assemble plasmids from DNase I fragmented libraries. These methods have not discerned the ratio of linear versus circular DNA in the vials. While plasmid DNA is more competent and stable, linear DNA may have higher genome integration risks.

The intercalating dyes used in the Qubit™ 3 and Agilent systems are known to have low fluorescent cross talk with DNA and RNA but it is unknown to what degree N1-methylpseudouridine alters the specificity of these intercalating dyes. As a result, we have relied on the CT offsets between RT-qPCR and qPCR with the vector and spike sequence as the best relative assessment of the EMA ratio-metric regulation. These qPCR and RT-qPCR reagents may be useful in tracking these contaminants in vaccines, blood banks or patient tissues in the future.

Methods

Purifying the mRNA from the LNPs

LiDs/SPRI purification

100µl of each vial was sampled (1/3rd to 1/5th of a dose)

- 5µl of 2% LiDs was added to 100µl of Vaccine to dissolve LNPs
- 100µl of 100% Isopropanol
- 233µl of Ampure (Beckman Genomics)
- 25µl of 25mM MgCl2 (New England Biolabs)

Samples were tip mixed 10X and incubated for 5 minutes for magnetic bead binding. Magnetic Beads were separated on a 96-well magnet plate for 10 minutes and washed twice with 200µl of 80% EtOH. The beads were left to air dry for 3 minutes and eluted in 100µl of ddH20. 2µl of eluted sample was run on an Agilent Tape Station™.

CTAB/Chloroform/SPRI purification of Vaccines

Some variability in qPCR performance was noted with our LiDs/SPRI purification method of the vaccines. This left some samples opaque and may represent residual LNPs in the purification. A CTAB/Chloroform/SPRI isolation was optimized to address this and used for further qPCR and Agilent electrophoresis. Briefly, 300µl of Vaccine was added to 500µl of CTAB (MGC solution A in SenSATIVAx MIP purification kit. #420004). The sample was then vortexed and heated for 5 minutes at 37°C. 800µl of chloroform was added, vortexed and spun at 19,000 rpms for 3 minutes. The top 250µl of aqueous phase was collected and added to 250µl of solution B and 1ml of magnetic binding buffer. Samples were vortexed and incubated for 5 minutes and magnetically separated. The supernatant was removed and the beads washed with 70% Ethanol two times. Samples were finally eluted in 300µl of MGC elution buffer.

Simple boil preparation for evaluating vaccine qPCR.

This boil prep process simply takes 1-10µl of the vaccine and dilutes it into a PCR compatible leaf lysis buffer and heats it (Medicinal Genomics part number 420208).

- 65°C for 6 minutes
- 95°C for 2 minutes

Library Construction for Sequencing

50µl of each 100µl sample was converted into RNA-Seq libraries for Illumina sequencing using the NEB NEBNext UltraII Directional RNA library Kit for Illumina (NEB#E7760S).

To enrich for longer insert libraries the fragmentation time was reduced from 15 minutes to 10 minutes and the First strand synthesis time was extended at 42°C to 50 minutes per the long insert recommendations in the protocol.

No Ribo depletion or PolyA enrichment was performed as to provide the most unbiased assessment of all fragments in the library. The library was amplified for 16 cycles according to the manufacturers protocol. A directional library construction method was used to evaluate the single stranded nature of the mRNA. This is an important quality metric in the EMA and TGA disclosure documents as dsRNA (>0.5%) can induce an innate immune response. dsRNA content is often estimated using an ELISA. Directional DNA sequencing offers a more comprehensive method for its estimation and was previously measured and 99.99% in Jeong et al. It is unclear how this may vary lot to lot or within the new manufacturing process for the newer bivalent vaccines.

RNase A treatment of the Vaccines

RNase A cleaves both uracils and cytosines. N1-methylpseudouridine is known to be RNAse-L resistant but RNase A will cleave cytosines which still exist in the mRNAs. This leaves predominantly DNA for sequencing. Vaccine mRNA that was previously sequenced and discussed here, was treated at 37°C for 30 minutes with 10µl of 20 Units/µl Monarch RNase A from NEB. The RNase reaction was purified using 1.5X of SenSATIVAx (Medicinal Genomics #420001). Sample were eluted in 20µl ddH20 after DNA purification. 15µl was used for DNA sequencing.

DNase treatment of the vaccines

50µl of CTAB purified vaccine was treated at 37°C for 30 minutes with 2µl DNase I and 6µl of DNase I buffer (Grim reefer MGC#420143). 2.5µl of LiDs Lysis buffer was added to stop the DNase reaction. Reactions were purified using 60µl 100% Isopropanol, 140µl Ampure, 15µl MgCl2. Magnetic beads were tip mixed 10 times, left for 5 minutes to incubate, magnetically separated and then washed twice with 80% EtOH.

Whole genome shotgun of RNase'd Vaccines.

15µl of the DNA was converted into sequence ready libraries using Watchmakers Genomics WGS library construction kit. This kit further fragments the DNA to smaller sizes making fragment length in the vaccines difficult to predict.

Qubit™ 3 Fluorometry

Qubit™ 3 fluorometry was performed using Biotum AccuBlue RNA Broad Range kit (#31073) and Biotum AccuGreen High Sensitivity dsDNA Quantitation Kit (#31066) according to the manufacturers instructions.

E.coli qPCR

Medicinal Genomics PathoSEEK™ E.coli Detection assay (#420102) was utilized according to the manufacturers instructions.

qPCR and RT-qPCR Spike Assay

- MedGen-Moderna_Pfizer_Janssen_Vax-Spike_Forward
- >AGATGGCCTACCGGTTCA
- MedGen-Moderna_Pfizer_Janssen_Vax-Spike_Reverse
- >TCAGGCTGTCCTGGATCTT
- MedGen-Moderna_Pfizer_Janssen_Vax-Spike_Probe
- >/56-FAM/CGAGAACCA/ZEN/GAAGCTGATCGCCAA/3IABkFQ/

qPCR and RT-qPCR Vector Origin Assay

- MedGen_Vax-vector_Ori_Forward
- >CTACATACCTCGCTCTGCTAATC
- MedGen_Vax-vector_Ori_Reverse
- GCGCCTTATCCGGTAACTATC
- MedGen_Vax-vector_Ori_Probe
- /5HEX/AAGACACGA/ZEN/CTTATCGCCACTGGC/3IABkFQ/

Elute primer to 100uM according to IDT instructions.

Make 50X primer-probe mix.

1. 25µl 100uM Forward Primer
2. 25µl 100uM Reverse Primer
3. 12.5µl 100uM Probe
4. 37.5µl nuclease free ddH20.

Use 15µl of this mixture in the **qPCR master mix** setup seen below. (0.5µl primer/probe per reaction)

Use 10µl of this mixture in the **RT-qPCR master mix** setup seen below.

Medicinal Genomics Master Mix kits used

1. https://store.medicinalgenomics.com/qPCR-Master-Kit-v3-200-rxns
2. https://store.medicinalgenomics.com/pathoseek-rt-qpcr-master-kit

Reaction setup for 30 reactions of qPCR

- 114µl Enzyme Mix (green tube)
- 24µl Reaction Buffer (blue tube)
- 246µl nuclease free ddH20
- 15µl of Primer-Probe set Spike
- 15µl of Primer-Probe set Ori

Use 13.8µl of above MasterMix and 5µl of purified sample (1µl Vax DNA/RNA + 4µl ddH20 if CT <15)

Reaction setup for 34 reactions of RT-qPCR

- 200µl Enzyme mix
- 96µl nuclease free ddH20
- 20µl RNase Inhibitor (purple tube)
- 4µl DTT (green tube)
- 10µl Primer-Probe set Spike
- 10µl Primer-Probe set Ori

10µl of MasterMix and 1µl of Vax DNA/RNA

Medicinal Genomics MIP DNA Purification Kit used

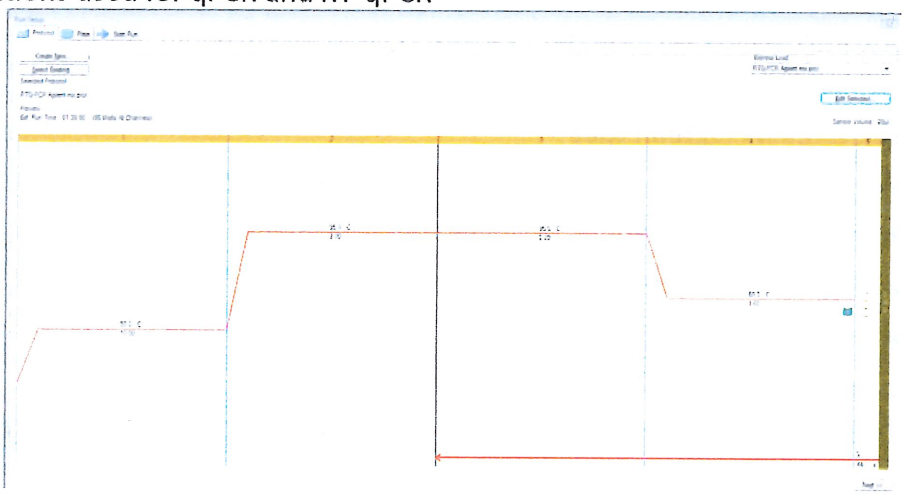
1. https://store.medicinalgenomics.com/SenSATIVAx-DNA-Extraction-Kit-200-reactions_2

he CTAB/Chloroform/SPRI based DNA/RNA isolation methods are described above.

Cycling conditions

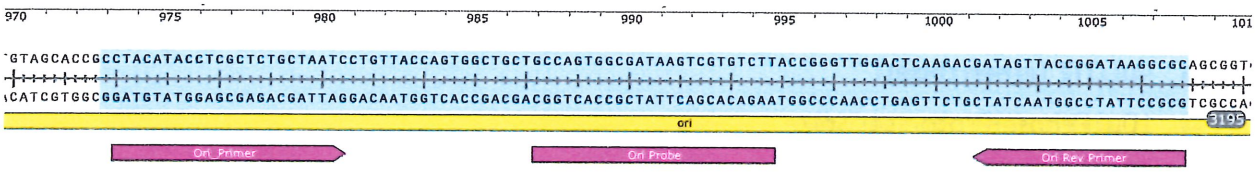
These conditions work for both qPCR and RT-qPCR. Note: The 50°C RT step can be skipped with qPCR. The MGC qPCR MasterMix kits used have a hot start enzyme which are unaffected by this 50°C step. For the sake of controlling RNA to DNA comparisons, we have put qPCR and RT-qPCR assays on the same plate and run the below program with the RT step included for all samples.

Cycling Conditions used for qPCR and RT-qPCR

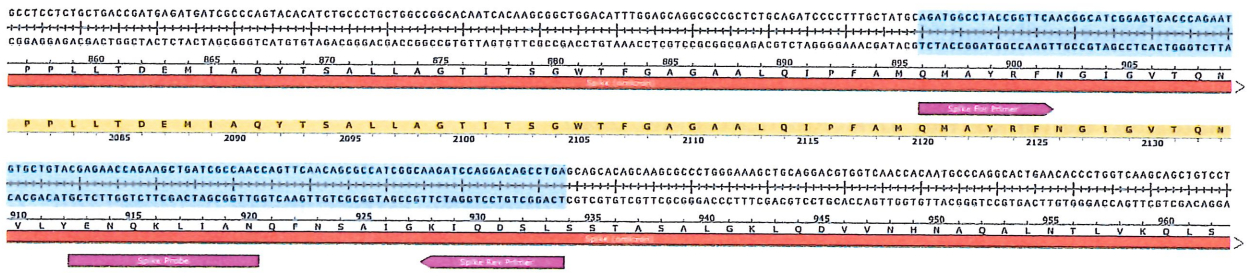


Sequences of amplicons for gBlock Positive Controls. Ori = 106bp, Spike = 114bp.

Ori target



Spike target



Sequencing Data

Raw Illumina Reads RNA-seq

- Pfizer Bivalent Vial 1 Forward reads
- Pfizer Bivalent Vial 1 Reverse reads
- Pfizer Bivalent Vial 2 Forward reads
- Pfizer Bivalent Vial 2 Reverse reads
- Moderna Vial 1 Forward reads
- Moderna Vial 1 Reverse reads
- Moderna Vial 2 Forward reads
- Moderna Vial 2 Reverse reads

Read files are run through sha256 (Hash and stash) and etched onto the DASH blockchain. The sha256 hash of the read file is spent into the OP_RETURN of an immutable ledger. If the hash of the file doesn't match the hash in these transactions, the file has been tampered with.

- Pfizer Vial 1 Forward hash
- Pfizer Vial 1 Reverse hash
- Pfizer Vial 2 Forward hash
- Pfizer Vial 2 Reverse hash
- Moderna Vial 1 Forward hash
- Moderna Vial 1 Reverse hash
- Moderna Vial 2 Forward hash
- Moderna Vial 2 Reverse hash

Megahit Assemblies

- Pfizer Vial 1
- Pfizer Vial 2
- Moderna Vial 1
- Moderna Vial 2

Illumina Reads mapped back to Megahit Assemblies

- Pfizer Vial 1 BAM File. Index File
- Pfizer Vial 2 BAM File. Index File
- Moderna Vial 1 BAM File. Index File
- Moderna Vial 2 BAM File. Index File

Q30 Filtered Illumina Reads (use these for transcriptional error rate estimates)

FastQ-Filter download: usage> fastq-filter -e 0.001 -o output.fastq input.fastq

- Pfizer bivalent Vial 1 Forward Reads
- Pfizer bivalent Vial 1 Reverse Reads
- Pfizer bivalent Vial 2 Forward Reads
- Pfizer bivalent Vial 2 Reverse Reads
- Moderna bivalent Vial 1 Forward Reads
- Moderna bivalent Vial 1 Reverse Reads
- Moderna bivalent Vial 2 Forward Reads
- Moderna bivalent Vial 2 Reverse Reads

Q30 BAM files. Q30 Reads mapped against Megahit assemblies

- Pfizer Vial 1 q30-BAM file. Index File
- Pfizer Vial 2 q30-BAM file. Index File
- Moderna Vial 1 q30-BAM file. Index File
- Moderna Vial 2 q30-BAM file. Index File

IGVtools error by base on q30 reads

Fields = Position in contig, Positive stand (+)A, +C, +G, +T, +N, +Deletion, +Insertion, Negative strand -A, -C, -G, -T, -N, -Deletion, -Insertion

- Moderna Vial 1

- Moderna Vial 2
- Pfizer Vial 1
- Pfizer Vial 2

Analysis pipeline

Reads were demultiplexed and processed with

- Trimgalore - Removes Illumina Sequencing adaptors.
- Megahit- assembles reads into contigs.
- Megahit for SARs-CoV-2
- Samtools- generates BAM files for viewing in IGV.
- Samtools stats used to calculate outie reads.
- BWA-mem- Short read mapper used to align reads back to the assembled references.
- SnapGene software- (www.snapgene.com)- Used to visualize and annotate expression vectors
- IGV- Integrated Genome Viewer used to visualize Illumina sequencing reads.

RNase Treated Libraries-BAM files

contig specific BAM files were created using samtools

samtools view -h input.bam contig_name -O BAM > contig.bam; samtools index contig.bam;

Samtools stats run on a each contig in each assembly.

for out_prefix in `ls *.sort.bam | perl -pe "s/.sort.bam//"`; do mkdir -p ${out_prefix}-samtools-stats; for contig in `samtools view -H ${out_prefix}.sort.bam | grep "^@SQ" | cut -f 2 | perl -pe "s/SN\://"`; do echo "Now calculating stats for ${contig}/$out_prefix..."; samtools stats ${out_prefix}.sort.bam $contig > ${out_prefix}-samtools-stats/${contig}-samtools-stats.txt; done; done

- Pbiv1_RNase_WM_k141_107.fa
- Pbiv1_RNase_WM_k141_107.bam
- Pbiv1_RNase_WM_k141_107.bam.bai
- Pbiv2_RNase_WM_k141_23.fa
- Pbiv2_RNase_WM_k141_23.bam

- Pbiv2_RNase_WM_k141_23.bam.bai

Author contributions

KJM- constructed the sequencing libraries, designed the qPCR assays, ran Qubit™ 3s and Agilent Tape Station™ and performed the analysis, drafted the manuscript.
YH-Optimized DNA isolations, Tape Station™ and qPCR results.
SM, LTK- assisted in demultiplexing and trimming the reads and assembly troubleshooting

Conflicts of interest- Authors of this paper are employees of Medicinal Genomics which manufacturers some of the qPCR and DNA isolation kits used in this study.

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SECTION BREAK

11.5% Herd loss

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19A5.R8
True Name	Swine Influenza Vaccine, N1 & N2, RNA Particle
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Sequivity - Merck Animal Health
Date of Compilation Summary	June 24, 2022

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

11.5% Herd Loss

3.2% immediate death the rest wasting disease, neurological, and other horrible deaths.

VeDDRA Code	Total Animals	Percent of All Animals
No adverse events	525	70.20%
Anorexia	55	7.40%
Death	24	3.20%
Lameness	20	2.70%
Loss of Condition	12	1.60%
Diarrhea	11	1.50%
Unthrifty	7	0.90%
Anaphylaxis^	3	0.40%
Central Nervous System Disorder*	3	0.40%
Lethargy	3	0.40%
Respiratory Tract Infection*	3	0.40%
Arthritis	2	0.30%
Meningitis	2	0.30%
Musculoskeletal Disorder*	2	0.30%
Trauma*	2	0.30%
Abdominal Caviry Hernia	1	0.10%
Abscess*	1	0.10%

*Not otherwise specified

^Related to IVP

USDA Approval Date	December 13, 2021

Vaccines by drinking milk

An oral vaccine for SARS-CoV-2 RBD mRNA-bovine milk-derived exosomes induces a neutralizing antibody response *in vivo*

Quan Zhang, Miao Wang, Chunle Han, Zhijun Wen, Xiaozhu Meng, Dongli Qi, Na Wang, Huanqing Du, Jianhong Wang, Lu Lu, Xiaohu Ge

doi: https://doi.org/10.1101/2022.12.19.517879

Abstract

The severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) that causes the coronavirus disease 2019 (COVID-19) has presented numerous challenges to global health. The vaccines, including lipid-based nanoparticle mRNA, inactivated virus and recombined protein, have been used to prevent SARS-CoV-2 infections in clinics and are immensely helpful against the epidemic. Here, we first present an oral mRNA vaccine based on bovine milk-derived exosomes (milk-exos), which encodes the SARS-CoV-2 receptor binding domain (RBD) as an immunogen. The results indicated that RBD mRNA delivered by milk-derived exosomes can produce secreted RBD peptide in 293 cells *in vitro* and stimulated neutralizing antibodies against RBD in mice. These results indicated that bovine milk-derived exosome-based mRNA vaccine could serve as a new strategy for preventing SARS-CoV-2 infection. Meanwhile, it also can work as a new oral delivery system for mRNA.

One Sentence Summary Oral SARS-CoV-2 mRNA vaccine based on bovine milk-derived exosomes can stimulate neutralizing antibodies in mice.

Competing Interest Statement

Advances in Biotechnology. 2013 Oct 22 : 207–226. PMCID: PMC7120417

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Edible Vaccines

to humans & livestock

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Jyoti Saxena and Shweta Rawat

Abstract

In recent years edible vaccine emerged as a new concept developed by biotechnologists. Edible vaccines are subunit vaccines where the selected genes are introduced into the plants and the transgenic plant is then induced to manufacture the encoded protein. Foods under such application include potato, banana, lettuce, corn, soybean, rice, and legumes. They are easy to administer, easy to store and readily acceptable delivery system for different age group patients yet cost effective. Edible vaccines present exciting possibilities for significantly reducing various diseases such as measles, hepatitis B, cholera, diarrhea, etc., mainly in developing countries. However, various technical and regulatory challenges need to overcome in the path of this emerging vaccine technology to make edible vaccine more efficient and applicable. This chapter attempts to discuss key aspects of edible vaccines like host plants, production, mechanism of action, advantages and limitations, applications, and different regulatory issues concerned to edible vaccines.

Keywords: Human Immunodeficiency Virus, Transgenic Plant, Human Papilloma Virus, Newcastle Disease Virus, Rabies Virus

Introduction

in 2016

Bayer Partners with BioNTech to Develop mRNA Vaccines, Drugs for Animal Health

May 10, 2016

Bayer will partner with BioNTech to develop novel, first-in-class mRNA vaccines and therapeutics for animal health indications, the companies said today, under a collaboration whose value was not disclosed.

Bayer agreed to secure exclusive rights to BioNTech's mRNA technology and intellectual property for development of mRNA vaccines for animal health applications. BioNTech is also contributing its formulation and immunology know-how to the partnership, the companies said.

In return, BioNTech will gain exclusive access to Bayer's expertise in veterinary medicine. BioNTech said new knowledge developed through the collaboration beyond animal health applications will benefit the company's human health program.

The companies said their partnership is the first of its kind focused on developing mRNA therapeutics specifically for animal health applications.

"This alliance is in line with our strategy to collaborate with companies that share our passion for developing and commercializing truly innovative and disruptive prophylactic and therapeutic products that have a major impact on disease," BioNTech founder and CEO Prof. Ugur Sahin, said in a statement.

Infectious disease vaccines is the focus of one of the three therapy platforms BioNTech is building through mRNA technologies; the other two are cancer immunotherapies and protein replacement. The three platforms are designed to produce pharmacologically optimized protein coding RNA for targeted *in vivo* delivery.

×

"We are very impressed with BioNTech, who have built a very promising and rapidly adaptable mRNA technology platform which represents a unique opportunity in the development of novel therapeutics and new vaccines to meet new disease challenges for both humans and animals," added Sabine Bongaerts, Head of Drug Discovery Animal Health at Bayer.

Bayer will invest in the collaboration through its Bayer Lifescience Center, the pharma giant's novel strategic innovation unit that directly reports to Bayer's Board of Management. The Center's mission includes enabling partnerships with entrepreneurial best-in-class biotechnology companies to uncover, encourage, and unlock fundamental scientific and medical breakthroughs more rapidly.

microorganisms

MDPI

Review

A Review of Fish Vaccine Development Strategies: Conventional Methods and Modern Biotechnological Approaches

Jie Ma [1,2], Timothy J. Bruce [1,2], Evan M. Jones [1,2] and Kenneth D. Cain [1,2,*]

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Abstract: Fish immunization has been carried out for over 50 years and is generally accepted as an effective method for preventing a wide range of bacterial and viral diseases. Vaccination efforts contribute to environmental, social, and economic sustainability in global aquaculture. Most licensed fish vaccines have traditionally been inactivated microorganisms that were formulated with adjuvants and delivered through immersion or injection routes. Live vaccines are more efficacious, as they mimic natural pathogen infection and generate a strong antibody response, thus having a greater potential to be administered via oral or immersion routes. Modern vaccine technology has targeted specific pathogen components, and vaccines developed using such approaches may include subunit, or recombinant, DNA/RNA particle vaccines. These advanced technologies have been developed globally and appear to induce greater levels of immunity than traditional fish vaccines. Advanced technologies have shown great promise for the future of aquaculture vaccines and will provide health benefits and enhanced economic potential for producers. This review describes the use of conventional aquaculture vaccines and provides an overview of current molecular approaches and strategies that are promising for new aquaculture vaccine development.

Keywords: aquaculture; conventional vaccines; alternative vaccine; technologies

1. Introduction

Despite multiple approaches to innovative therapy, fish diseases remain a major economic issue in commercial aquaculture worldwide. Although antibiotics or chemotherapeutics may be implemented for disease treatment, there are some clear drawbacks, such as drug resistance issues and safety concerns [1]. Vaccination, as an effective method of preventing a wide range of bacterial and viral diseases, and contributes to environmental, social, and economic sustainability in global aquaculture. Since the first reports in the 1940s of fish vaccination for disease prevention [2], there have been many vaccines developed that significantly reduced the impact of bacterial and some viral diseases in fish [3]. Millions of fish are vaccinated annually, and in some areas of the world there has been a transition away from antibiotics and toward vaccination. For example, there has been a dramatic reduction in the use of antibiotics in Norwegian salmon farming since the introduction of vaccines [4], and vaccination has become the most cost-effective and sustainable method of controlling infectious fish diseases [5].

A typical fish vaccine either contains or produces a substance that serves as an antigen. This component then stimulates an innate and/or adaptive immune response within the fish against a particular pathogen. Research on fish vaccines and fish immunology has increased throughout the 20th century, and there have been over 10,000 scholarly publications on fish vaccines in just the past

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Revolutionizing vaccine production

SEQUIVITY RNA Particle Technology is used to create innovative, highly advanced vaccine solutions that are:

- Flexible
- Safe
- Precise

HOW RNA-BASED VACCINES WORK

Vaccination is key to preventing disease and has been a major advancement in protecting animal and human health. Classically, vaccines mimic infection using inactivated whole pathogens (antigens) to stimulate the immune system.

Exposing the body to antigens leads to the production of antibodies specifically directed against them. Memory cells release antibodies and other factors to enable a more rapid and efficient response the next time the cell is exposed to the antigen.

RNA vaccines, a new class of vaccines, rely on a different way to present an antigen.

For a conventional vaccine, the antigen is grown in the lab, deactivated or killed and then presented to the body. However, in the case of this revolutionary technology, an electronic gene sequence is utilized.

With SEQUIVITY RNA Particle Technology utilizes only the known gene of interest, specific to the pathogen. The gene of interest provides instructions to the dendritic (immune) cells to translate the sequence into proteins which act as antigens. Then, when presented with an actual pathogen challenge, the animal's immune system recognizes the antigen and a targeted immune response is triggered.

This remarkable technology targets specific pathogens to produce prescription customized, herd-specific vaccines against both viral and bacterial pathogens. It also gives veterinarians and producers a tool to help address specific diseases that cannot always be addressed by conventional measures.

MERCK Animal Health

SEQUIVITY™

WHAT MAKES SEQUIVITY UNIQUE

In a world where diseases evolve and mutate continuously, Merck Animal Health is making sure producers can address their animals' health with strain-specific vaccines.

This unique way to approach vaccine production offers a safe and innovative solution to today's herd health challenges. The Merck Animal Health proprietary RNA Particle Technology takes a genetic sequence from a targeted pathogen, isolated from an infected animal, to create a herd-specific vaccine in a matter of weeks.

In most cases, the process starts with the veterinary herd visit. A sample is collected from the infected herd and sent to a diagnostic lab where the pathogen strain's gene sequence is identified and sent electronically to Merck Animal Health. This maximizes safety and biosecurity.

After receiving the gene sequence, the gene is synthesized and inserted synthetically into the RNA production platform. After incubation, RNA particles (RP) released from the production cells are then harvested, purified and formulated into a final vaccine.

The RPs are able to enter immune cells and carry the GOI of the disease identified. Each RP targets the dendritic cells of the pig, the cells that are involved in presenting an antigen to the immune system. The pig's immune system recognizes the protein encoded by the GOI and triggers an immune response.

Because RPs are designed just to deliver the information and not to replicate themselves, safety is maximized. SEQUIVITY RNA Particle Technology also lets producers and veterinarians target multiple pathogens and farm specific strains with a single injection.

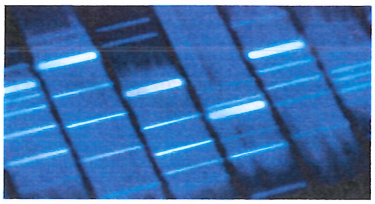
BIOLOGICALS OF THE FUTURE – AVAILABLE TODAY

Using SEQUIVITY RNA Particle Technology, Merck Animal Health offers an innovative, safe, flexible and precise solution when herd health management requires the most advanced, tailored vaccination solutions.

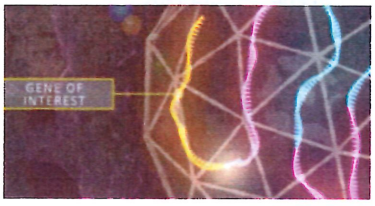
Our Process

Gene of Interest = GOI
RNA Particles = RPs

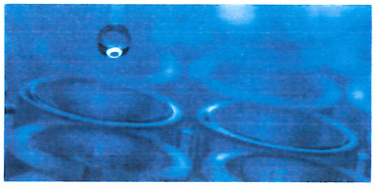
1. A sample is collected and sent to the lab by a veterinarian.



2. GOI is identified and sent electronically.



3. GOI is synthesized and inserted into the RNA production platform.



4. After incubation, RNA particles released from the production cells are harvested, purified and formulated into a final vaccine.

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